Research Institute for Tropical Medicine - Department of Health
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Tel Nos.: (632) 8809-7599 / 8807-2631/32/37 • Website: www.ritm.gov.ph

17 August 2021

LILIBETH C. DAVID, MD, MPH, MPM, CESO I
Undersecretary of Health
Health Facilities and Infrastructure Development Team
Department of Health

SUBJECT: RESPONSE TO THE FREEDOM OF INFORMATION (FOI) REQUEST OF A PRIVATE CITIZEN

Dear Usec David:

Greetings from the Institute.

This is to respectfully provide you with our response regarding the request for the Freedom of Information (FOI) from a private citizen (Mr. Nicanor Perlas) dated May 31, 2021 and August 10, 2021. Below is the summary of our comments, for your reference:

1ST BATCH OF FOI REQUESTS (May 31, 2021)	RITM COMMENTS
I. Cycle Threshold from March 15,2020 to present	There is no single database of all Ct values of all PCR tests done from the start of the pandemic to present. It must be noted that Ct value interpretation is dependent on the PCR kits that are used. These are NOT comparable across brands.
II. Models/Brands of RT-PCR tests used	RITM may provide the list of models/brands of RT-PCR tests used based on information generated from the RITM QA Programme for the COVID-19 Lab Network. We have attached this as Annex 1.
III. All DOH communications regarding the RT-PCR tests whether from DOH or to DOH	The request is very broad and is not very clear. RITM defers the request to DOH as to what communications are referred to in this request. For additional reference, the DOH issues public guidelines and advisories on the response to COVID-19, including laboratory testing. The requesting party is directed to the DOH website: https://doh.gov.ph/COVID-19-policies
IV. All communications from and to the World Health Organization (WHO) regarding the use of RT-PCR tests	The request is very broad and is not very clear. RITM defers the request to DOH as to what communications are referred to. For additional reference, the WHO has been releasing technical guidance on the laboratory testing of COVID-19, which includes PCR tests: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications?publicationtypes=f85a3610-b102-4287-a6df-f3bc0b2e9f7c

2ND BATCH OF FOI REQUESTS (August 10, 2021)	RITM COMMENTS
I. Documents and/or communications regarding the Certified Reference Material (CRM) being used by DOH and its authorized testing centers to determine whether a person is positively infected with SARS-CoV-2.	Real-time PCR technology is reliant on the ability of the thermocycling machine's camera to correctly detect successive exponential increases in the fluorescence intensity against erratic fluorescence signals that behave as background noise. As such, the primary determinant whether a person is classified as positive is the presence of the viral RNA target in their sample. In the context of the PCR procedure, the "CRM" referred here may pertain to the "positive" control that is incorporated as part of the components of the real-time PCR kit. The primary function of a positive template control is to serve as a validity checkpoint to detect general failures or errors assumed to be related to all samples belonging to the same run; that is to say that if a positive control fails, then all samples belonging to the same run are retested. The final outcome of each tested sample is tied to the performance of the positive control.
II. Documents, lab results, and/or communications including but not limited to scientific articles demonstrating, using procedures that satisfy Koch's Postulates, that this Certified Reference Material is the successfully isolated SARS-CoV-2 virus	The real-time RT-PCR test for SARS-CoV-2 does not "isolate" the virus but rather detects short target sequences of the virus in clinical samples. If these target sequences are detected in clinical samples, these can be amplified and detected through the test. The positive control material included in the PCR kit is likewise not a whole virus but rather nucleic acid fragments taken from the virus or synthesized, and that which serve as the basis for (1) comparing if a clinical sample that is tested is positive for the virus; and (2) provide supporting information that the assay is working. As originally stated, the four criteria known as "Koch's postulates" are: (1) The microorganism must be found in diseased but not healthy individuals; (2) The microorganism must be cultured from the diseased individual; (3) Inoculation of a healthy individual with the cultured microorganism must recapitulated the disease; and finally (4) The microorganism must be re-isolated from the inoculated, diseased individual and matched to the original microorganism. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3775492/). Ethically, it is not appropriate or acceptable to inoculate a healthy individual with a virus such as SARS-CoV-2 and check for development of COVID-19, to satisfy Koch's postulates. Therefore, it is probably impossible to get any actual data on experiments that involve this. At the outset of the pandemic, clusters of cases in Wuhan exhibited similar symptoms, and, subsequently on conduct of various diagnostic techniques to include virus isolation and sequencing, it was determined that a novel coronavirus, was present among the affected as the causative agent of the disease. We do not have any additional information requested as we do not perform Virus Isolation for SARS-CoV-2 in RITM.

III. Documents, lab results, and/or scientific and other communications, demonstrating that said isolate, that has now become the Certified Reference Material (CRM) for the RT-PCR tests, is the isolate of a complete SARS-CoV-2 virus	We do not have such information as we do not perform Virus Isolation for SARS-CoV-2 in RITM.
IV. Documents showing the source of the CRM that DOH and authorized testing centers have been using and are using for its/their RT-PCR tests	COVID-19 laboratories use various brands of commercial PCR detection kits for SARS-CoV-2. The positive controls are included as part of the components of the PCR kit. Manufacturers may be contacted as to the source of their positive controls, subject to their policies on the confidentiality of their product information.

Let us know if there are any additional queries.

Sincerely yours,

CELIA C. CARLOS, MD, CESO III, FPPS, FPIDSP, FPSMID
Director IV
Research Institute for Tropical Medicine

CC: **NESTOR F. SANTIAGO, JR., MD, MPHC, MHSA, CESO II**
Assistant Secretary of Health
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ANNEX 1 – LIST OF MODELS/BRANDS OF RT-PCR TESTS
used in the COVID-19 Laboratory Network
(as of August 17, 2021)

1	DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit. Manufactured by Solgent Co., Ltd.
2	GenAmplify™ Corona Virus Disease-2019 (COVID-19) rRT-PCR Detection Kit. Manufactured by Manila HealthTek Inc.
3	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing). Manufactured by Sansure Biotech Inc.
4	TibMolbiol LightMix® by Roche Diagnostics
5	genesig Real-Time PCR Coronavirus (COVID-19) CE IVD kit. Manufactured by Primerdesign Ltd.
6	STANDARD M nCoV Real-Time Detection kit. Manufactured by SD Biosensor, Inc.
7	A*STAR FORTITUDE KIT 2.0. Manufactured by MiRXES Pte Ltd.
8	A*STAR FORTITUDE KIT 2.1. Manufactured by MiRXES Pte Ltd.
9	LightCycler® Multiplex RNA Virus Master Manufactured by Roche Molecular Systems, Inc.
10	LightMix® Modular SARS-CoV-2 (COVID19) RdRP by Roche Diagnostics
11	Real-Time Fluorescent RT-PCR kit for detecting 2019-nCoV(SARS-CoV-2). Manufactured by BGI Biotechnology Co., Ltd.
12	TaqPath™ COVID-19 Combo Kit. Manufactured by Thermo Fisher Scientific, Inc.
13	Logix Smart Coronavirus Disease 2019 (COVID-19) kit. Manufactured by Co-Diagnostics, Inc.
14	GeneFinder™ COVID-19 Plus RealAmp Kit. Manufactured by OSANG Healthcare Co., Ltd.
15	Allplex™ 2019-nCoV Assay. Manufactured by Seegene Inc.
16	FTD SARS-CoV-2. Manufactured by Fast Track Diagnostics Luxembourg S.à.r.l.
17	abTES™ COVID-19 qPCR I Kit. Manufactured by AITbiotech Pte Ltd.
18	PerkinElmer® New Coronavirus Nucleic Acid Detection Kit. Manufactured by PerkinElmer, Inc.
19	PerkinElmer® SARS-CoV-2 Real-time RT-PCR assay. Manufactured by PerkinElmer Inc, SYM-BIO LiveScience Co., Ltd
20	Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence Probing) manufactured by Da An Gene Co., Ltd. of Sun Yat-sen University
21	Fosun COVID-19 RT-PCR Detection Kit. Manufactured by Shanghai Fosun Long March Medical Science Co., Ltd.
22	xABT Multiple Real-Time PCR Kit for Detection of 2019-nCoV. Manufactured by Genecraft Labs.
23	OPTI SARS-CoV-2 RT-PCR Test. Manufactured by OPTI Medical Systems, Inc.
24	GenePro SARS-CoV-2 Test. Manufactured by Gencurix Inc.

25	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR). Manufactured by Wuhan Easy Diagnosis Biomedicine Co., Ltd.
26	SARS-CoV-2 Nucleic Acid Detection Kit (PCR-Fluorescent Probe Method). Manufactured by ZYBIO INC.
27	Diagnostic Kit for Novel - Coronavirus (2019-nCoV) RNA - EasyNat. Manufactured by Ustar Biotechnologies (Hangzhou) Ltd.
28	cobas® SARS-CoV-2 & Influenza A/B assay. Manufactured by Roche Diagnostics GmbH.
29	DirectDetect™ SARS-CoV-2 qPCR Kit. Manufactured by Coyote Bioscience Co., Ltd .
30	BioFire® Respiratory 2.1 (RP2.1) Panel. Manufactured by BioFire Diagnostics.
31	1copy™ COVID-19 qPCR Multi Kit. Manufactured by 1drop Inc.
32	Total Solution of Novel Coronavirus 2019-nCoV Nucleic Acid Detection. Manufactured by Shenzhen Uni-Medica Technology Co., Ltd. (Uni-medica)
33	STAT-NAT® COVID-19 MULTI. Manufactured by SENTINEL CH. SpA
34	SARS-CoV-2 Fluorescent PCR Kit. Manufactured by Maccura Biotechnology Co., Ltd.
35	BD SARS-CoV-2 Reagents for BD MAX™ System. Manufactured by Becton, Dickinson and Company
36	GeneXpert Xpert Xpress SARS-CoV-2. Manufactured by Cepheid.

Tribunal Administrativo de Círculo de Lisboa

Juízo Administrativo Comum

Processo n.º 525/21.4BELSB

SENTENÇA

I. Relatório

[redacted] e [redacted] doravante abreviadamente designados, em conjunto, por "Requerentes", vêm requerer a intimação da DGS – Direcção Geral de Saúde ("DGS") e do MINISTÉRIO DA SAÚDE (*rectius*, apenas deste último, atento o disposto no artigo 10.º, n.ºs 2 e 4, do CPTA, doravante abreviadamente designado por "Requerido"), todos melhor identificados a fls. 5-6 dos autos no SITAF, tendo em vista a disponibilização, por este último, de um conjunto de relatórios, pareceres e publicações de carácter científico relativos à COVID-19.

Juntam 10 documentos.

Citado o Requerido para, querendo, responder, veio este fazê-lo, sustentando, então, em síntese, que:

– Relativamente ao pedido de informação não procedimental, constatou-se que nenhum dos documentos, relatórios, provas e informações solicitados nas alíneas a) a q) do artigo 4.º dos requerimentos se encontram na posse da DGS, tal como, de resto, informou os Requerentes, circunstância que torna impossível o prosseguimento dos autos;

- No que se refere às alíneas l) e m) daqueles mesmos requerimentos, a 19.04.2021 a DGS acrescentou informação relativa ao número de óbitos, considerando-se, então, satisfeito o pedido formulado pelos Requerentes, com a consequente extinção da instância, por inutilidade da lide;
- Vindo os Requerentes solicitar informação ao abrigo do artigo 68.º, n.º 2, alínea a), do CPA, não alegaram, no entanto, quais os bens públicos que pretendiam defender com o pedido de informação, o que ditaria, então, a sua ilegitimidade activa.

Pugna, a final, pela extinção da instância, por impossibilidade e inutilidade superveniente da lide, e, sem conceder, pela procedência da excepção de ilegitimidade activa dos Requerentes, com a sua absolvição da instância.

Junta 12 documentos.

Instados a pronunciarem-se sobre as questões prévias suscitadas pelo Requerido, vieram os Requerentes redarguir, essencialmente, que aquele primeiro nunca lhes respondeu no prazo de que dispunha para esse efeito, mas tão-somente já na pendência da presente intimação, pelo que a impossibilidade arguida pelo Requerido era da sua exclusiva responsabilidade, e que, bem assim, são parte legítima na presente intimação, não estando obrigados a demonstrar perante a Administração uma qualquer lesão de interesses difusos.

Pugnam, a final, pela improcedência da excepção de ilegitimidade activa e pela condenação do Requerido no pagamento das custas processuais.

Juntam 1 documento.

*

Em face do exposto, o objecto do litígio consiste, em suma, em aquilatar se os Requerentes são parte legítima na presente acção de intimação, se se verifica, ou não, a invocada impossibilidade e inutilidade superveniente da lide e se, bem assim, os Requerentes têm direito à informação solicitada, sendo estas as questões que ao Tribunal cumpre decidir *in casu*.

II. Saneamento

Conforme se fez menção, o Requerido vem suscitar um conjunto de questões prévias que, a verificarem-se, poderão, efectivamente, obstar ao conhecimento do mérito da causa, com a sua absolvição ou a extinção da instância.

No entanto, e na medida em que o conhecimento dessas questões depende da prévia fixação da respectiva factualidade pertinente, protela-se o seu conhecimento para a fundamentação de direito da presente decisão.

III. Fundamentação

III.1. De facto

Consideram-se provados os seguintes factos, pertinentes para a decisão da causa:

1. Em 24.02.2021, os Requerentes remeteram requerimentos ao Requerido, cujos teores se transcrevem parcialmente *infra*:
   (...) *[N]o gozo dos seus direitos civis e políticos, ao abrigo do artigo 268º, nº 2, da Constituição da República Portuguesa (CRP), e dos artigos 13º, nº 1, 17º, e 68º, nº2, al.a), todos do Código do Procedimento Administrativo (CPA), bem como nos termos do disposto no artigo 5º, nº 1, da Lei nº 26/2016, de 22 de Agosto, com a redação que lhe foi conferida pela Lei nº 58/2019, de 8 de Agosto, vem*

REQUERER a V. Exa. se digne fornecer-lhe, no prazo legal de dez (10) dias, reprodução por fotocópia ou por qualquer outro meio técnico, designadamente electrónico, do teor dos relatórios, pareceres, e publicações de carácter científico, disponíveis, nos vossos arquivos referentes à doença Covid-19 declarada pela Organização Mundial da Saúde como "epidemia de Covid-19":

I - Cópia de publicação científica, revista por pares (peer-review), referente ao estudo sobre o grau de infeção provocada nos humanos, pelo vírus SARS-Cov2, responsável pela doença Covid-19, a partir de uma amostra não adulterada retirada de um humano doente;

II - Cópia de publicação científica, revista por pares (peer review), referente ao estudo sobre o grau de infecção nos humanos provocada pelo SARS-Cov2 obtida por via empírica e que prove que foram cumpridos os postulados de Koch/Evans (1976), indicando a data e o(s) autor(es) que realizaram o isolamento e purificação do vírus em laboratório;

III - Cópia da publicação científica, revista por pares (peer review), relativamente ao teste RT-PCR (polimerase chain reaction, ou, em português, reação em cadeia da polimerase) como ferramenta de diagnóstico fiável para identificar a infecção por vírus SARS-Cov2 em humanos, i.é, se o teste RT-PCR identifica a presença do RNA viral e a presença do referido vírus infeccioso;

IV - Cópia da publicação científica, revista por pares (peer-review), em que o resultado do teste PCR indica especificadamente, sem margem de erro, a presença do vírus SARS-Cov2 em humanos que manifestem sintomas semelhantes aos sintomas da gripe;

V - Cópia da publicação científica, revista por pares (peer-review), que demonstre que o resultado positivo do teste PCR indica, sem margem de erro, a presença de infecção por SARS-Cov2 em humanos sem sintomas (assintomáticos) e que estes transmitem a doença a terceiros;

VI - Cópia da publicação científica, revista por pares (peer-review), identificando os sintomas da nova doença resultante de infeção por SARS-Cov2 e o que distingue a nova, e alegada doença, da doença sazonal gripe / influenza e da doença provocada pelas já conhecidas estirpes 229E, NL63, OC43 e HKU1 de coronavírus;

VII - Informação documentada sobre o ciclo de amplificação definido para os testes PCR usados em Portugal, e indicação da entidade que determinou o ciclo definido;

VIII - Informação sobre os testes PCR usados em Portugal para detetar infecção por SARS-Cov2, se os mesmos conseguem distinguir matéria inactiva e reprodutiva;

IX - Informação sobre quais os tipos de vírus, e respectivas estirpes, detectáveis por via do teste PCR usado massivamente na obtenção de "infectados covid-19" entre a população em Portugal;

IX [sic] – Prova científica, revista por pares, que fundamenta a aplicação de medidas de quarentena e confinamento a pessoas testados positivo, via teste PCR, e assintomáticos;

X - Cópia do documento publicado e elaborado pelos cientistas chineses, revisto por pares (peer-review), do mapeamento do código genético do novo coronavírus SARS-Cov2;

XI - Informação/relatório sobre o número de mortes em Portugal, desde o início da declarada pandemia, causadas por infeção SARS-Cov2, tendo a causa da morte sido objetiva e legalmente aferida por via de autópsia a cadáveres;

XII - Informação/relatório sobre o número de mortes em Portugal, desde o início da declarada pandemia, causada por infeção SARS-Cov2, tendo a causa da morte sido unicamente aferida por via do teste PCR;

XIII - Prova científica da eficácia do distanciamento social, com a respetiva fundamentação empírica revista por pares (peer-review), no âmbito da doença covid-19;

XIV - A Organização Mundial de Saúde (OMS) publicou em 6 de Abril de 2020 uma reavaliação sobre o uso das máscaras de protecção individual, incidindo sobre o assunto específico do SARS-COV2, e concluiu: "as máscaras continuam a estar recomendadas apenas para certos grupos específicos – doentes infectados com o SARS-Cov2, pessoas com sintomas, cuidadores ou profissionais de saúde em contacto com doentes infectados ou suspeitos.".

Assim, e em sequência da referida publicação pela OMS, requer-se cópia das publicações com evidências científica, na posse da DGS, de estudos revistos por pares (peer-review), que provem, sem margem para dúvidas, da inexistência de dano colateral para a saúde física e psíquica resultante do uso de máscara facial por crianças, jovens e adultos em espaços fechados e abertos;

XV - Prova científica, das publicações realizadas por especialistas e revistas por pares, que demonstre que o confinamento de pessoas sem sintomas, de estarem doentes, reduz de forma significativa a transmissão de doença respiratória covid-19, e do benefício do confinamento para a saúde da população;

XVI - Prova, devidamente documentada, em como as chamadas vacinas experimentais de mRNA de última geração não representam manipulação genética e que no todo não constituem perigo de dano, a médio e longo prazo, na saúde de quem já foi e está a ser vacinado com vacinas ainda não aprovadas e sem dados clínicos avaliados, todavia, recomendados à população pela Direcção Geral da Saúde.

Pelo que, e ao abrigo do direito à informação não procedimental, com respaldo nas leis acima indicadas, consubstanciado no direito de acesso a documentos administrativos integrantes de procedimentos já finalizados ou a arquivos ou registos administrativos, conferido a todos os cidadãos, e tendo em vista a defesa de interesses difusos – artigo 52º, da C.R.P." (cf.

cópias dos requerimentos juntas a fls. 22-106 dos autos n SITAF, documentos que se dão por integralmente reproduzidos).

2. Em 30.03.2021, os Requerentes apresentaram a juízo o r.i. dos presentes autos de intimação (cf. cópia da mensagem electrónica junta a fls. 1 dos autos no STAF, documento que se dá por integralmente reproduzido).
3. Em 12.04.2021, a DGS remeteu oficios aos Requerentes, cujos teores se reproduzem parcialmente *infra*:

> Analisado atentamente o requerimento de V. Exa., rececionado nesta Direção-Geral, informa-se, que o pedido não se enquadra no disposto na Lei nº 26/2016, de 22 de agosto, na sua versão atual, porquanto, as cópias, provas e informações solicitadas não se referem a documentos administrativos desta Direção-Geral, nos termos definidos na alínea a) do nº 1 da referida Lei.
>
> A matéria referida e questionada no requerimento, segue os termos do disposto no artº 102º e seguintes do Código do Procedimento Administrativo, CPA.
>
> Com efeito, não tendo sido apresentada a exposição dos factos em que se baseia o pedido, os quais devem ser adequados à pretensão e aos fins a que se destina, convida-se V. Exa., querendo, a suprir a deficiência do requerimento, nos termos do disposto no artº 102º do CPA.

(cf. cópias dos oficios juntas a fls. 132-141 dos autos no SITAF, documento que se dão por integralmente reproduzidos).

4. Em 19.04.2021, o Requerido apresentou a sua resposta no âmbito dos presentes autos de intimação, aí declarando que não possuía "*nenhum documento administrativo correspondente às alíneas a) a j) e de n) a q) do art.º 4º do requerimento de intimação*", mais dando conta de que:
"*Após análise da base réplica do SICO desde 01-01-2020 até 18.04.2021, conseguimos apurar até ao momento as seguintes distribuições:*
Entre 2020 e 2021 foram emitidos 152 certificados de óbito pelos médicos que trabalham para a tutela Ministério da Justiça (INMLCF) cuja causa básica de morte foi devido a COVID 19 de acordo com a seguinte distribuição:
• *Dos 152 certificados de óbito, 132 óbitos a causa básica foi U071 (COVID 19-vírus identificado) e 20 óbitos a causa básica foi U072 (COVID 19 -não identificado laboratorialmente).*

• *Dos 152 certificados de óbito, a 148 óbitos foi dispensada autópsia, sendo que 129 óbitos a causa básica de morte foi U071 e 19 óbitos a causa básica d morte foi U072.*

Dos 152 óbitos, a 4 óbitos não foi dispensada autópsia, sendo que 3 óbitos a causa básica de morte foi U071 e 1 óbito a causa básica foi UO72" (cf. resposta junta a fls. 115-126 dos autos no SITAF, documento que se dá por integralmente reproduzido).

5. Por ofício de 27.04.2021, os Requerentes foram notificados da resposta a que se alude no ponto anterior (cf. ofício junto a fls. 150 dos autos no SITAF, documento que se dá por integralmente reproduzido)

A prova dos factos fixados *supra* assenta no teor dos documentos juntos aos autos, conforme referido a respeito de cada um deles.

Nada mais foi provado com interesse para a decisão da causa.

III.2. De direito

Como é sabido, o direito à informação administrativa encontra guarida constitucional no artigo 268.º da Lei Fundamental, segundo o qual:

"*1. Os cidadãos têm o direito de ser informados pela Administração, sempre que o requeiram, sobre o andamento dos processos em que sejam directamente interessados, bem como o de conhecer as resoluções definitivas que sobre eles forem tomadas.*

2. Os cidadãos têm também o direito de acesso aos arquivos e registos administrativos, sem prejuízo do disposto na lei em matérias relativas à segurança interna e externa, à investigação criminal e à intimidade das pessoas.".

Os ditames constitucionais citados consagram, assim, aquilo que a jurisprudência e a doutrina têm designado por "*direito à informação procedimental*" e "*direito à informação não procedimental*", respectivamente, os quais se encontram regulados pelos artigos 82.º a 85.º do actual CPA (artigos 61.º a 65.º do anterior CPA) e pelo disposto na Lei n.º 26/2016, de 22.08 (a qual revogou a Lei n.º 46/2007, de 24.08, vulgo "LADA" ou "Lei de Acesso aos Documentos Administrativos").

A este respeito, atente-se ao acórdão prolatado pelo Tribunal Central Administrativo ("TCA") Norte, em 22.06.2006, no âmbito do processo n.º 00028/06.7BEPNF, no qual se explicita, com meridiana clareza, a interpretação a fazer das disposições legais enunciadas e cujo entendimento continua a deter plena actualidade:

"*[A] existência e o âmbito do direito à informação dependem, essencialmente, da relação existente entre os requerentes e o objecto a esclarecer.*

*Por princípio, o direito à informação cabe aos directamente interessados no procedimento a que se reportam as pretendidas informações (cfr. arts. 61.º e 62.º do CPA) e "por extensão", tal direito cabe "*a quaisquer pessoas que provem ter interesse legítimo no conhecimento dos elementos que pretendam*" (cfr. art. 64.º, n.º 1 do CPA); fora destes casos, qualquer pessoa pode aceder aos registos e arquivos administrativos (cfr. art. 65.º do CPA) que não exijam reserva, mas tal acesso pressupõe a prévia conclusão do procedimento e se forem nominativos, o direito de acesso é limitado à pessoa a que digam respeito ou a terceiros que demonstrem "*interesse directo e pessoal*" (cfr. art. 07.º, n.ºs 1, 2 e 5 da LADA)*".

No mesmo sentido, e de forma particularmente impressiva, afirma-se no acórdão proferido pelo TCA Sul em 20.03.2014, no âmbito do processo n.º 10919/14, que:

"*Se quisermos utilizar duas expressões consagradas na dogmática, o direito à informação administrativa procedimental define-se como um direito* uti singulis, *sendo*

que o direito de acesso a arquivos e registos administrativos se caracteriza por ser um direito uti cives.

Ou, nas palavras de J. M. Sérvulo Correia, o direito à informação administrativa procedimental configura a "publicidade erga partes*" e o direito de acesso a arquivos e registos administrativos, independentemente de um procedimento, a "publicidade* erga omnes*" (*in O direito à informação e os direitos de participação dos particulares no procedimento e, em especial, na formação da decisão administrativa, *Cadernos de Ciência e Legislação/1994, nºs.9-10, pp. 135).*

O primeiro perspectiva o indivíduo enquanto administrado, em sentido estrito, no quadro de uma específica e concreta relação com a Administração Pública e portador de interesses eminentemente subjectivos.

Já o segundo considera o particular como cidadão face ao poder, em termos mais genéricos.

Dizendo ainda de outra forma, o direito à informação administrativa procedimental visa a tutela de interesses e posições subjectivas directas, enquanto o direito de acesso a arquivos e registos administrativos está configurado como um dos instrumentos de protecção de interesses mais objectivos partilhados pela comunidade jurídica, designadamente o da transparência da acção administrativa.".

A orientação acabada de descrever e que aqui se acolhe, sem reservas, encontra ainda eco na mais recente doutrina produzida a este respeito, referindo MÁRIO AROSO DE ALMEIDA e CARLOS ALBERTO FERNANDES CADILHA (*in "Comentário ao Código de Processo nos Tribunais Administrativos"*, Almedina, 2017, 4.ª edição, páginas 855 e 856), em anotação ao artigo 104.º do CPTA, que:

"Como resulta textualmente do n.º 1, a intimação destina-se, em primeira linha, a efetivar jurisdicionalmente, quer o direito à informação sobre o andamento dos procedimentos e o conhecimento das decisões, que integra o direito à informação procedimental, quer o direito de acesso aos arquivos e registos administrativos, que corresponde a um direito à informação não procedimental. E, neste sentido, o preceito

concretiza, no plano processual, os direitos e garantias consagrados no artigo 268.º, n.ºs 1 e 2, da CRP, que se encontram regulados, no plano do direito substantivo, respetivamente, pelos artigos 82.º a 85.º do CPA e pela Lei n.º 46/2007, de 24 de agosto (alterada pelo Decreto-Lei n.º 214-G/2015, de 2 de outubro).

Em tese geral, o direito à informação procedimental reporta-se a factos, atos ou documentos que integram ou resultam de um concreto procedimento administrativo que se encontre ainda em curso; o direito à informação não procedimental respeita a documentos contidos em arquivos ou registos administrativos, aí se incluindo os documentos existentes em procedimentos já findos, independentemente da correlação com qualquer procedimento administrativo que esteja pendente".

Ora, na situação *sub judice*, ficou acima demonstrado que os Requerentes se arrogam unicamente à obtenção de "*informação não procedimental, com respaldo nas leis acima indicadas, consubstanciado no direito de acesso a documentos administrativos integrantes de procedimentos já finalizados ou a arquivos ou registos administrativos, conferido a todos os cidadãos, e tendo em vista a defesa de interesses difusos*" (cf. facto 1. firmado *supra*).

Neste pressuposto, importa, então, no plano infraconstitucional, atender ao disposto nos artigos 3.º, n.º 1, alínea a), e 5.º, n.º 1, ambos da LADA, segundo os quais "*Todos, sem necessidade de enunciar qualquer interesse, têm direito de acesso aos documentos administrativos* [*id est*, "*qualquer conteúdo, ou parte desse conteúdo, que esteja na posse ou seja detido em nome dos órgãos e entidades referidas no artigo seguinte, seja o suporte de informação sob forma escrita, visual, sonora, eletrónica ou outra forma material*"], *o qual compreende os direitos de consulta, de reprodução e de informação sobre a sua existência e conteúdo*" (cf. artigos 3.º, n.º 1, alínea a), e 5.º, n.º 1, ambos da LADA).

Definido o quadro legal que, em tese, é aplicável ao presente dissídio, desçamos, então, de novo, ao caso dos autos, a fim de aí identificar a solução legal aplicável.

Como se viu, o Requerido vem, a certo ponto, sufragar que, vindo os Requerentes solicitar informação ao abrigo do artigo 68.º, n.º 2, alínea a), do CPA, não alegariam, no entanto, quais os bens públicos que pretendiam defender com o pedido de informação, circunstância que, defende, carrearia à sua ilegitimidade activa – mas sem que lhe assista aqui qualquer razão, como se verá.

Com efeito, é certo que os Requerentes invocam, a certo ponto dos requerimentos tendentes à obtenção da informação aqui pretendida, o artigo 68.º, n.º 2, alínea a), do CPA, segundo o qual "*Os cidadãos no gozo dos seus direitos civis e políticos e os demais eleitores recenseados no território português*" têm "*legitimidade para a proteção de interesses difusos perante ações ou omissões da Administração passíveis de causar prejuízos relevantes não individualizados em bens fundamentais como a saúde pública, a habitação, a educação, o ambiente, o ordenamento do território, o urbanismo, a qualidade de vida, o consumo de bens e serviços e o património cultural*".

Porém, e conforme exsuda do seu próprio teor e inserção sistemática, este comando normativo respeita à *legitimidade procedimental para reagir perante acções e omissões da Administração*, e não à legitimidade para aceder a informação administrativa não procedimental.

Essa, como se viu, encontra-se plasmada no supracitado artigo 5.º, n.º 1, da LADA, aí se preceituando, em termos inequivocamente abertos, que "*Todos, sem necessidade de enunciar qualquer interesse, têm direito de acesso aos documentos administrativos*", sem necessidade de invocar ou demonstrar um qualquer particular interesse na obtenção de tal informação.

Improcede, por isso, a invocada excepção de ilegitimidade activa dos Requerentes.

*

De seguida, e ainda a título de questão prévia, vem o Requerido sindicar que nenhum dos documentos, relatórios, provas e informações solicitados pelos Requerentes se encontraria na sua posse, o que carrearia, então, à impossibilidade da lide; e que, bem assim, teria, no entanto, disponibilizado informação aos Requerentes quanto à informação solicitada acerca do número de mortes em Portugal, o que ditaria, neste particular, a inutilidade superveniente da lide, com a consequente extinção da instância.

Neste conspecto, limitaram-se os Requerentes a redarguir que a impossibilidade que o Requerido agora vem invocar seria da sua exclusiva responsabilidade, pugnando, então, pela sua condenação nas respectivas custas processuais.

Principiando por aquele segundo segmento assinalado, ficou acima provado que os Requerentes solicitaram, a certo ponto dos seus requerimentos, que lhes fosse disponibilizada "*XI - Informação/relatório sobre o número de mortes em Portugal, desde o início da declarada pandemia, causadas por infeção SARS-Cov2, tendo a causa da morte sido objetiva e legalmente aferida por via de autópsia a cadáveres; // XII - Informação/relatório sobre o número de mortes em Portugal, desde o início da declarada pandemia, causada por infeção SARS-Cov2, tendo a causa da morte sido unicamente aferida por via do teste PCR*" (cf. facto 1. firmado *supra*).

A este respeito, viria, então, o Requerido retorquir que:

"*Após análise da base réplica do SICO desde 01-01-2020 até 18.04.2021, conseguimos apurar até ao momento as seguintes distribuições:*

Entre 2020 e 2021 foram emitidos 152 certificados de óbito pelos médicos que trabalham para a tutela Ministério da Justiça (INMLCF) cuja causa básica de morte foi devido a COVID 19 de acordo com a seguinte distribuição:

• *Dos 152 certificados de óbito, 132 óbitos a causa básica foi U071 (COVID 19-virus identificado) e 20 óbitos a causa básica foi U072 (COVID 19 -não identificado laboratorialmente).*

• *Dos 152 certificados de óbito, a 148 óbitos foi dispensada autópsia, sendo que 129 óbitos a causa básica de morte foi U071 e 19 óbitos a causa básica d morte foi U072.*

Dos 152 óbitos, a 4 óbitos não foi dispensada autópsia, sendo que 3 óbitos a causa básica de morte foi U071 e 1 óbito a causa básica foi UO72" (cf. facto 4. firmado *supra*).

Ora, tal como vem sendo pacificamente entendido pela jurisprudência e doutrina, "*A lide torna-se inútil quando ocorre um facto ou circunstância, ulterior à sua instauração, que torna desnecessário que sobre ela recaia pronúncia judicial, nomeadamente porque o pedido formulado já foi atingido por outro meio*" (neste sentido, *vide*, a título exemplificativo, o aresto prolatado pelo Supremo Tribunal Administrativo, em 28.09.2017, no âmbito do processo n.º 049/17).

Na situação *sub judice*, do cotejo do segmento em apreciação dos pedidos formulados pelos Requerentes no âmbito dos requerimentos por si apresentados com o teor da resposta oferecida pelo Requerido no âmbito dos presentes autos de intimação, resulta evidente, para este Tribunal, que a pretensão do Requerente se encontra, neste particular, satisfeita, pelo que a prolação de decisão se afiguraria, *in concretu*, desprovida de qualquer utilidade.

Considerando que, de harmonia com o disposto na alínea e) do artigo 277.º do CPC, aplicável *ex vi* artigo 1.º do CPTA, a instância se extingue com a impossibilidade ou inutilidade superveniente da lide, não restam, então, alternativas a este Tribunal que não concluir por essa mesma inutilidade, no que tange aos pontos XI e XII dos requerimentos para prestação de informações apresentados pelos Requerentes, com a consequente extinção parcial da instância.

Nos demais pontos de tais requerimentos, e considerando que, tal como invocado pelo Requerido – sem que haja oposição dos Requerentes ou, de resto, se vislumbrem quaisquer motivos para que se duvide de tal asserção –, o mesmo não se encontra na posse dos elementos pretendidos pelos Requerentes, afigura-se inescapável a conclusão em como a presente lide é, nesse particular, impossível, na medida em que, como se infere, o Requerido não poderá ser intimado a facultar aos Requerentes elementos de que não dispõe.

No entanto, e atendendo a que, diversamente do que refere o Requerido, o mesmo em momento algum deu conta de tal facto aos Requerentes no prazo de que dispunha para lhes responder – limitando-se apenas a, em 12.04.2021, e já na pendência da presente acção de intimação, endereçar-se aos mesmos, convidando-os a aperfeiçoar os requerimentos apresentados, cf. factos 2. e 3. firmados *supra* – julgo essa mesma impossibilidade imputável à sua pessoa, condenando-o na totalidade das custas devidas pelo presente processo.

IV. Decisão

Em face do que antecede:

(i) Declaro a inutilidade superveniente parcial da lide relativamente aos pontos XI e XII dos requerimentos apresentados pelos Requerentes [redacted] e, em consequência, julgo parcialmente extinta a instância, ao abrigo da alínea e) do artigo 277.º do CPC;

(ii) No mais, declaro a impossibilidade da lide e julgo parcialmente extinta a instância, ao abrigo da alínea e) do artigo 277.º do CPC.

Atendendo a que, tal como resultou provado, o Requerido prestou a informação ora em crise ulteriormente à propositura da presente intimação (cf. factos 2. a 5. firmados *supra*), julgo a impossibilidade e inutilidade superveniente da presente lide imputáveis ao mesmo e, em consequência, condeno-o na totalidade das custas, de acordo com o preceituado nos n.os 3 e 4 do artigo 536.º do CPC, aplicável *ex vi* artigo 1.º do CPTA, conjugadamente com o disposto no artigo 12.º, n.º 1, alínea b), e tabela I-B, linha 1, ambos do Regulamento das Custas Processuais.

Valor da causa: EUR 30.000,01, de harmonia com o disposto nos artigos 31.º e 34.º, n.os 1 e 2, ambos do CPTA, e nos artigos 296.º, n.º 1, 299.º, n.º 1, e 306.º, n.os 1 e 2, *in fine*, todos do CPC, aplicável *ex vi* artigo 1.º do CPTA.

Registe e notifique.

Lisboa, 19 de Maio de 2021

O Juiz de Direito

PEDRO MOREIRA

(Texto processado em computador e incorporado no SITAF, com aposição de assinatura electrónica qualificada – artigo 24.º, n.º 1, do CPTA e artigo 16.º, n.º 1, da Portaria n.º 380/2017, de 19.12)

Public Health Scotland

Date 7 October 2020]
Our Ref 2020-000133
Enquiries to phs.foi@nhs.net

Dear Athanasios Kandias

Freedom of Information Reference: 2020-000133

I refer to your request of 9 September 2020 under the above legislation for information about:

All records in the possession, custody or control of Public Health Scotland, describing the isolation of a SARS-COV-2 virus, directly from a sample taken from a diseased patient, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka vero cells; liver cancer cells).
*Please note that I am using "isolation" in the every-day sense of the word: the act of separating a thing(s) from everything else. I am not requesting records where "isolation of SARS-COV-2" refers *instead* to:*

- *the culturing of something, or*
- *the performance of an amplification test (i.e. a PCR test), or*
- *the sequencing of something.*

Please also note that my request is not limited to records that were authored by the PHS or that pertain to work done by the PHS. My request includes any sort of record, for example (but not limited to) any published peer-reviewed study that the PHS has downloaded or printed.

I am writing to advise you that following a search of our records, I have established that under Section 17(1) of the Freedom of Information (Scotland) Act 2002, Public Health Scotland (PHS) does not hold the information you requested.

PHS has not been involved in any studies where methods of isolation described have been performed. Such studies may have been performed in a number of Universities but PHS is not aware of any specific studies to be able to direct you to them for more information.

If you have any questions please contact me on phs.foi@nhs.net.

If you are unhappy with our response to your request, you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this correspondence, and we will reply within 20 working days of receipt.

The review will be undertaken by a reviewer who was not involved in the original decision-making process. The reviewer can be contacted as follows:

The FOI Reviewer
.
Public Health Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB
Email: phs.foi@phs.scot

If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at www.itspublicknowledge.info/Appeal. If you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.

Yours sincerely

Vicki Bibby
Head of Strategy, Governance and Performance
Public Health Scotland

Public Health Scotland

Date 6 November 2020
Our Ref 2020-000158
Enquiries to phs.foi@phs.scot

[redacted]

Freedom of Information Reference: 2020-000158

I refer to your request of 9th October 2020 under the above legislation for information about:

all records in the possession, custody or control of Public Health Scotland describing the isolation of a SARS-COV-2 virus, directly from a sample taken from a diseased patient, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka vero cells; lung cells from a lung cancer patient). This is not limited to records that were authored by Public Health Scotland or that pertain to work done by Public Health Scotland. The request includes any sort of record, for example (but not limited to) any published peer-reviewed study that Public Health Scotland has downloaded or printed.

I am writing to advise you that following a search of our records, I have established that under Section 17(1) of the Freedom of Information (Scotland) Act 2002, Public Health Scotland does not hold the information you requested.

If you are unhappy with our response to your request, you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this correspondence, and we will reply within 20 working days of receipt. The review will be undertaken by a reviewer who was not involved in the original decision-making process. The reviewer can be contacted as follows:

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Public Health Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB
Email: PHS.FOI@phs.scot

If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at www.itspublicknowledge.info/Appeal. If you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.

Yours sincerely

Victoria Bibby
Head of Strategy, Governance and Performance
Public Health Scotland

Република Србија
МИНИСТАРСТВО ЗДРАВЉА
Број: 500-01-1144/2021-16
Датум: 01.09.2021.године
Београд

УДРУЖЕЊЕ „РОДИТЕЉИ НЕСТАЛИХ БЕБА СРБИЈЕ“

ул. Едварда Грига 1/9 улаз I
Београд-Ресник

Поштовани,

На основу Закона о слободном приступу информацијама од јавног значаја („Службени гласник РС“ бр. 120/04; 54/07; 104/09 и 36/10) и Ваших захтева за приступ информацијама од јавног значаја број: 416-21/1, 417-21/2 и 418-21/3 од 28.08.2021. године, заведени у Министарству здравља под бројем: 500-01-1144/2021-16, а који се односе на достављање информација о научној студији која недвосмислено доказује способност и максималну поузданост PCR и RT/PCR метода у детекцији SARS-COV2 узрочника, односно научну студију која недвосмислено доказује „златни стандард“ са највећим степеном осетљивости и највећим степеном специфичности PCR и RT/PCR метода у детекцији SARS-COV2 узрочника; научни доказ о постојању-изоловању вируса SARS-COV2; сертификате произвођача личне заштитне опреме прописаних у члану 17. став 10а Закона о заштити становништва од заразних болести и заштитних маски прописаних у члану 2. Уредбе о мерама за спречавање и сузбијање заразне болести ЦОВИД-19 са научним истраживањима и научним доказом да наведена заштитна опрема и заштитне маске пружају заштиту од преноса вируса SARS-COV2, као и научна истраживања и научне доказе који гарантују да наведена заштитна опрема и заштите маске не изазивају нежељена дејства по живот и здравље људи, као и на остале информације наведене у захтевима, обавештавамо Вас да Министарство здравља не поседује тражене информације.

С поштовањем,

ДРЖАВНИ СЕКРЕТАР

др Мирсад Ђерлек

[The Coat of Arms]
Republic of Serbia
MINISTRY OF HEALTH
Number: 500-01-1144 / 2021-16
Date: 01.09.2021
Belgrade

ASSOCIATION "PARENTS OF MISSING BABIES OF SERBIA"

st. Edward Grieg 1/9 entrance I
Belgrade-Resnik

Respected,

Based on the Law on Free Access to Information of Public Importance ("Official Gazette of RS" No. 120/04; 54/07; 104/09 and 36/10) and your requests for access to information of public importance number: 416-21 / 1, 417-21 / 2 and 418-21 / 3 of 28.08.2021, registered in the Ministry of Health under number: 500-01-1144 / 2021-16, which relate to the [1.] submission of information on a scientific study that unequivocally proves the ability and maximum Reliability of PCR and RT / PCR methods in the detection of SARS-COV2 pathogens, i.e. a [2.] scientific study that unequivocally proves the "gold standard" with the highest degree of sensitivity and the highest degree of specificity of PCR and RT / PCR methods in the detection of SARS-COV2 pathogens; isolation of SARS-COV2 virus; certificates of manufacturers of personal protective equipment prescribed in Article 17, paragraph 10a of the Law on Protection of the Population from Infectious Diseases and Protective Masks prescribed in Article 2 of the Regulation on Measures to Prevent and Suppress Infectious Diseases COVID-19 with [3.] scientific research and scientific evidence that protective masks provide protection against the transmission of SARS-COV2 virus, as well as scientific research and scientific [4.] evidence that guarantees that the said protective equipment and protective masks do not cause adverse effects on the life and health of the people, as well as other information stated in the requests, we inform you that the Health Ministry does not have the requested information.

[seal]
REPUBLIC OF SERBIA
MINISTRY OF HEALTH
BELGRADE
With respect,
Dr. Mirsad Djerlek
/Signature/

Dekanat
UL Medicinske fakultete

Univerza v Ljubljani
Medicinska fakulteta

Vrazov trg 2
1000 Ljubljana
E: dekanat@mf.uni-lj.si

Št. 074-4/2020-9
Ljubljana, 30. november 2020

UL Medicinska fakulteta izdaja na podlagi drugega odstavka 22. člena Zakona o dostopu do informacij javnega značaja (Uradni list RS, št. 51/06 – uradno prečiščeno besedilo, 117/06 – ZDavP-2, 23/14, 50/14, 19/15 – odl. US, 102/15 in 7/18), v nadaljevanju: ZDIJZ in skladno s 15. členom ZDIJZ v upravni zadevi presoje utemeljenosti zahteve prosilke [redacted], za dostop do informacij javnega značaja

O D L O Č B O

1. Zahteva prosilke [redacted] za dostop do informacij javnega značaja se zavrne v delu, ki se nanaša na posredovanje znanstvenih dokazov o izolaciji virusa Sars-Cov-2 v skladu s Kochovimi postulati in posredovanja študije, ki bi dokazala vzročno zvezo med Sars-Cov-2 in domnevno nalezljivo boleznijo Covid-19.

2. Stroški postopka niso nastali.

Obrazložitev:

Organ je dne 23. 11. 2020 s strani Ministrstva za zdravje, Direktorata za javno zdravje prejel odstop zahteve prosilke [redacted] v delu glede 3., 4. in 5. točke zahteve, in sicer glede:

- 3. točke - znanstveni dokazi o izolaciji virusa Sars-Cov-2 v skladu s Kochovimi postulatiin študije, ki bi dokazala vzročno zvezo med Sars-Cov-2 in domnevno nalezljivo boleznijo Covid-19,
- 4. točke - certifikati o ustreznosti PRC testa za odkrivanje okužbe s Sars-Cov-2 in
- 5. točke - podatek o številu amplifikacijskih ciklov, ki se jih uporablja v Sloveniji od začetka testiranja do danes, po mesecih.

Skladno s 4. členom ZDIJZ je informacija javnega značaja tista informacija, ki izvira iz delovnega področja organa, nahaja pa se v obliki dokumenta, zadeve, dosjeja, registra, evidence ali drugega dokumentarnega gradiva (v nadaljevanju: dokument), ki ga je organ izdelal sam, v sodelovanju z drugim organom, ali pridobil od drugih oseb. Iz navedene določbe izhajajo trije osnovni pogoji, ki morajo biti kumulativno izpolnjeni, da lahko govorimo o obstoju informacije javnega značaja, in sicer:

1. informacija mora izvirati iz delovnega področja organa,

2. organ mora z njo razpolagati in
3. nahajati se mora v neki materializirani obliki.

Prosilka v 3. točki zahteva posredovanje znanstvenih dokazov o izolaciji virusa Sars-Cov-2 v skladu s Kochovimi postulati ter posredovanje študije, ki bi dokazala vzročno zvezo med Sars-Cov-2 in domnevno nalezljivo boleznijo Covid-19. UL MF Inštitut za mikrobiologijo in imunologijo znanstvene študije, ki bi izpeljala dokaz o izolaciji virusa Sars-Cov-2 v skladu s Kochovimi postulati, ni izvajal. UL MF Inštitut za mikrobiologijo in imunologijo prav tako ni izvedel znanstvene študije, ki bi dokazovala vzročno zvezo med Sars-Cov-2 in domnevno nalezljivo boleznijo Covid-19. Organ tako z zahtevanim dokumentom ne razpolaga, zaradi česar je bilo potrebno glede 3. točke zahteve odločiti, kot izhaja iz izreka tega sklepa.

Glede 4. točke zahteve prosilki sporočamo, da je število amplifikacijskih ciklov, ki se jih uporablja v Sloveniji od začetka testiranja do danes, 40.

Glede 5. točke prosilki v prilogi pošiljamo certifikat o ustreznosti PCR testa za odkrivanje okužbe s Sars-Cov-2.

V zvezi z izdajo te odločbe niso nastali posebni stroški. Ta odločba je v skladu s 30. točko 28. člena Zakona o upravnih taksah (Ur. l. RS, št. 106/10 – uradno prečiščeno besedilo, 14/15 – ZUUJFO, 84/15 – ZzeIP-J, 32/16 in 30/18) oproščena plačila upravne takse.

Pouk o pravnem sredstvu:
Zoper to odločbo je v zavrnilnem delu dovoljena pritožba Informacijskemu pooblaščencu RS, Zaloška 59, 1000 Ljubljana v roku 15 dni od dne prejema te odločbe. Pritožba se vloži pisno ali ustno na zapisnik pri UL Medicinski fakulteti, Vrazov trg 2, 1000 Ljubljana ali pošije priporočeno po pošti na ta isti naslov. V tem roku se lahko stranka pravici do pritožbe tudi odpove. Pritožba je takse prosta.

S spoštovanjem,

Prof. dr. Igor Švab, dr. med.
dekan

UNIVERZA V LJUBLJANI
Medicinska fakulteta
15-1
Ljubljana

Priloga:
- Certifikat certifikati o ustreznosti PRC testa za odkrivanje okužbe s Sars-Cov-2

Poslati:
- [redacted], Stara ulica 8, 9000 Murska Sobota

Vrazov trg

University of Ljubljana 1000 Ljub,
Faculty of Medicine

Ljubljana, 30 November 2020

The Faculty of Medicine issues on the basis of the second paragraph of Article 22 of the Access to Public Information Act (Official Gazette of the Republic of Slovenia, No. 51/06 - official consolidated text, 117/6 - ZdavP-2, 23/14, 50/14, 19 / 15 - decisions US, 102/15 and 7/18), hereinafter: ZDIJZ and in accordance with Article 15 of ZDIJZ in the administrative case of assessing the merits of the request of the applicant [applicant name] for access to public information

DECISION

1, The request from [applicant name] for access to public information is rejected in so far as it relates to the provision of scientific evidence on the isolation of Sars-Cov-2 virus in accordance with Koch's postulates and the submission of a study proving a causal link between Sars-Cov-2 and suspected infectious disease Covid-19.

2. No costs have been incurred.

Justification:

On 23 November 2020, the Authority received from the Ministry of Health, Directorate for Public Health, the resignation of the request of the applicant [applicant name] in the part regarding points 3, 4 and 5 of the request, namely regarding:

• Point 3: scientific evidence on the isolation of Sars-Cov-2 virus according to Koch's postulates and studies proving a causal link between Sars-Cov-2 and the suspected infectious disease Covid-19,

• Point 4: certificates of suitability of the PRC test for the detection of Sars-Cov-2 infection and

• Point 5: data on the number of amplification cycles used in Slovenia from the beginning of testing until today by months.

In accordance with Article 4 of the ZDIJZ, information of a public nature is information that originates from the work area of the body and is in the form of a document, case, dossier, register, record or other documentary material (hereinafter: document) produced by the body itself, in cooperation with another body, or obtained from other persons. Three basic conditions derive from that provision, which must be cumulatively fulfilled in order to be able to speak of the existence of information of a public nature, namely:

1. the information must come from the scope of work of the body,
2. it must be at the disposal of the authority; and
3. it must be in some materialized form.

In point 3, the applicant requests the submission of scientific evidence on the isolation of Sars-Cov-2 virus in accordance with Koch’s postulates and the transmission of a study

proving a causal link between Sars-Cov-2 and suspected infectious disease Covid-19. UL MF Institute of Microbiology and Immunology a scientific study to provide evidence of Sars-Cov-2 virus isolation according to Koch's postulates has not been performed. UL ME Institute of Microbiology and Immunology also did not conduct a scientific study, which would demonstrate a causal link between Sars-Cov-2 and the suspected infectious disease Covid-19. The authority thus does not have the required document at its disposal, which is why it was necessary regarding point 3 requirements to decide as follows from the operative part of this decision.

Regarding point 4 of the request, we inform the applicant that the number of amplification cycles used is in Slovenia from the beginning of testing until today, 40.

Regarding point 5, we are sending the applicant a certificate of suitability of the PCR test for the detection of infection with Sars-Cov-2.

No specific costs were incurred in issuing this decision. This decision is in accordance with point 30 of Article 28 Of the Administrative Fees Act (Official Gazette of the Republic of Slovenia, No. 106/10 - officially consolidated text, 14/15 – ZUUJFO, 84/15 - ZzelP-J, 32/16 and 30/18) exempt from administrative fees.

Remedy instruction:

An appeal against this decision is allowed in the rejection part to the Information Commissioner of the Republic of Slovenia, Zaloška 59, 1000 Ljubljana within 15 days from the date of receipt of this decision. The appeal shall be lodged in writing or orally to the minutes at the UL Faculty of Medicine, Vrazov trg 2, 1000 Ljubljana or send by registered mail by post to that same address. Within this period, the party may also waive the right to appeal. Complaint is tax free.

With respect,

Prof. dr. Igor Švab, Ph.D. med.

NACIONALNI LABORATORIJ ZA ZDRAVJE, OKOLJE IN HRANO

SKUPNE STROKOVNE SLUŽBE

Datum: 15.3.2021

Številka: 161-0-7-IJZ-3/2021

Nacionalni laboratorij za zdravje, okolje in hrano, Prvomajska ulica 1, Maribor, ki ga zastopa direktorica mag. Tjaša Žohar Čretnik, dr. med., spec., izdaja na podlagi prvega odstavka 21. člena ter drugega odstavka 22. člena Zakona o dostopu do informacij javnega značaja (Ur. l., št. RS, 51/06 - UPB-2 in 117/06 - ZdavP-2, 23/2014, 50/2014) in na podlagi četrtega odstavka 26. člena Sklepa o ustanovitvi Nacionalnega laboratorija za zdravje, okolje in hrano (štev. 01403-26/2013/4 z dne 25. 7. 2013), v upravni zadevi dostopa do informacij javnega značaja po vloženi zahtevi prosilca [redacted]

O D L O Č B O

o delni zavrnitvi zahteve za dostop do informacije javnega značaja

1. Zahtevi za dostop do informacij javnega značaja prosilca [redacted] vloženi dne 9.2.2021, s e delno u g o d i v delu, ki se nanaša na cepivo proti bolezni Covid-19

2. V ostalem se zahtevo prosilca zavrne.

3. Nacionalni laboratorij za zdravje, okolje in hrano in prosilec krijeta vsak svoje stroške postopka.

O b r a z l o ž i t e v:

Prosilec je dne 9.2.2021 na Nacionalni laboratorij za zdravje, okolje in hrano (v nadaljevanju: NLZOH) v elektronski pošti naslovil Zahtevo za dostop do informacij javnega značaja. Zaradi molka NLZOH se je prosilec pritožil, zato je Informacijski pooblaščenec NLZOH pozval k odločitvi v skladu z ZDIJZ oz. sporočilo, zakaj odločba ni bila izdana pravočasno, če za to obstajajo opravičeni razlogi.

Vlagatelj je na NLZOH naslovil zahtevo s sledečo vsebino:

A. Virus SARS-CoV-2 (v nadaljevanju: Virus) in bolezen Covid-19 (v nadaljevanju: C19)

10. Glede na z državnimi predpisi določenimi vlogo in namenom ter pomenom NLZOH na področju javnega zdravja, Vlagatelj domneva, da je NLZOH v lastnem laboratoriju dokazal fizični obstoj Virusa iz vzorcev okuženih oseb ob upoštevanju Kochovih in/ali Riverjevih postulatov, zato Vlagatelj od NLZOH Vlagatelj pričakuje listinsko informacijo, v kateri NLZOH to izkazuje.

11. Če NLZOH fizični obstoj Virusa ni dokazal, Vlagatelj pričakuje, da mu NLZOH predloži listinsko informacijo laboratorija, ki je dokazal fizični obstoj Virusa.

12. Če fizični obstoj Virusa (sploh) ni laboratorijsko dokazan po Kochovih in/ali Riverjevih postulatih, Vlagatelj od NLZOH pričakuje listinsko informacijo, ki (kakorkoli) dokazuje obstoj Virusa.

13. Ali se je celotna (izolirana) DNA sekvenca Virusa pridobila iz okuženih pacientov ali računalniško z algoritmi iz vzorcev vzetih iz genske banke? Vlagatelj pričakuje, da mu

NLZOH predloži listinsko informacijo kdo je prvi izvedel celotno (biokemično karakterizacijo) DNA sekvenco virusa?

14. Ali so bili opravljeni vsi potrebni kontrolni eksperimenti, da se izloči možnost, da ta sekvenčna struktura, i.e. genetski sev, ki je pripisan temu virusu, ne izvira iz drugega vira in da je neškodljiv?

15. Ali so bili opravljene vse potrebne kontrole, da se izloči, da eksperimentalna priprava, i.e. okužba celične kulture (e.g. VeroE6 celice/celice iz jeter opic), s katero se je obdelala celična kultura, ni posledica afekta, ki bi se tako pomotoma pripisal zaznavanju virusa?

16. Glede na (uradno) informacijo, da Virus povzroča C19, Vlagatelj od NLZOH pričakuje listinsko informacijo, ki pri ljudeh to vzročnost Virusa in C19 dokazuje.

17. Ali NLZOH pri odkrivanju Virusa s PCR testom uporablja Corman-Drostenov protokol ali kateri drug protokol? Vlagatelj od NLZOH pričakuje ali pritrditev ali listinsko informacijo o protokolu, ki ga pri svojem delu upošteva NLZOH.

18. Glede na zapis v javno dostopni informaciji "PCR testi so zanesljivi." avtorjev Petra Vovko, mikrobiologinja v sodelovanju z Majo Bombek Ihan ter Matjažem Reteljem, da gre za osebna/strokovna mnenja in ne nujno mnenja delodajalca (NLZOH), in v kateri je navedeno, da se za detekcijo Virusa s PCR testom opravi 40 ciklov (pomnoževanj) kratkih zaporedij DNA, medtem ko Corman-Drostenov protokol navaja 45 ciklov.

18.1. NLZOH naj Vlagatelju pojasni, zakaj ta razlika, ali je znanstveno/strokovno ali drugače utemeljena, ter Vlagatelju predloži listinsko informacijo utemeljitve odstopanja.

18.2. NLZOH naj Vlagatelju pojasni, ali dosledno in ves čas od marca 2020 pri detekciji Virusa s PCR testom upošteva navodila proizvajalcev glede števila.

18.3. NLZOH naj Vlagatelju pojasni, ali dosledno in ves čas od marca 2020 uporablja na isti/enaki napravi isto število ciklov za detekcijo Virusa.

18.4. Če je NLZOH spreminjal število ciklov, naj Vlagatelju predloži listinsko informacijo o razlogih in ciljih spreminjanja števila ciklov ter o rezultatih odkrivanja in potrjevanja Virusa z različnim številom pomnoževanj kratkih zaporedij DNA.

19. V javno dostopni informaciji "PCR testi so zanesljivi." je navedeno: "Vrednost Ct je zaporedna številka cikla, pri katerem signal vzorca doseže prag, ki je potreben za pozitiven rezultat. Če je Ct nizek, je bilo v vzorcu veliko virusnih genov. Če je Ct visok, je bilo v vzorcu malo virusnih genov.".

19.1. Ker Vlagatelju ni jasno, v kakšni povezavi so navedbe v javno dostopni informaciji "PCR testi so zanesljivi." s "standardnimi" 40 Ct, od NLZOH pričakuje pojasnilo, ali kljub vsemu obstaja minimum pomnoževanj, ki dokazuje prisotnost Virusa in s tem pozitivnost testirane osebe, ter maksimum pomnoževanj, ki dokazuje odsotnost Virusa in s tem negativnost testirane osebe7, kot npr. Ct 35 za pozitivnost in Ct 40 za negativnost?
19.2. Ali PCR odkrije celotno sekvenco domnevnega virusa?
19.3. Ali je "količina" Virusa merljiva in če, kako?
19.4. Ali že vsaka dokazana "količina" Virusa dokazuje okuženost z Virusom?
19.5. Ali lahko PCR časovno določi, kdaj je človek pridobil virus?
19.6. Ali lahko PCR najde virusne delce iz preteklih okužb?
19.7. Ali lahko PCR zazna druge sorodne koronaviruse?

19.8. Ali že vsaka s PCR testom ugotovljena prisotnost Virusa pri neki osebi, ne glede na "količino" Virusa, de facto že pomeni obolelost te osebe s C19?
19.9. Če vzorec preverimo s PCR testom pri 30 Ct in isti vzorec testiramo pri 40 Ct, ,bo vrednost enaka ali bo vplivalo na rezultat, ter bi želel reference do teh podatkov?

20. Vlagatelj prilaga kopijo (anonimiziranega) izvida o prisotnosti oz. detekciji Virusa pri osebi, ki ga je opravil Inštitut za mikrobiologijo in imunologijo iz Ljubljane (IMI).

20.1. Vlagatelj, izhajajoč iz predloženega izvida testiranja in ker iz javno dostopnih virov in informacij ni mogel razbrati in z gotovostjo ugotoviti, od NLZOH pričakuje, da mu predloži listinsko informacijo, ki vsebuje navedbo državnega predpisa, na podlagi katerega je IMI, tako kot NLZOH po 23.c členu ZNB, javno pooblaščen za izvajanje mikrobioloških preizkušanj na področju medicinske mikrobiologije za potrebe izvajalcev zdravstvene dejavnosti, ter od ECDC priznan nacionalni referenčni laboratorij.
20.2. Vlagatelj, ki mu v izvidu, po laičnem prepričanju, manjka vsaj podatek o številu opravljenih pomnoževanj, od NLZOH pričakuje, da mu predloži listinsko informacijo - predpis oz. akt, ki določa vsebino izvida testiranja oz. izvida neposrednega dokazovanja Virusa, ter predloži tudi en primerek lastnega (anonimiziranega) izvida dejansko opravljenega dokazovanja Virusa.
20.3. Vlagatelj od NLZOH pričakuje, da mu navede dejansko skupno število (vseh) opravljenih PCR testiranj ter skupno število (vseh) testiranih oseb (i) v letu 2020 in (ii) v januarju 2021.

B. Cepivo proti C19 (v nadaljevanju: Cepivo)

21. Je NZLOH kakorkoli sodeloval z EMA pri izbiri ter kontroli in potrjevanju Cepiva, in če, kako? Vlagatelj od NZLOH pričakuje ali pisno zanikanje sodelovanja ali predložitev listinskih informacij, ki izkazujejo sodelovanje NZLOH z EMA.
22. Je NLZOH, pred dejanskim potrjevanjem Cepiva vsakega proizvajalca v promet oz. uporabo na področju RS, samostojno in neodvisno ali po nalogu JAZMP analizno preskusil Cepivo, bodisi kot redno bodisi kot izredno kontrolo kakovosti Cepiva?
22.1. Če DA, Vlagatelj od NLZOH pričakuje listinsko informacijo o opravljeni kontroli kakovosti Cepiva vseh proizvajalcev.
22.2. Če NE, Vlagatelj od NLZOH pričakuje listinsko informacijo o opravljeni kontroli kakovosti Cepiva vseh proizvajalcev od (evropskega) uradnega kontrolnega laboratorija, ki je opravil kontrolo kakovosti.
23. Ali je NZLOH pri določanju redne in izredne kontrole kakovosti, ter nerutinskih ali posebnih preskusov samostojna in suverena inštitucija, ali je podrejena nekemu drugemu in kateremu organu oz. entiteti, ter, ali lahko predlaga nerutinske ali posebne preskuse civilna družba in pod kakšnimi pogoji?

Vlagatelj pričakuje od NLZOH, javnega zavoda z izjemno pomembnimi pooblastili in nalogami na področju javnega zdravja in tudi v vlogi nacionalnega referenčnega laboratorija, da bo
- Vlagatelju odgovoril na v tej zahtevi postavljena vprašanja,
- Vlagatelju predložil zahtevane listinske informacije, bodisi v obliki elektronskih zapisov (word, PDF) ali prepisov (kopija/scan) listin bodisi v obliki elektronskih povezav do spletnih strani, na katerih bodo relevantne listinske informacije Vlagatelju prosto dosegljive, ter
- Vlagateljeve zahtevke po informacijah v obliki vprašanj ali listin, ki ne sodijo v delovno področje NLZOH, nemudoma odstopil pristojni inštituciji ali (državnemu) organu, Vlagatelju pa hkrati posredoval dopis o odstopljenih zadeva pisno obvestil.
- Vse pisne odpravke NZLOH pričakuje Vlagatelj na e-naslov [redacted]

NACIONALNI LABORATORIJ ZA
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Zahtevi za informacijo javnega značaja se ugodi v delu, ki se nanaša na informacije o cepivih, tako, da se mu odgovor posreduje na elektronski naslov: [redacted]
V ostalem se prosilčeva zahteva za informacijo javnega značaja zavrne.

Po določilu 4. člena Zakona o dostopu do informacij javnega značaja je informacija javnega značaja informacija, ki izvira iz delovnega področja organa, nahaja pa se v obliki dokumenta, zadeve, dosjeja, registra, evidence ali drugega dokumentarnega gradiva(v nadaljnjem besedilu: dokument), ki ga je organ izdelal sam, v sodelovanju z drugim organom, ali pridobil od drugih oseb.

Z dokumenti, zaprošenimi pod točkami 10. do 17. NLZOH ne razpolaga v takšni obliki, ki jo zahteva prosilec, ker NLZOH za diagnostiko Covid19 ne uporablja gojitvenih metod, temveč za dokazovanje virusne RNK v kužninah uporablja teste, ki so validirani, imajo CE-IVD oznako, izvaja jih od prvega dne epidemije po protokolih proizvajalca, pred uporabo jih verificira po internih navodilih za delo, ki so izključno namenjeni laboratorijskemu osebju in so opredeljeni kot poslovna skrivnost, zato prosilca napotuje na svetovni splet, kjer so številni peer-viewed članki, v katerih je opisano gojenje virusa SARS-CoV-2 na celičnih kulturah.

V nadaljevanju prosilec prosi za pojasnila (tč. 18. in 19.). Ob tem NLZOH pojasnjuje, da skladno s 4. členom ZDIJZ informacijo javnega značaja predstavlja samo dokument, ki že obstaja v neki materialni obliki oz. tisti dokument, ki ga je organ v okviru svojega delovnega področja že izdelal oz. pridobil in ga ni dolžan ustvariti šele na podlagi zahteve. Pojasnilo tako ne predstavlja informacije javnega značaja, saj to ni dokument, s katerim bi NLZOH že razpolagal.

V zvezi s tč. 20 prosilčevih vprašanj je potrebno pojasniti, da NLZOH ni pristojen za interpretacijo izvidov drugih izvajalcev, da izvid vsebuje posebne vrste osebnih podatkov, katerega razkritje bi pomenilo kršitev varstva osebnih podatkov, vsebina izvida je določena v Pravilniku o pogojih, ki jih morajo izpolnjevati laboratoriji za izvajanje preiskav na področju laboratorijske medicine, podatki o skupnem številu opravljenih PCR testiranj in skupnem številu testiranih oseb so vsakodnevno objavljeni na tiskovnih konferencah Vlade RS in na https://covid-19.sledilnik.org/sl/stats.

Ob tem velja še poudariti, da upoštevaje naloge, ki jih NLZOH v skladu s 23. členom Zakona o zdravstveni dejavnosti izvaja, ni organ, ki bi izvajal naloge oblasti in ob znani epidemiološki situaciji priprava zahtevnih strokovnih pojasnil še dodatno obremenjuje vrhunski strokovni kader, ki mora biti na razpolago za izvajanje zakonskih nalog.

Upoštevaje vse zgoraj ugotovljeno je odločeno kot izhaja iz izreka.

Nacionalni laboratorij za zdravje, okolje in hrano in prosilec krijeta vsak svoje stroške postopka.

Pouk o pravnem sredstvu: Zoper to odločbo je dovoljena pritožba na Informacijskega pooblaščenca, Dunajska cesta 22, 1000 Ljubljana, v 15 dneh po vročitvi odločbe. Pritožba se vloži pisno ali ustno na zapisnik pri organu, ki je izdal to odločbo. Pritožba je takse prosta.

Po pooblastilu direktorice:
Vlasta Likar, univ. dipl. prav.

Vročiti:

- [redacted]
- v vednost: Informacijski pooblaščenec
- Arhiv – tu.

ENGLISH TRANSLATIONS (AS PROVIDED BY THE FOI SUBMITTER)
OF QUESTIONS 10-17 AND NLZOH'S INITIAL RESPONSE

10) Glede na z državnimi predpisi določeno vlogo in namenom ter pomenom NLZOH na področju javnega zdravja, Vlagatelj domneva, da je NLZOH v lastnih laboratoriju dokazal fizični obstoj virusa iz vzorcev okuženih oseb ob upoštevanju Kochovig in/ ali Riverjevih postulatov, zato Vlagatelj pričakuje listinsko informacijo, v kateri NLZOH to izkazuje.

Given the role and purpose determined by state regulations and the importance of NLZOH in the field of public health, the Applicant assumes that NLZOH proved in its own laboratory the physical existence of the virus from samples of infected persons taking into account Kochovig and / or River's postulates, which NLZOH demonstrates this.

11) Če NLZOH fizični obstoj virusa ni dokazal, Vlagatelj pričakuje, da mu NLZOH predloži listinsko informacijo laboratorija, ki je dokazal fizični obstoj virusa?

If the NLZOH has not proved the physical existence of the virus, does the Applicant expect the NLZOH to provide him with documentary information from the laboratory that proved the physical existence of the virus?

12) Če fizični obstoj virusa(sploh) ni laboratorijsko dokazan po Kochovih in/ali Riverjevih postulatih, vlagatelj pričakuje listinsko informacijo,ki (kakorkoli) dokazuje obstoj virusa?

If the physical existence of the virus (at all) is not laboratory proven according to Koch's and / or River's postulates, does the applicant expect documentary information that (in any way) proves the existence of the virus?

13) Ali se je celotna (izolirana) DNA sekvenca virusa pridobila iz okuženih pacientov ali računalniško z algoritmi iz vzorcev genske banke? Vlagatelj pričakuje,da mu NLZOH predloži listinsko informacijo kdo je prvi izvedel celotno(biokemično karakterizicijo) DNA sekvenco virusa?

Has the entire (isolated) DNA sequence of the virus been obtained from infected patients or by computer algorithms from gene bank samples? The applicant expects the NLZOH to provide him with documentary information as to who first performed the entire (biochemical characterization) DNA sequence of the virus?

14) Ali so bili opravljeni vsi potrebni kontrolni eksperimenti, da se izloči možnost,da ta sekvenčna struktura i.e. genetski sev, ki je pripisan temu virusu, ne izvira iz drugega vira in da je neškodljiv?

Have all the necessary control experiments been performed to rule out the possibility that this sequence structure i.e. the genetic strain attributed to this virus does not originate from another source and is harmless?

15)Ali so bile opravljene vse potrebne kontrole, da se izloči,da eksperimentalna priprava, i.e. okužba celične kulture(e.g. VeroE6 celice/celice iz jeter opic), s katero se je obdelala celična kultura, ni posledica afekta, ki bi se tako pomotoma pripisal zaznavanju virusa?

Have all the necessary controls been carried out to rule out that the experimental preparation, i.e. is the cell culture infection (eg VeroE6 cells / monkey liver cells) treated with the cell culture not the result of an affect so mistakenly attributed to virus detection?

16) Glede na (uradno) informacijo, da virus povzroča C19, vlagatelj od NLZOH pričakuje listinsko informacijo, ki pri ljudeh to vzročnost virusa in C19 dokazuje?

According to (official) information that the virus causes C19, does the applicant expect from NLZOH documentary information that proves this causality of the virus in humans and C19?

17) Ali NLZOH pri odkrivanju virusa s PCR testom uporablja Corman-Drosten protokol ali kateri drugi protokol? Vlagatelj pričakuje od NLZOH pričakuje ali potrditev ali listinsko informacijo o protokolu, ki ga pri svojem delu upošteva NLZOH.

Does NLZOH use the Corman-Drosten protocol or any other protocol to detect the virus by PCR test? The applicant expects from the NLZOH either confirmation or documentary information on the protocol that the NLZOH follows in its work.

ANSWER from NLZOH regarding questions 10-17

Z dokumenti, zaprošenimi pod točkami 10. do 17. NLZOH ne razpolaga v takšni obliki, ki jo zahteva prosilec, ker NLZOH za diagnostiko C19 ne uporablja gojitvenih metod,temveč za dokazovanje virusne RNK v kužninah uporablja teste, ki so validirani in imajo CE-IVD oznako, izvaja jih od prvega dne epidemije po protokolu proizvajalca, pred uporabo jih verificira po internih navodilih za delo, ki so izključno namenjeni laboratorijskemu osebju in so opredeljeni kot poslovna skrivnost, zato prosilca napotuje na svetovni splet, kjer so številni peer-viewed članki, v katerih je opisano gojenje virusa SARS-CoV-2 na celičnih kulturah

The documents requested under points 10 to 17 are not available to the NLZOH in the form required by the applicant, as the NLZOH does not use culture methods to diagnose C19, but uses tests that are validated and CE-certified to detect viral RNA in infectious diseases. IVD label, carried out from the first day of the epidemic according to the manufacturer's protocol, verified before use according to internal work instructions, which are exclusively intended for laboratory staff and are defined as a business secret, so the applicant is referred to the World Wide Web, where many peer-viewed articles , which describe the cultivation of SARS-CoV-2 virus on cell cultures

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Številka: 090-121/2021/7
Datum: 7. 6. 2021

Informacijski pooblaščenec po inforrmacijski pooblaščenki Mojci Prelesnik, v nad. IP, na podlagi 2. člena Zakona o Informacijskem pooblaščencu (Ur. l. RS, št. 113/05 in 51/07-ZUstS-A, v nad. ZInfP), 3. in 4. odstavka 27. člena Zakona o dostopu do informacij javnega značaja (Ur. l. RS, št. 51/06 – UPB, 117/06 – ZDavP-2, 23/14, 50/14, 19/15 – odl. US in 102/15; v nad. ZDIJZ) ter 1. odstavka 248. člena ter 1. in 3. odstavka 251. člena Zakona o splošnem upravnem postopku (Ur. l. RS, št. 24/06 – UPB, 105/06–ZUS-1, 126/07-ZUP-E, 65/08-ZUP-F in 8/10-ZUP-G in 82/13-ZUP-H; v nad. ZUP), o pritožbi [redacted] z dne 1. 4. 2021, zoper odločbo **Nacionalnega laboratorija za zdravje, okolje in hrano**, Prvomajska ulica 1, 2000 Maribor (v nad. organ), št. 161-0-7-IJZ-3/2021 z dne 15. 3. 2021, v zadevi dostopa do informacij javnega značaja, izdaja naslednjo

O D L O Č B O

1. Pritožbi prosilca z dne 1. 4. 2021 zoper odločbo Nacionalnega laboratorija za zdravje, okolje in hrano, št. 161-0-7-IJZ-3/2021 z dne 15. 3. 2021, se delno ugodi in se izpodbijana odločba delno odpravi ter se zadeva v delu, ki se nanaša na 17. in 20.2. točko zahteve prosilca, vrne organu v ponovno odločanje. Organ je dolžan o zahtevi prosilca v tem delu odločiti brez odlašanja, najpozneje pa v 30 (tridesetih) dneh od prejema te odločbe.

2. V preostale delu se pritožba prosilca zavrne.

3. V postopku reševanja te pritožbe niso nastali posebni stroški.

OBRAZLOŽITEV:

Prosilec je dne 9. 2. 2021 na organ vložil zahtevo za dostop do informacij javnega značaja s sledečo vsebino:
A. Virus SARS-CoV-2 (v nad.: virus) in bolezen Covid-19 (v nad.: C19)
10. Prosilec domneva, da je organ, iz vzorcev okuženih oseb, ob upoštevanju Kochovih in/ali Riverjevih postulatov, v lastnem laboratoriju dokazal fizični obstoj virusa, zato prosilec od organa pričakuje listinsko informacijo, v kateri organ to izkazuje.
11. Če organ fizičnega obstoja virusa ni dokazal, naj predloži listinsko informacijo laboratorija, ki je dokazal fizični obstoj virusa.
12. Če fizični obstoj virusa (sploh) ni laboratorijsko dokazan po Kochovih in/ali Riverjevih postulatih, prosilec prosi za listinsko informacijo, ki (kakorkoli) dokazuje obstoj virusa.
13. Ali se je celotna (izolirana) DNA sekvenca virusa pridobila iz okuženih pacientov ali računalniško, z algoritmi iz vzorcev vzetih iz genske banke? Prosilec pričakuje, da mu organ predloži listinsko informacijo, kdo je prvi izvedel celotno (biokemično karakterizacijo) DNA sekvenco virusa.
14. Ali so bili opravljeni vsi potrebni kontrolni eksperimenti, da se izloči možnost, da ta sekvenčna struktura, i.e. genetski sev, ki je pripisan temu virusu, ne izvira iz drugega vira in da je neškodljiv.
15. Ali so bili opravljene vse potrebne kontrole, da se izloči, da eksperimentalna priprava, i.e. okužba celične kulture (e.g. VeroEG celice/celice iz jeter opic), s katero se je obdelala celična kultura, ni posledica afekta, ki bi se tako pomotoma pripisal zaznavanju virusa.
16. Glede na (uradno) informacijo, da virus povzroča C19, prosilec pričakuje listinsko informacijo, ki pri ljudeh to vzročnost virusa in C19 dokazuje.
17. Ali organ pri odkrivanju virusa s PCR testom uporablja Corman-Drostenov protokol ali kateri drug protokol? Prosilec pričakuje ali pritrditev ali listinsko informacijo o protokolu, ki ga pri svojem delu upošteva organ.
18. Glede na zapis v javno dostopni informaciji "PCR testi so zanesljivi." avtorjev Petra Vovko, mikrobiologinja v sodelovanju z Majo Bombek Ihan ter Matjažem Reteljem, da gre za osebna/strokovna mnenja in ne nujno mnenja delodajalca (organa) in v kateri je navedeno, da se za detekcijo virusa s PCR testom opravi 40 ciklov (pomnoževanj) kratkih zaporedij DNA, medtem ko Corman-Drostenov protokol navaja 45 ciklov.

18.1. Organ naj pojasni, zakaj ta razlika (ali je znanstveno/strokovno ali drugače utemeljena) ter prosilcu predloži listinsko informacijo utemeljitve odstopanja.
18.2. Organ naj pojasni, ali dosledno in ves čas (od marca 2020) pri detekciji virusa s PCR testom upošteva navodila proizvajalcev glede števila.
18.3. Organ naj pojasni, ali dosledno in ves čas (od marca 2020) uporablja na isti/enaki napravi isto število ciklov za detekcijo virusa.
18.4. Če je organ spreminjal število ciklov, naj prosilcu predloži listinsko informacijo o razlogih in ciljih spreminjanja števila ciklov ter o rezultatih odkrivanja in potrjevanja virusa z različnim številom pomnoževanj kratkih zaporedij DNA.
19. V javno dostopni informaciji "PCR testi so zanesljivi." je navedeno: "Vrednost Ct je zaporedna številka cikla, pri katerem signal vzorca doseže prag, ki je potreben za pozitiven rezultat. Če je Ct nizek, je bilo v vzorcu veliko virusnih genov. Če je Ct visok, je bilo v vzorcu malo virusnih genov.
19.1. Ker prosilcu ni jasno, v kakšni povezavi so navedbe v javno dostopni informaciji "PCR testi so zanesljivi." s "standardnimi" 40 Ct, od organa pričakuje pojasnilo, ali kljub vsemu obstaja minimum pomnoževanj, ki dokazuje prisotnost virusa in s tem pozitivnost testirane osebe ter maksimum pomnoževanj, ki dokazuje odsotnost virusa in s tem negativnost testirane osebe, kot npr. Ct 35 za pozitivnost in Ct 40 za negativnost.
19.2. Ali PCR odkrije celotno sekvenco domnevnega virusa?
19.3. Ali je "količina" virusa merljiva in če, kako?
19.4. Ali že vsaka dokazana "količina" virusa dokazuje okuženost z virusom?
19.5. Ali lahko PCR časovno določi, kdaj je človek pridobil virus?
19.6. Ali lahko PCR najde virusne delce iz preteklih okužb?
19.7. Ali lahko PCR zazna druge sorodne koronaviruse?
19.8. Ali že vsaka s PCR testom ugotovljena prisotnost virusa pri neki osebi, ne glede na "količino" virusa, pomeni obolelost te osebe s C19?
19.9. Če vzorec preverimo s PCR testom pri 30 Ct in isti vzorec testiramo pri 40 Ct, bo vrednost enaka ali bo vplivalo na rezultat? Prosilec bi želel reference do teh podatkov.
20. Prosilec prilaga kopijo (anonimiziranega) izvida o prisotnosti oz. detekciji virusa pri osebi, ki ga je opravil Inštitut za mikrobiologijo in imunologijo iz Ljubljane (v nad. IMI).
20.1. Prosilec, izhajajoč iz predloženega izvida testiranja in ker iz javno dostopnih virov in informacij ni mogel razbrati in z gotovostjo ugotoviti, od organa pričakuje, da mu predloži listinsko informacijo, ki vsebuje navedbo državnega predpisa, na podlagi katerega je IMI, tako kot organ po 23.c členu ZNB, javno pooblaščen za izvajanje mikrobioloških preizkušanj na področju medicinske mikrobiologije za potrebe izvajalcev zdravstvene dejavnosti, ter od ECDC priznan nacionalni referenčni laboratorij.
20.2. Prosilec, ki mu v izvidu, po laičnem prepričanju, manjka vsaj podatek o številu opravljenih pomnoževanj, od organa pričakuje, da mu predloži listinsko informacijo – predpis oz. akt, ki določa vsebino izvida testiranja oz. izvida neposrednega dokazovanja virusa, ter predloži tudi en primerek lastnega (anonimiziranega) izvida dejansko opravljenega dokazovanja virusa.
20.3. Prosilec od organa pričakuje, da mu navede dejansko skupno število (vseh) opravljenih PCR testiranj ter skupno število (vseh) testiranih oseb v letu 2020 in v januarju 2021.

B. Cepivo proti C19 (v nad.: cepivo)

21. Je organ kakorkoli sodeloval z EMA pri izbiri ter kontroli in potrjevanju cepiva, in če, kako. Prosilec od organa pričakuje ali pisno zanikanje sodelovanja ali predložitev listinskih informacij, ki izkazujejo sodelovanje organa z EMA.
22. Je organ, pred dejanskim potrjevanjem cepiva vsakega proizvajalca v promet oz. uporabo na področju RS, samostojno in neodvisno ali po nalogu JAZMP analizno preskusil cepivo, bodisi kot redno bodisi kot izredno kontrolo kakovosti cepiva.
22.1. Če da, prosilec od organa pričakuje listinsko informacijo o opravljeni kontroli kakovosti cepiva vseh proizvajalcev.
22.2. Če ne, prosilec od organa pričakuje listinsko informacijo o opravljeni kontroli kakovosti cepiva vseh proizvajalcev od (evropskega) uradnega kontrolnega laboratorija, ki je opravil kontrolo kakovosti.
23. Ali je organ pri določanju redne in izredne kontrole kakovosti, ter ne-rutinskih ali posebnih preskusov samostojna in suverena institucija, ali je podrejena nekemu drugemu in kateremu organu oz. entiteti, ali lahko predlaga ne-rutinske ali posebne preskuse civilna družba in pod kakšnimi pogoji?
Vlagatelj pričakuje od organa, da bo:
- odgovoril na v tej zahtevi postavljena vprašanja,
- predložil zahtevane listinske informacije, bodisi v obliki elektronskih zapisov (word, pdf) ali prepisov (kopija/scan) listin, bodisi v obliki elektronskih povezav do spletnih strani, na katerih bodo relevantne listinske informacije prosilcu prosto dosegljive,

- zahtevke po informacijah v obliki vprašanj ali listin, ki ne sodijo v delovno področje organa, nemudoma odstopil pristojni inštituciji ali (državnemu) organu, prosilcu pa hkrati posredoval dopis o odstopljenih zadeva pisno obvestil.

Organ je o zahtevi prosilca odločil z odločbo št. 161-0-7-IJZ-3/2021 z dne 15. 3. 2021, s katero je zahtevi ugodil v delu, ki se nanaša na cepivo, v preostalem delu pa je zahtevo prosilca zavrnil. V obrazložitvi izpodbijane odločbe je organ navedel sledeče:
- Organ z dokumenti, zaprošenimi pod točkami od 10. do 17., ne razpolaga v takšni obliki, ki jo zahteva prosilec, ker organ za diagnostiko Covid-19 ne uporablja gojitvenih metod, temveč za dokazovanje virusne RNK v kužninah uporablja teste, ki so validirani, imajo CE-IVD oznako. Teste izvaja od prvega dne epidemije po protokolih proizvajalca, pred uporabo jih verificira po internih navodilih za delo, ki so namenjeni izključno laboratorijskemu osebju in so opredeljeni kot poslovna skrivnost. Organ zato prosilca napotuje na svetovni splet, kjer so številni peer-viewed članki, v katerih je opisano gojenje virusa SARS-CoV-2 na celičnih kulturah.
- Pod točko 18. in 19. prosilec prosi za pojasnila, pri čemer organ pojasnjuje, da skladno s 4. členom ZDIJZ informacijo javnega značaja predstavlja samo dokument, ki že obstaja v neki materialni obliki oz. tisti dokument, ki ga je organ v okviru svojega delovnega področja že izdelal oz. pridobil in ga ni dolžan ustvariti šele na podlagi zahteve. Pojasnilo tako ne predstavlja informacije javnega značaja, saj to ni dokument, s katerim bi organ že razpolagal.
- V zvezi s točko 20. organ pojasnjuje, da ni pristojen za interpretacijo izvidov drugih izvajalcev ter da izvid vsebuje posebne vrste osebnih podatkov, katerega razkritje bi pomenilo kršitev varstva osebnih podatkov. Vsebina izvida je določena v Pravilniku o pogojih, ki jih morajo izpolnjevati laboratoriji za izvajanje preiskav na področju laboratorijske medicine. Podatki o skupnem številu opravljenih PCR testiranj in skupnem številu testiranih oseb so vsakodnevno objavljeni na tiskovnih konferencah Vlade RS in na https://covid-19.sledilnik.org/sl/stat.
Organ še poudarja, da upoštevaje naloge, ki jih izvaja v skladu s 23. členom Zakona o zdravstveni dejavnosti (Ur. l. RS, št. 23/05 – UPB, 15/08 – ZPacP, 23/08, 58/08 – ZZdrS-E, 77/08 – ZDZdr, 40/12 – ZUJF, 14/13, 88/16 – ZdZPZD, 64/17, 1/19 – odl. US, 73/19, 82/20 in 152/20 – ZZUOOP, v nad. ZZDej), ni organ, ki bi izvajal naloge oblasti in ob znani epidemiološki situaciji priprava zahtevnih strokovnih pojasnil še dodatno obremenjuje vrhunski strokovni kader, ki mora biti na razpolago za izvajanje zakonskih nalog.

Zoper odločbo organa je prosilec dne 1. 4. 2021 vložil pritožbo, v kateri oporeka odločitvi organa v zavrnilnem delu in navaja sledeče:
1. Prosilec je po ZDIJZ na organ naslovil vprašanja od št. 10 do št. 16, vsa v zvezi z virusom SARS-CoV-2 in boleznijo Covid-19, ker je domneval, da je organ za izvajanje svojega ustanovitvenega namena in poslanstva, predvsem po 23. členu ZZDej, (1) bodisi v svojih laboratorijih po Kochovih postulatih dokazal obstoj virusa SARS-CoV-2 ter vzročnost virusa SARS-CoV-2 in bolezni Covid-19, (2) bodisi, da organ uporablja dokaze nekega drugega priznanega slovenskega, evropskega ali svetovnega laboratorija. Slovenski medicinski slovar za Kochove postulate določa, da se sme nekemu mikrobu, med katere sodijo tudi virusi, priznati vzročnost pri določeni bolezni samo, kadar so izpolnjeni naslednji pogoji: (i) mikrob moramo najti pri vsakem primeru bolezni, ne pa tudi pri zdravih osebah, (ii) treba ga je osamiti od bolnika v čisti kulturi, (iii) treba ga je vcepiti zdravim občutljivim živalim, pri katerih mora povzročiti isto bolezen, in (iv) isti mikrob moramo znova osamiti iz okuženih živali. Direktorica organa je na novinarski konferenci o aktualnem stanju glede bolezni Covid-19 dne 24. 2. 2021 predstavila nacionalno strategijo sledenja znanim in novim različicam virusa SARS-CoV-2. Navedla je, da bodo sledenje v humanih vzorcih pokrivali organ, IMI Medicinske fakultete in Klinični inštitut za specialno laboratorijsko diagnostiko na pediatrični kliniki UKC Ljubljana. Namen spremljanja je hitro zaznavanje novih variant virusa z večjo prenosljivostjo oz. težjim potekom bolezni ter spremljanje njihovih vzorcev širjenja. Načrt spremljanja in pojavljanja širjenja novih variant virusa zajema 5 sklopov. Prvi sklop je spremljanje novih variant pri okuženih osebah z različnimi tehnikami sekvenciranja in sekvenciranjem celotnega virusnega genoma. To spremljanje bo potekalo kontinuirano z zajemom 5-10% PCR pozitivnih vzorcev iz celotne populacije v skladu s priporočilom Evropske komisije in še posebej v posebnih ciljnih skupinah teh bolnikov. Drugi sklop je prav tako spremljanje novih variant, vendar s pomočjo dodatnega testiranja s presejalnimi PCR testi. Iz navedb direktorice organa prosilec sklepa, da organ (i) prejme kužnine, (ii) na katerih opravi PCR teste in (iii) opravi sekvenciranje, delnega in/ali celotnega genoma virusa. Ob trditvi NIJZ, da virus SARS-CoV-2 povzroči bolezen Covid-19 in ob zgornjih navedbah je prosilec prepričanja, da delo organa v zvezi z virusom temelji na znanosti ter na strokovnih raziskavah, dejstvih in dognanjih, ki dokazujejo (i) tudi fizični obstoj virusa SARS-CoV-2, in ne zgolj njegov (računalniško simuliran) genom, ter (ii) njegovo vzročnost bolezni Covid-19.
2. Prosilec je po ZDIJZ na organ naslovil vprašanja od št. 17 do št. 22, vsa v zvezi s PCR testom, ker organ za ugotavljanje virusa SARS-CoV-2 in bolezni Covid-19 uporablja PCR test, kar nedvoumno potrjuje del obrazložitve organa v l./l., nenazadnje pa tudi navedena izjava direktorice organa. S PCR testom se dokazuje materija, ki se mora zaradi majhnosti (začetnega) vzorca po točno določenem tehnično-tehnološkem postopku

multiplicirati, da se sploh lahko ugotovi njen obstoj. Materija pa je izključno fizična. Pri večini informacij, za katere organ smatra, da bi terjale pojasnilo, sploh ne gre za pojasnjevanje, ampak za odgovor da/ne in pa za informacijo v obliki listine ali spletne povezave, na podlagi katerih temelji delo organa, razen pri točki 18.1., saj gre za odstopanje med Corman-Drostenov protokolom in protokolom, kot je opisan v javno dostopni informaciji "PCR testi so zanesljivi." avtorjev Petra Vovko, mikrobiologinja v sodelovanju z Majo Bombek Ihan ter Matjažem Reteljem. Razlaga organa, da je protokol oz. navodila, po katerem opravlja teste, interne narave in poslovna skrivnost, prosilcu ni sprejemljiva. Prosilec je v točki 17. v zahtevi postavil neposredno in preprosto vprašanje, brez vsakršnega potrebnega pojasnjevanja. Corman-Drostenov protokol je javna listina, dosegljiva na spletni strani WHO, zato prosilec ne vidi temelja razlage organa, da gre za interno navodilo in poslovno skrivnost. Tudi napotilo organa, da naj prosilec poišče informacije na svetovnem spletu, prosilcu ni informacija v smislu 5. odstavka 6. člena ZDIJZ, ker niti ni konkretizirana do te mere, da bi prosilec in organ zagotovo imela isto informacijo, niti prosilec ne more vedeti, da na njej temelji delo organa, in je zato brezpredmetno.
3. Prosilec se strinja z delom obrazložitve organa, da ni pristojen dajati interpretacije izvidov drugih izvajalcev, vendar prosilec niti ni zahteval interpretacije, temveč informacijo v obliki listine ali povezave na svetovni splet, iz katere je razvidno pooblastilo drugih slovenskih laboratorijev za opravljanje nalog po 23.c členu ZZDej. Prosilec se organu zahvaljuje za v obrazložitvi dano informacijo o Pravilniku, ne more pa sprejeti trditve organa, da je število testiranih oseb javno dostopna prosta informacija. Znano je skupno število opravljenih testov in pa število okuženih oseb, koliko prebivalcev Slovenije je bilo dejansko testiranih, pa je podatek, ki prosilcu ni dosegljiv in mu je tako neznan.
4. Poudarjanje organa, da ni organ oblasti itd., je prosilcu brezpredmetno. V kolikor organ ne bi bil zavezanec za informacije po ZDIJZ, ga pritožbeni organ ne bi niti pozval, da pritožniku odgovori in mu posreduje zahtevane informacije. Virusa SARS-CoV-2 in bolezen Covid-19 sta v letu 2020 močno prizadela Svet in Slovenijo. Predvsem na svetovnem spletu je najti mnogo informacij, na verodostojnost le-teh pa slovenske prebivalce opozarjajo tako predstavniki oblasti kot strokovnjaki, ki z oblastjo sodelujejo pri reševanju zdravstvene krize. Ravno zato je prosilcu povsem nesprejemljiv izgovor organa, da mu dajanje informacije javnosti predstavlja obremenitev. Bolezen je vprašanje, ki najprej zadeva osebno človekovo sfero, če je bolezen razširjena, pa tudi javno. Molk javnih strokovnih institucij po prosilčevem prepričanju vodi v nezaupanje prebivalstva do teh institucij ter v informacijski kaos, kot smo mu priča tudi v zadnjem letu. Prosilec na organ zahteve sploh naslovil ne bi, v kolikor bi vse informacije, po katerih v zahtevi povprašuje, bile prosto dostopne z objavo na spletni strani organa.

IP je dne 19. 4. 2021 prejel dopis organa št. 161-0-7-IJZ-3/2021-1 z dne 16. 4. 2021, s katerim mu je ta, na podlagi 245. člena ZUP, odstopil pritožbo, kot dovoljeno, pravočasno in vloženo s strani upravičene osebe.

Na podlagi poziva IP št. 090-121/2021/2 z dne 4. 5. 2021, je organ IP posredoval dopis št. 161-0-7-IJZ-3/2021, z dne 10. 5. 2021, kateremu je priložil splošno dokumentacijo sistema vodenja kakovosti (t.i. interna navodila za delo oz. uporabo opreme). Dodatno je organ navedel, da je predmetno dokumentacijo v Klasifikacijskem načrtu organa, št. 020-1/2020 z dne 10. 7. 2020, opredelil kot poslovno skrivnost po Zakonu o poslovni skrivnosti (Ur. l. RS, št. 22/19, v nad. ZPosS), da jo ohrani kot skrivnost, saj zajema nerazkrito strokovno znanje, izkušnje in poslovne informacije, ki niso splošno znane ali lahko dosegljive osebam v krogih, ki se običajno ukvarjajo s to vrsto informacij, temveč je izključno namenjena laboratorijskemu osebju za izvajanje mikrobioloških preizkušanj znotraj organa in ima tržno vrednost. Zahtevana dokumentacija je dejansko zaščitena kot dokumentacija, za katero velja poslovna skrivnost že po subjektivnem kriteriju (sodba Upravnega sodišča v zadevi I U 1573/2014 z dne 18. 11. 2015 v povezavi s sodbo Upravnega sodišča v zadevi I U 599/2014-20 z dne 03. 11. 2015). Nedvomno gre tudi za dela, ki so izražena in predstavljajo intelektualno stvaritev avtorjev in spadajo v znanstveno področje človeške ustvarjalnosti po Zakonu o avtorskih in sorodnih pravicah (Ur. l. RS, št. 16/07 – UPB, 68/08, 110/13, 56/15 in 63/16 – ZKUASP; v nad. ZASP). IP je v podobni zadevi (npr. odločba št. 090-95/2012/12 z dne 20. 06. 2012) že odločal in je zahtevo prosilca zavrnil, ker zahtevani dokumenti (navodila za uporabo opreme) predstavljajo varovano avtorsko delo. Zoper točki zahteve št. 21. in 22. se prosilec ne pritožuje, zato nista predmet odločanja v pritožbenem postopku, glede točk zahteve do 10. do 20. pa organ podaja sledeča pojasnila, po posameznih točkah zahteve:
Točka 10.: Organ ne razpolaga z listinsko informacijo, ker v vzorcih ne dokazuje obstoja viabilnega virusa z gojitvenimi metodami, temveč v vzorcih dokazuje prisotnost nukleinske kisline (NK), to je fizični del virusa.
Točka 11.: Organ ne razpolaga z listinsko informacijo, ker v vzorcih ne dokazuje obstoja viabilnega virusa z gojitvenimi metodami. Fizični obstoj virusa na celičnih kulturah in živalskih modelih je izpričan v več člankih, ki so dosegljivi na spletu (prosto ali proti plačilu) in si jih lahko prosilec poišče sam. Kot primer organ navaja: DOI:10.1093/cid/ciaa325.10.1038/S41586-020-2342-5. 10.1016/i.virusres.2007.03.013.
Točka 12.: Organ ne razpolaga z listinsko informacijo, ker v vzorcih ne dokazuje obstoja viabilnega virusa z gojitvenimi metodami. Virusi SARS-CoV-2, ki so jih v celičnih kulturah izolirali na IMI Medicinske fakultete so

deponirani in registrirani v Evropskem arhivu virusov EVAg, dostopno na https://www.european-virus-archive.com/evag-portal/field provider/ul-123.
Točke 13., 14., 15., 18. (18.1.,18.2., 18.3., 18.4.), 19. (19.1., 19.2., 19.3., 19.4., 19.5., 19.6., 19.7., 19.8., 19.9.): To je vprašanje in ni informacija javnega značaja, kot jo določa 4. člen ZDIJZ. ZDIJZ organu ne nalaga obveznosti, da bi za prosilca ustvaril ali pridobil dokumente, s katerimi v času odločanja o njegovi zahtevi ne razpolaga. Ravno tako organu informacij za prosilca ni treba obdelovati, povezovati, analizirati ali mu dajati pojasnil.
Točka 16.: Organ ne razpolaga z listinsko informacijo, ker ne izvaja kliničnih poskusov in je diagnostični medicinski laboratorij. V diagnostiki okužb laboratoriji CMM dokazujejo prisotnost virusnih NK v vzorcu bolnika.
Točka 17.: Laboratorij pri svojem delu uporablja na tržišču dostopne molekularne metode za dokazovanje NK virusa v vzorcih, pri postopkih in interpretaciji sledi navodilom proizvajalca testov. Navodila so priloga dopisu in so zaščitena kot poslovna skrivnost. Organ pri tem pripominja, da prosilec motiva oz. utemeljitve zahteve po pridobitvi listinske informacije o protokolu, ki ga pri svojem delu upošteva organ, ni podal, kar je pomembno pri tehtanju pravice do dostopa ter javnega interesa po razkritju z interesom prizadete stranke, da do razkritja ne pride zaradi varstva poslovnih skrivnosti (stališče Upravnega sodišča v sodbi v zadevi I U 599/2014-20 z dne 03. 11. 2015).
Točka 20. (20.1.): Organ ni pristojen za podajanje informacij drugih izvajalcev, zato prosilca napotuje, da za zahtevane informacije zaprosi IMI ter ga napotuje na spletno stran http://www.imi.si/o-institutu/nasa-kakovost. Pri tem pripominja, da so naloge organa izrecno določene v 23.c členu ZZDej in ne po ZBN, kot zmotno navaja prosilec, v navedeni določbi pa tudi ni določeno pooblastilo za izvajanje mikrobioloških preizkušanj na področju medicinske mikrobiologije za potrebe izvajalcev zdravstvene dejavnosti za IMI. Ministrstvo za zdravje skladno s 4. členom Pravilnika o pogojih, ki jih morajo izpolnjevati laboratoriji za izvajanje preiskav na področju laboratorijske medicine izda dovoljenje. ECDC ni institucija, ki presoja laboratorije. Referenčnost laboratorijev določi vsaka država sama.
Točka 20.2.: Organ izvida, ki vsebuje posebne vrste osebnih podatkov, pritožniku ne posreduje, ker bi razkritje pomenilo kršitev varstva osebnih podatkov. Vsebino izvida določa 13. člen Pravilnika o pogojih, ki jih morajo izpolnjevati laboratoriji za izvajanje preiskav na področju laboratorijske medicine. V zvezi s tem organ pojasnjuje, da je način podajanja rezultata preiskave v pristojnosti stroke. PCR, ki se izvaja za detekcijo SARS-CoV-2, je kvalitativna metoda in noben predpis ne določa, da je treba podajati število ciklov. Analogno je pri kvalitativnih PCR metodah za diagnostiko drugih virusov, kjer število ciklov prav tako ni podano.
Točka 20.3.: Organ prosilca ponovno napotuje na spletno stran Covid-19 sledilnik, kjer so objavljeni številni podatki, med drugim tudi podatki o testiranjih PCR, potrjenih primerih, itd., in sicer za vsak dan - od začetka testiranja dalje. V primeru, da prosilec ne zna uporabljati navedene aplikacije, ga organ napotuje na upravljavca aplikacije Covid-19 ali NIJZ, ki vodi in upravlja zbirke podatkov s področja zdravja in zdravstvenega varstva skladno s 23.a členom ZZDej.
Glede pritožbenih navedb prosilca organ po točkah pojasnjuje sledeče:
Točka 1.: Vsekakor delo organa, ki izvaja mikrobiološka preskušanja na področju medicinske mikrobiologije za potrebe izvajalcev zdravstvene dejavnosti v skladu s 23.c členom ZZDej temelji na znanosti in strokovnih raziskavah. Za dokazovanje virusov (velja za SARS-CoV-2 in druge viruse) se danes najpogosteje uporabljajo molekularne tehnike, kjer dokazujemo prisotnost nukleinske kisline, to je genoma virusa v odvzetem vzorcu. Za ta postopek ne potrebujemo viabilnega („živega") virusa, zato vzorec že na začetku inaktiviramo in tako je postopek varen za izvajalca. Najpogosteje uporabljena molekularna tehnika je v ta namen PCR (Polymerase Chain Reaction oz. Verižna reakcija s polimerazo). Odvisno od uporabljenih metod in naprav postopki trajajo od ene do približno štirih ur. Dokazovanje virusne nukleinske kisline (RNK) v vzorcu je podobno kot forenziki dokazujejo genom (DNK) iskanega človeka na kraju dogodka. Kadar želimo dokazati obstoj viabilnega virusa (virusa, ki je sposoben okužiti naslednjo celico), nanesemo vzorec (npr. bris nosno-žrelnega predela) na ustrezno celično kulturo z ustreznim gojiščem. Nato več dni opazujemo pod mikroskopom, ali se je pojavil citopatogen učinek, ki nam pove, da se virus v celicah namnožuje. To potem dodatno dokažemo še z drugimi tehnikami (npr. imunofluorescenca). Ker delamo z viabilnim virusom in je SARS-CoV-2 dobro prenosljiv in lahko povzroči resno obolenje, je za tako delo predpisano, da se ga lahko izvaja le v laboratoriju s stopnjo biološke varnosti III. Postopek traja približno štiri do osem dni in se ga v diagnostične namene ne izvaja, ker bi preiskava trajala predolgo. Za preprečevanje širjenja nalezljive bolezni kot je Covid-19 je potrebno hitro ukrepanje, zato gojitvenih metod za dokazovanje viabilnega virusa SARS-CoV-2 v diagnostične namene, ki so predmet pritožnikovih vprašanj, pri organu ne izvajajo, zato tudi ne razpolagajo z zahtevano listinsko dokumentacijo.
Točka 2.: Kot je bilo že večkrat pojasnjeno, organ v vzorcih ne dokazuje obstoja viabilnega virusa z gojitvenimi metodami, temveč v vzorcih dokazuje prisotnost nukleinske kisline (NK). Organ za preiskovanje vzorcev uporablja metode, ki so znanstveno preizkušene in jih priznavajo mednarodna ali domača strokovna združenja, skladno z 10. členom Pravilnika o pogojih, ki jih morajo izpolnjevati laboratoriji za izvajanje preiskav na področju laboratorijske medicine. Prosilec je v svoji zahtevi III. del: A. Virus SARS-CoV-2 in bolezen Covid-19 posredoval 20 vprašanj s podvprašanji in zahteva od organa, da mu odgovori na vprašanja. Pri tem organ pripominja, da

vprašanja niso informacija javnega značaja kot jo določa 4. člen ZDIJZ. ZDIJZ organu ne nalaga obveznosti, da bi moral prosilcu posredovati informacijo kot odgovor na vprašanje, ki je vezano na delovno področje organa, kot to določa 45. člen ZMed, kar pa ne velja za prosilca. Zato je zmotno stališče prosilca, da mu je organ dolžan odgovoriti z da/ne.
Točka 3.: Pristojnost za opravljanje nalog določenih v 23.c členu ZZDej ima samo organ. Ni mogoče slediti navedbi prosilca, da število testiranih oseb ni javno dostopna prosta informacija in da podatek prosilcu ni dosegljiv in ne znan. Kot je bilo že pojasnjeno, so podatki o številu testiranj PCR na posamezni dan, že od začetka testiranj dostopni na spletni strani Covid-19 sledilnik https://covid-19.sledilnik.org/sl/stats. kjer lahko prosilec izbere tudi obdobje za katero želi imeti podatke.
Točka 4. Organ pripominja, da prosilec ne loči dveh pravnih oseb, in sicer NIJZ in NLZOH, ki opravljata različne naloge, NIJZ skladno s 23.a členom ZZDej in NLZOH skladno s 23.c členom ZZDej. Tako prosilec v pritožbi zmotano naslavlja organ kot NIJZ. Organ se nikakor ne strinja s prosilcem, da bi morale biti vse informacije, po katerih v svoji zahtevi povprašuje, prosto dostopne z objavo na spletni strani organa, ker vse povpraševane informacije, kot je bilo že večkrat pojasnjeno, ne izvirajo iz delovnega področja organa in se ne nahajajo v materializirani obliki. Organ javnosti ažurno poroča relevantne strokovne informacije v zvezi z virusom SARS-CoV-2, ki izvirajo iz njegovega delovnega področja tudi na tiskovnih konferencah vlade in prosilca napotuje na spletno stran https://www.gov.si/neposredni-prenos/, da spremlja neposredni prenos ali pa si informacije ogleda za nazaj na spletni strani https://4d.rtvslo.si/arhiv/tv-informativni/.
Organ ponovno poudarja, da glede na naloge, ki jih izvaja v skladu s 23.c členom ZZDej, z vidika zavezanosti po ZDIJZ ni organ, ki bi izvajal naloge oblasti, še posebno ob dejstvu, da ob znani epidemiološki situaciji priprava strokovnih pojasnil in odgovorov na vprašanja za posamezne državljane dodatno obremenjuje vrhunski strokovni kader, ki mora biti na razpolago za izvajanje zakonsko opredeljenih nalog. Vsekakor pa strokovno usposobljeno osebje ažurno pripravlja odgovore na vprašanja, ki jih novinarji skladno z ZMed naslovijo na organ, zato je javnost obveščena. Glede na to, da so navodila za delo in uporabo opreme izključno namenjena strokovno usposobljenemu laboratorijskemu osebju organa, na podlagi katerih izvajajo laboratorijske preiskave in niso prosto dostopna ter zanj prav gotovo ne obstoji javni interes o podrobnih postopkih izvedbe preiskav in uporabe specifične opreme, organ meni, da je izpodbijana odločba pravilna in zakonita ter temelji na določbah ZDIJZ. Dopisu je organ, poleg Klasifikacijskega načrta organa z dne 10. 7. 2020, priložil še sledeče dokumente, vse z oznako poslovna skrivnost:

- Declaration of conformity NeuMoDx SARS-CoV2 ASSAY, z dne 19. 3. 2020 (1 stran),
- Delo z aparatom NeuMoDx 96 ND-IV-NLZOH-OMMMB-08-31, z dne 7. 9. 2020 (8 strani),
- Dokazovanje virusa SARS-Cov-2 s testom NeuMoDx ND-IV-NLZOH-OMMMB-08-32, z dne 7. 9. 2020 (6 strani),
- Neumodox SARS-CoV-2 Assay Instruction For Use, januar 2021 (23 strani).

Pritožba je delno utemeljena.

IP uvodoma pojasnjuje, da je kot organ druge stopnje, v skladu z 247. členom ZUP, dolžan preizkusiti odločbo v delu, v katerem jo pritožnik oz. prosilec izpodbija. Odločbo preizkusi v mejah pritožbenih navedb, po uradni dolžnosti pa preizkusi, ali ni prišlo v postopku na prvi stopnji do bistvenih kršitev postopka in ali ni prekršen materialni zakon.

V obravnavanem primeru ni sporno, da organ sodi med organe, zavezane po ZDIJZ.

Kot izhaja iz določbe 1. odstavka 4. člena ZDIJZ in tudi določbe 1. odstavka 1. člena ZDIJZ, informacijo javnega značaja predstavlja samo dokument, ki že obstaja, je že ustvarjen, oz. dokument, ki ga je organ v okviru svojega delovnega področja že izdelal oz. pridobil. Gre za pogoj, ki je v teoriji poznan kot »kriterij materializirane oblike«. Organi, ki so zavezanci po ZDIJZ, so namreč dolžni omogočiti dostop le do že obstoječih informacij in niso dolžni ustvariti novega dokumenta ali pridobiti oz. vzpostaviti dokumenta, ki ga v času zahteve nimajo.

Predmet tega pritožbenega postopka je vprašanje, ali je organ upravičeno zavrnil dostop do 10., 11., 12., 13., 14., 15., 16., 17., 18. (18.1. - 18.4.), 19. (19.1., - 19.9.) in 20. (20.1., - 20.3.) točke zahteve prosilca.

- **K 1. točki izreka (17. in 20.2. točka zahteve prosilca)**

V pritožbenem postopku je IP ugotovil, da je organ z izpodbijano odločbo prosilcu zavrnil dostop do dokumenta oz. dokumentov, ki so predmet zahteve prosilca pod 17. točko, s sklicevanjem na izjemo iz 2. točke 6. člena ZDIJZ (poslovna skrivnost), brez da bi se organ uvodoma sploh opredelil do zahtevanega dokumenta oz. brez navedbe, kateri konkretni dokument oz. dokumenti so predmet presoje in po mnenju organa predstavljajo

poslovno skrivnost. Organ se je v izpodbijani odločbi v tem delu tudi le pavšalno skliceval na poslovno skrivnost, brez izkazovanja izpolnjevanja kriterijev za obstoj zatrjevane izjeme po ZPosS, in sicer za vsak posamezni dokument, na katerega se nanaša zahteva prosilca oz. ustreza zahtevi prosilca, niti iz izpodbijane odločbe ni razvidno čigavo poslovno skrivnost organ, kot javni zavod, v konkretnem primeru sploh varuje.
Prav tako je organ zavrnil tudi zahtevo prosilca iz 20.2. točke, ki se nanaša na primer lastnega (anonimiziranega) izvida dejansko opravljenega dokazovanja virusa, s sklicevanjem na izjemo varstva osebnih podatkov (3. točka 1. odstavka 6. člena ZDIJZ), brez opredelitve, kateri konkretni dokument je bil predmet presoje, niti ni navedel, katere (varovane) oz. posebne vrste osebnih podatkov dokument vsebuje. Prav tako se organ ni opredelil, ali je informacije mogoče izločiti iz dokumenta ali ne oz. ali je obravnavanem primeru mogoče uporabiti t.i. institut delnega dostopa (7. člen ZDIJZ) - če je organ ocenil, da bi bila z razkritjem podatkov, vsebovanih na zahtevanem dokumentu, ogrožena njihova zaupnost, bi moral pojasniti, zakaj ob prekritju teh delov, prosilca ne bi bilo mogoče seznaniti z vsebino preostalega dela dokumenta. Hkrati bi organ moral bolj določno pojasniti tudi, kako bi dostop do zahtevanih podatkov kazal na točno določeno oz. določljivo osebo. Osebni podatek (npr. zdravstveno stanje) namreč ne more biti varovan že zgolj zaradi samega sebe, temveč le zato, ker je iz njega mogoče razbrati tudi identiteto posameznika ali posameznikovo lastnost, ki ga dela določljivega.

Na podlagi navedenega je IP ugotovil, da se odločbe, zaradi pomanjkljive obrazložitve, v tem delu ne da preizkusiti in so posledično podane bistvene kršitve pravil postopka po 7. točki 2. odstavka 237. člena ZUP. IP je zato pritožbi prosilca v delu zahteve, ki se nanaša na 17. in 20.2. točko ugodil in na podlagi 3. odstavka 251. člena ZUP, izpodbijano odločbo v tem delu odpravil ter zadevo vrnil organu prve stopnje v ponovno odločanje, kot izhaja iz 1. točke izreka te odločbe.

Vrnitev zadeve v ponovno odločanje IP utemeljuje z razlogi ekonomičnosti postopka. Poseben vidik načela ekonomičnosti iz 14. člena ZUP je tudi načelo učinkovitosti, ki od organov zahteva, da se preskrbi vse, kar je potrebno za pravilno ugotovitev dejanskega stanja in za zavarovanje pravic strank ter javnih koristi. To pa bo najlažje dosegel prav prvostopenjski organ, ker se zahteva prosilca nanaša na dokumente, ki so del dokumentacije organa, posledično organ razpolaga z vso dokumentacijo, ki je predmet presoje in razpolaga z vsemi podatki, ki jih potrebuje za ustrezno rešitev predmetne zahteve. Poleg navedenega se organ (še) ni spustil v vsebinsko obravnavo zadeve in se ni opredelil do zahtevanih informacij, pri čemer mu je ta možnost dana prav z vrnitvijo v ponovno odločanje.

V ponovljenem postopku je organ uvodoma dolžan jasno opredeliti, kateri dokumenti, ki jih zahteva prosilec, so predmet presoje, torej konkretno za vsak dokument, do katerega prosilec v 17. in 20.2. točki zahteve zahteva dostop oz. za vsak dokument, ki ustreza zahtevi prosilca. V primeru obstoja katere od izjem po določbah 5.a in 6. člena ZDIJZ je dolžan presojati tudi, ali je mogoče uporabiti institut delnega dostopa v skladu z določbami 7. člena ZDIJZ in 19. člena Uredbe o posredovanju in ponovni uporabi informacij javnega značaja (Ur. l. RS, št. 24/16; v nad. Uredba) ter natančno in določno opredeliti, v katerem delu se posamezni dokument prekrije in na podlagi katere konkretne izjeme od prostega dostopa. Določba 19. člena Uredbe namreč določa, da če dokument ali njegov del le delno vsebuje informacije iz 5.a in 6. člena ZDIJZ, se šteje, da jih je mogoče izločiti iz dokumenta, ne da bi to ogrozilo njegovo zaupnost, če jih je mogoče fizično odstraniti, prečrtati, trajno prekriti ali drugače napraviti nedostopne, če gre za dokument v fizični obliki; zbrisati kodirati, blokirati, omejiti oz. drugače napraviti nedostopne, če gre za dokument v elektronski obliki (1. odstavek). Ne glede na zapisano se šteje, da informacije iz dokumenta ni mogoče izločiti, če bi bilo tako izločeno informacijo mogoče razbrati iz drugih informacij v dokumentu (2. odstavek 19. člena Uredbe). Delni dostop je torej potrebno omogočiti vedno, ko (in če) delno razkritje ne bi ogrozilo zaupnosti varovanih informacij. Pomembna sta torej tehnični in vsebinski vidik.

Pri tem IP opozarja na določbo 44. člena ZUP, po kateri mora organ ves čas med postopkom po uradni dolžnosti skrbeti za to, da so v postopku udeleženi vsi, na katerih pravice ali pravne koristi bi lahko vplivala odločba. Opustitev te dolžnosti (če osebi, ki bi morala biti udeležena kot stranka ali stranski udeleženec v postopku, ta možnost ni bila dana) pa predstavlja bistveno kršitev pravil postopka po 2. točki 2. odstavka 237. člena ZUP. Organ mora postopek voditi skladno z ZUP in stranke, za katere meni, da bi odločitev lahko vplivala na njihove pravice in pravne koristi, povabiti k sodelovanju v postopku na formalno pravilen način.

Glede na to, da se je organ v izpodbijani odločbi in v odgovoru na poziv IP, pri dostopu do določenih/zahtevanih dokumentov, pavšalno skliceval na določene izjeme po ZDIJZ, IP v nadaljevanju opozarja na njihovo pravilno razlago in podaja nekaj napotkov, v zvezi z zatrjevanimi izjemami, ki jih mora organu upoštevati v ponovljenem postopku. V tem delu IP še dodaja, da dokazno breme, da so določene informacije izvzete iz prostega dostopa, nosi organ.

- *Izjema iz 2. točke 1. odstavka 6. člena (poslovna skrivnost)*

Pri zatrjevanju izjeme poslovne skrivnosti mora organ uvodoma upoštevati, da so zahtevani dokumenti nedvomno nastali po 20. 4. 2019, ko je začel veljati ZPosS, kar pomeni, da so podvrženi opredelitvi poslovne skrivnosti po določbah ZPosS in posledično mora organ izkazati izpolnjevanje kriterijev za obstoj poslovne skrivnosti po določba ZPosS. Da so zahtevani dokumenti nedvomno nastali po začetku veljave ZPosS izhaja iz datumov na dokumentih, ki jih je organ IP posredoval skupaj z odgovorom na poziv in jih prepoznal kot dokumente, ki ustrezajo zahtevi prosilca pod 17. točko.

Za poslovno skrivnost, kot izjemo iz 2. točke 1. odstavka 6. člena ZDIJZ, se sicer štejejo informacije, ki izpolnjujejo zahteve za poslovno skrivnost v skladu z zakonom, ki ureja poslovne skrivnosti (ZPosS). Pojem poslovne skrivnosti po 2. členu ZPosS zajema nerazkrito strokovno znanje, izkušnje in poslovne informacije, ki izpolnjuje naslednje zahteve:
- je skrivnost, ki ni splošno znana ali lahko dosegljiva osebam v krogih, ki se običajno ukvarjajo s to vrsto informacij;
- ima tržno vrednost;
- imetnik poslovne skrivnosti je v danih okoliščinah razumno ukrepal, da jo ohrani kot skrivnost.
Domneva se, da je zahteva iz tretje alineje prejšnjega odstavka izpolnjena, če je imetnik poslovne skrivnosti informacijo določil kot poslovno skrivnost v pisni obliki in o tem seznanil vse osebe, ki prihajajo v stik ali se seznanijo s to informacijo, zlasti družbenike, delavce, člane organov družbe in druge osebe. Za poslovno skrivnost se ne morejo določiti informacije, ki so po zakonu javne, ali informacije o kršitvi zakona ali dobrih poslovnih običajev.

Glede na navedeno so poslovna skrivnost le tisti podatki, pri katerih so vse tri zgoraj naštete zahteve kumulativno izpolnjene. Kot izhaja iz komentarja k 2. členu predloga zakona[1], poslovna skrivnost pomeni strokovno znanje in izkušnje ter dragocene poslovne informacije, ki imetnikom omogočajo večjo konkurenčnost in uspešnost na trgu in s tem povečujejo donosnost, zaradi česar je v interesu imetnikov poslovnih skrivnosti, da te ostanejo nerazkrite oz.zaupne. Ob tem IP pripominja, da je v skladu s slovensko sodno prakso dokazno breme pri pojasnjevanju, zakaj zahtevane informacije pomenijo konkurenčno prednost, na subjektu, ki poslovno skrivnost zatrjuje.[2]

V tem delu IP še dodaja, da organ kot javni zavod, ki, na podlagi določb ZZdej opravlja naloge na področju zdravja, okolja in hrane, določene s posebnimi predpisi, ter na celotnem območju države združuje vse laboratorije in pripadajoče strokovne dejavnosti nekdanjih ZZV in IVZ, ne more zatrjevati poslovne skrivnosti za dokumente, ki izkazujejo njegovo javnopravno delovanje in morajo biti podvrženi transparentnosti. S tem se zagotavlja učinkovit nadzor nad delovanjem organa, kar zmanjšuje korupcijska tveganja, veča vestnost, poštenost, skrbnost in zaupanje, kar prispeva k temu, da ima tak organ večjo legitimnost, da se poveča zaupanje v razmerju do navedenega organa in da se poveča odgovornost organa do vseh državljanov v demokratični družbi. Organ pri svojem delovanju nedvomno zasleduje javni interes, kar pomeni, da so pomembni vsi temeljni podatki, na katerih temelji odločitev organa, ki jih ima javnost pravico izvedeti, zato je že pojmovno nemogoče, da bi tovrstni podatki, v celoti predstavljali poslovno skrivnost.

- *Izjema iz 3. točke 1. odstavka 6. člena (osebni podatek)*

Za obstoj opisane izjeme morata biti izpolnjena dva pogoja, in sicer:
- podatek mora ustrezati definiciji osebnega podatka,
- za razkritje osebnega podatka ne obstaja pravna podlaga (tj. da gre za varovan osebni podatek).

Uredba (EU) 2016/679 Evropskega parlamenta in Sveta z dne 27. aprila 2016 o varstvu posameznikov pri obdelavi osebnih podatkov in prostem pretoku takih podatkov ter o razveljavitvi Direktive 95/46/ES (Uradni list Evropske unije, št. L 119 z dne 4. 5. 2106; v nad. Splošna uredba o varstvu podatkov)[1], ki se v Republiki Sloveniji uporablja neposredno, v členu 4(1) določa, da je osebni podatek katera koli informacija v zvezi z določenim ali določljivim posameznikom (v nad.: posameznik, na katerega se nanašajo osebni podatki); določljiv posameznik je tisti, ki ga je mogoče neposredno ali posredno določiti, zlasti z navedbo identifikatorja, kot je ime, identifikacijska številka, podatki o lokaciji, spletni identifikator, ali z navedbo enega ali več dejavnikov, ki so značilni za fizično, fiziološko, genetsko, duševno, gospodarsko, kulturno ali družbeno identiteto tega

[1] https://www.findinfo.si/download/razno/761d313c27b5103dc7b8.pdf
[2] Tako upravno sodna praksa, ki se sicer nanaša na določbe ZGD-1, ki so veljale pred uveljavitvijo ZPosS, vendar pravno vprašanje po mnenju IP ostaja enako: npr. sodbe, št. U 284/2008 z dne 27. 5. 2009, št. U 1276/2008 z dne 11. 2. 2010, št. I U 1132/2015 z dne 27. 1. 2016.

posameznika. Organ mora pri sklicevanju na izjemo varstva osebnih podatkov jasno navesti, katere vse podatke vsebuje posamezni zahtevani/presojani dokument in se jih šteje za osebne podatke (vrsta osebnega podatka), zakaj jih šteje za osebne (kako jih je mogoče povezati z določenim ali določljivim posameznikom) in katere od teh osebnih podatkov šteje za varovane, ker zakonodaja ne omogoča njihovega razkritja.

- *O avtorskopravnem varstvu*

V skladu s 5. členom ZASP je avtorsko delo individualna intelektualna stvaritev s področja književnosti, znanosti in umetnosti, ki je na kakršenkoli način izražena, če ni v ZASP drugače določeno. Iz navedene definicije in obstoječe sodne prakse ter pravne teorije izhaja pet predpostavk, ki morajo biti izpolnjene, da se posamezno delo šteje za avtorsko delo po ZASP, in sicer so to individualnost, intelektualnost oz. duhovnost, stvaritev, področje ustvarjalnosti in izraženost. Če torej posamezno delo izpolnjuje vse navedene predpostavke kumulativno, se šteje, da gre za avtorsko delo.

2. odstavek 25. člena ZDIJZ pravi, da se je na varstvo avtorske pravice v zvezi z omejitvijo načina seznanitve mogoče sklicevati le v primerih, ko je imetnik avtorskih pravic tretja oseba, in ne organ, ki je zavezanec za posredovanje informacij javnega značaja. Poleg navedenega 2. odstavek 25. člena ZDIJZ pravi, da se reprodukcija zahtevane informacije vendarle dovoli tudi v primerih, ko je imetnik avtorske pravice na njej tretja oseba, vendar gre za okoljske informacije.

Organ se mora v ponovljenem postopu pri sklicevanju na avtorsko delo uvodoma opredelil do vprašanja, kdo je imetnik materialnih avtorskih pravic na dokumentih, ki so predmet zahteve prosilca, pri tem pa IP opozarja, da zgolj dejstvo, da dokument predstavlja avtorsko delo, ne zadostuje za zavrnitev posredovanja.

- *Test interesa javnosti (2. odstavek 6. člena ZDIJZ)*

Test interesa javnosti je urejen v 2. odstavku 6. člena ZDIJZ, ki določa, da se ne glede na določbe 1. odstavka istega člena, dostop do zahtevane informacije dovoli, če je javni interes glede razkritja močnejši od javnega interesa ali interesa drugih oseb za omejitev dostopa do zahtevane informacije, razen v določenih primerih, ki so v zakonu tudi jasno določeni. Organ v ničemer ni pojasnil svoje odločitve, zakaj je zavzel stališče, da zahtevani dokumenti oz. podatki, vsebovani v zahtevanih dokumentih niso podatki, ki bi bili v javnem interesu, ampak je le pavšalno navedel, da prosilec ni izkazal, da bi bilo razkritje zahtevnih dokumentov v javnem interesu.

Bistvo presoje interesa javnosti je v možnosti relativizacije določene izjeme, ki mora biti omejena zgolj na tiste primere, ko je interes javnosti za razkritje določene izjeme močnejši od interesa, zaradi katerega je določena informacija zavarovana kot izjema. Pri uporabi testa prevladujočega interesa javnosti je treba presoditi tudi, ali je interes javnosti za razkritje informacije javnega značaja lahko močnejši od potencialno storjene škode, ki bi nastala z razkritjem informacije. V teoriji se poudarja, da ga je treba uporabljati z veliko mero previdnosti in skrbnosti, saj test interesa javnosti zahteva bistveno večjo kakovost odločanja v obliki tehtanja posameznih nasprotujočih si pravic oz. interesov. Test interesa javnosti zato pomeni izjemo od izjem, ki se mora uporabljati zelo premišljeno in zgolj takrat, ko bi s pomočjo tega testa odkrili nekaj, kar bi pripomoglo k širši razpravi in razumevanju nečesa pomembnega za širšo javnost. Javni interes za razkritje je na npr. močan v situacijah, ki se navezujejo na pridobivanje ali porabo javnih sredstev, javno varnost, javno zdravje, odgovornost in transparentnost odločanja, ki sprožijo javno ali parlamentarno razpravo, ipd.. Pojem interesa javnosti tako ni v vsaki zadevi enak ali vnaprej definiran, temveč se lahko kaže v različnih pojavnih oblikah. Prav tako se lahko javni interes s časom spreminja, saj je odvisen od številnih dejanskih okoliščin. Zasnova javnega interesa torej ni konstantna, ampak spremenljiva in odvisna od trenutnega dejanskega stanja. S tem pa je pri izvajanju testa javnega interesa omogočena presoja od primera do primera, ki upošteva različne in prav tako spremenljive dejavnike, ki tvorijo javni interes za razkritje. Pri tem IP izpostavlja še stališče sodne prakse, iz katere izhaja, da bi bil javni interes glede razkritja podan, »če bi bile ogrožene take vrednote kot je npr. življenje, zdravje ali varnost ljudi in podobno«.[3] Interes javnosti kot splošen interes, ki ne služi samo interesom ozke skupine oseb, je torej opredeljen kot nekaj, kar bi koristilo javnemu vedenju in s tem omogočilo nadzor in sodelovanje javnosti pri oblikovanju tistih tematik, nad katerimi bi morala ta biti z vso skrbnostjo.
Pri testu javnega interesa gre tako za tehtanje, pri katerem je potrebno presoditi, kdaj prevlada pravica javnosti vedeti nad kakšno drugo pravico oz. izjemo iz določb ZDIJZ in s tem ugotoviti, ali bo v konkretnem primeru javnemu interesu bolj zadoščeno z razkritjem ali z nerazkritjem informacije.

[3] Npr. sodbi Upravnega sodišča št. I U 1488/2011-95 in št. I U 199272010-28.

IP pripominja, da je že odločal o vsebinsko podobni zadevi, in sicer o dostopu do dokumentacije, ki se je nanašala na pridobitve in podaljšanja dovoljenja za promet z določenimi cepivi, pri čemer je IP presojal tudi javni interes za razkritje zahtevanih informacij ter ugotovil, da je podan velik javni interes, da se cepljenja s predmetnimi cepivi izvajajo, v smislu varovanja javnega zdravja in preprečevanja nalezljivih bolezni, in da ne gre zgolj za vprašanje poslovne skrivnosti.[4]

- *Poraba javnih sredstev (3. odstavek 6. člena ZDIJZ)*

Skladno z določbo 3. odstavka 6. člena ZDIJZ, se, ne glede na morebiten obstoj izjeme iz 1. odstavka tega člena (torej tudi obstoj poslovne skrivnosti), dostop do zahtevanih informacij javnega značaja dovoli, če gre za podatke o porabi javnih sredstev ali podatke, povezane z opravljanjem javne funkcije ali delovnega razmerja javnega uslužbenca, razen v primerih iz 1. in 5. do 8. točke prvega odstavka ter v primerih, ko zakon, ki ureja javne finance ali zakon, ki ureja javna naročila, določata drugače.

Iz navedenega jasno izhaja, da je že zakonodajalec pretehtal, da javni interes za razkritje podatkov pretehta vselej (tudi npr. ne glede na morebitno izjemo poslovne skrivnosti) kadar gre za podatke, ki predstavljajo podatke o porabi javnih sredstev.

- **K 2. točki izreka (10., 11., 12., 13., 14., 15., 16., 18. (18.1. - 18.4.), 19. (19.1., - 19.9.), 20. (20.1., 20.3.) točka zahteve prosilca)**

IP pojasnjuje, da so organi dolžni omogočiti prosilcem dostop le do že obstoječih informacij ter niso dolžni ustvarjati novih dokumentov, zbirati informacij, opravljati raziskav ali analizirati podatkov, da bi zadostili zahtevi prosilca. IP dodaja, da iz samega ZUP, Uredbe o upravnem poslovanju ter načela prijazne in odprte javne uprave, sicer izhaja obveznost organov, da odgovorijo na vsako vlogo stranke, torej, da po svojih najboljših močeh, predvsem pa upoštevajoč svojo (predvsem stvarno) pristojnost, pomagajo prosilcu, da pride do želenih podatkov. Vendar pa IP opozarja, da ZDIJZ ne predstavlja instrumenta za zagotavljanje informiranosti prosilcev izven dometa samega zakona, ki konkretizira pravico pridobivanja že ustvarjenih dokumentov, s katerimi organ tudi dejansko razpolaga.

Skladno s 4. členom ZDIJZ informacijo javnega značaja predstavlja samo dokument, ki že obstaja v neki materialni obliki, oz. tisti dokument, ki ga je organ v okviru svojega delovnega področja že izdelal oz. pridobil in ga ni dolžan ustvariti šele na podlagi zahteve. Navedeno pomeni, da na primer vloga, s katero se zahteva, da organ odgovori na vprašanja oz. pripravi pojasnilo, obrazložitev ipd. ne predstavlja zahteve za dostop do informacij javnega značaja. IP pojasnjuje, da ZDIJZ, ki omogoča pritožbo k IP, ne omogoča oz. predvideva pravice do odgovorov in pojasnil ter podobnega. Takšno stališče izhaja tudi iz sodbe Upravnega sodišča RS, št. I U 1351/2010-12 z dne 25. 5. 2011. Prosilec ima namreč po ZDIJZ pravico zahtevati dokumente, s katerimi organi zavezanci že razpolagajo, ne prosilci ne IP pa nimajo po tem zakonu nikakršnega vzvoda, s katerim bi prisilili organ, da posebej na zahtevo prosilca ustvari določen dokument (npr. pripravi odgovore na vprašanja, poda pojasnilo,, obrazložitve ipd.).

Iz zahteve prosilca jasno izhaja, da želi pridobiti določena pojasnila, obrazložitve in odgovore v zvezi s potekom testiranja oz. rezultati testiranj na Covid-19, pri čemer IP pri reševanju pritožbe ni posumil, da organ razpolaga ali bi lahko razpolagal z dokumenti, iz katerih bi izhajali odgovori na zastavljena vprašanja, pojasnil in obrazložitev v zvezi s konkretnimi vprašanji, niti odgovorov z da/ne na določeno zastavljeno vprašanje, pa organ, na podlagi določb ZDIJZ, prosilcu ni dolžan posredovati, na kar je večkrat pravilno opozoril tudi organ v izpodbijani odločbi in v odgovoru na poziv IP. **IP tako ne vidi utemeljenega razloga, da ne bi verjel organu, da z dokumenti, iz katerih bi izhajali odgovori na vprašanja prosilca, ne razpolaga, še zlasti, ker se vprašanja prosilca v določenem delu niti ne nanašajo na delovno področje organa, ki je podrobneje opredeljeno v 23.c členu ZZDej. Oprijemljivih dejstev, ki bi nakazovali na to, da organ z dokumenti razpolaga, ni navedel niti prosilec.** V tem delu IP še dodaja, da tudi sama odmevnost tematike in pisanje različnih medijev/strokovnjakov o tej temi še ne pomeni, da bi organ s temi informacijami tudi nedvomno moral razpolagati.

Glede pritožbenih navedbe prosilca, da splošno napotilo organa na svetovni splet, kjer so objavljeni različni tuji članki, iz katerih lahko prosilec pridobi zahteve informacije (npr. opisujejo gojenje virusa SARS-Cov-2 na celičnih kulturah), ni informacija v skladu z določbami ZDIJZ, pa IP pojasnjuje, da organ na podlagi določb ZDIJZ ni dolžan po svetovnem spletu iskati različne tuje članke ter ugotavljati/presojati, iz katerih člankov bi

[4] odločba št. 090-136/2013/59 z dne 18. 11. 2019 po sodbi Upravnega sodišča RS IU 1520/2016-80.

lahko izhajale informacije, na katere se nanaša zahteva prosilca in posledično prosilcu posredovati povezave na te članke.

Upoštevaje navedeno je IP pritožbo prosilca v tem delu, na podlagi 1. odstavka 248. člena ZUP, kot neutemeljeno zavrnil, kot izhaja iz 2. točke izreka te odločbe.

Na trditve organa, da ob znani epidemiološki situaciji priprava strokovnih pojasnil in odgovorov na vprašanja za posamezne državljane dodatno obremenjuje vrhunski strokovni kader organa, ki mora biti na razpolago za izvajanje zakonsko opredeljenih nalog, IP odgovarja, da za kakršno koli privilegirano obravnavo konkretnega organa, ne glede na epidemiološko situacijo v državi, nima zakonske podlage. Upravno poslovanje organa v času vložitve zahteve in do izdaje izpodbijane odločbe ni bilo ustavljeno ali prekinjeno, niti v tem času noben pravni akt ni določil kakršnihkoli ukrepov v zvezi z upravnimi oz. javnopravnimi zadevami – kamor sodi odločanje po ZDIJZ – ki bi omogočali posebno obravnavo.

Glede navedb organa, da prosilec ni podal motiva oz. utemeljitve zahteve po pridobitvi zahtevanih informacij, pa IP pojasnjuje, da se, v skladu z načelom prostega dostopa iz 5. člena ZDIJZ, za dostop do informacij javnega značaja pravni interes ne zahteva. V postopku dostopa do informacij javnega značaja tako prosilčev interes in pravne koristi niso relevantni. ZDIJZ namreč določa možnost vsakogar, da zahteva informacije, ki predstavljajo informacije javnega značaja, obenem pa ne pozna nobene »privilegirane« kategorije prosilcev. V kolikor gre pri določeni informaciji za prosto dostopno informacijo javnega značaja, je ta dostopna vsem, ne glede na njihov izkazan pravni interes. IP je v skladu z ZDIJZ dolžan vsebinsko presoditi le, ali zahtevana informacija izpolnjuje merila za informacijo javnega značaja in ali je zaradi tega prosto dostopna vsem, lat. *erga omnes*, ne le prosilcu. Pravni interes posameznika tako v postopku po ZDIJZ ni relevanten in ne vpliva na odločitev organa.

Sklepno

Na podlagi ugotovljenega v pritožbenem postopku je IP pritožbi prosilca delno ugodil in izpodbijano odločbo, v delu, ki se naša na 17. in 20.2. točko zahteve prosilca, v skladu s 1. in 3. odstavkom 251. člena ZUP, odpravil ter zadevo vrnil organu v ponovno odločanje. V delu zahteve, ki se nanaša na 10., 11., 12., 13., 14., 15., 16., 18. (18.1. - 18.4.), 19. (19.1., - 19.9.), 20. (20.1., 20.3.) točko zahteve prosilca, pa je IP, na podlagi 1. odstavka 248. člena ZUP, pritožbo prosilca kot neutemeljeno zavrnil.

Posebni stroški v tem postopku niso nastali. Ta odločba je v skladu s 30. točko 28. člena Zakona o upravnih taksah (Ur. l. RS, št. 106/10 – ZUT-UPB5 in 14/15 – ZUUJFO) oproščena plačila upravne takse.

Pouk o pravnem sredstvu:
Zoper 1. točko izreka te odločbe ni dovoljena pritožba, niti upravni spor. Zoper 2. in 3. točko izreka te odločbe lahko prosilec sproži upravni spor. Upravni spor se sproži s tožbo, ki se vloži v 30 dneh od vročitve te odločbe na Upravno sodišče, Fajfarjeva 33, Ljubljana. Tožba se lahko vloži pisno po pošti ali pri navedenem sodišču. Če se tožba pošlje priporočeno po pošti, se za dan izročitve sodišču šteje dan oddaje na pošto. Tožba z morebitnimi prilogami se vloži v najmanj treh izvodih. Tožbi je treba priložiti tudi to odločbo v izvirniku ali prepisu.

Postopek vodila:
Tanja Švab, dipl.upr.ved.,
raziskovalka IP

REPUBLIKA SLOVENIJA INFORMACIJSKI POOBLAŠČENEC LJUBLJANA

Informacijski pooblaščenec:
Mojca Prelesnik, univ. dipl. prav.,
informacijska pooblaščenka

Vročiti:
- Organ: Nacionalni laboratorij za zdravje, okolje in hrano, Prvomajska ulica 1, 2000 Maribor – z vročilnico
- Prosilec: [redacted]

Vložiti:
- zbirka dokumentarnega gradiva pri IP.

ENGLISH TRANSLATIONS (AS PROVIDED BY THE FOI SUBMITTER)
OF NLZOH'S FINAL RESPONSE TO SELECT QUESTIONS

Point 10: We do not have information as you asked, because we do not prove existence of viable virus with growing methods, but we prove in samples presence of nucleic acid, this is physical part of the virus.

Point 11: We do not have information as you asked, because we do not prove existence of viable virus with growing methods. Physical presence of virus in cell cultures and animal models is attested in many articles on line for free are pay

Point 12: We do not have information as you asked, because we do not prove existence of viable virus with growing methods. Virus SARS-CoV-2, which was isolated in cell culture by IMI is deposited and registered in European archive for viruses EVAg, available at https://www.european-virus-archive.com/virus/sars-cov-2-strain-sloveniasi-426520-d614g

Then on page 5 of this document:

Today for proving viruses (SARS-CoV-2 or other viruses) we mostly use molecular techniques where we prove presence of nucleic acid, this is genome of the virus in the sample. For this procedure we do not need viable (live) virus, that is why we inactivate the sample at the beginning, so the procedure is safe for technician. The most used molecular method today is PCR. Depending on the machine and used methods it takes about 1 to 4 hours. When we want to prove existence of viable virus (virus which is able to infect next cell), we put sample on appropriate cell culture with appropriate medium. We then observe for several days under a microscope whether a cytopathogenic effect has occurred, which tells us that the virus is spreading in the cells.

This is then further proven by other techniques (such as immunofluorescence). Because we work with a viable virus and the SARS-CoV-2 is well transmitted and can cause serious illness, such work is prescribed to be performed only in a laboratory with a biosafety level of III. The procedure takes about four to eight days and is not performed for diagnostic purposes because the investigation would take too long. Rapid action is needed to prevent the spread of the infectious disease, so the cultivation methods for the detection of viable virus for diagnostic purposes, which are the subject of the complainant, are not performed by us, and therefore we do not have the required documentation

REPUBLIKA SLOVENIJA
MINISTRSTVO ZA ZDRAVJE
DIREKTORAT ZA JAVNO ZDRAVJE

Štefanova ulica 5, 1000 Ljubljana

T: 01 478 60 07
F: 01 478 60 79
E: gp.mz@gov.si
www.mz.gov.si

INŠTITUT ZA MIKROBIOLOGIJO IN IMUNOLOGIJO MEDICINSKE FAKULTETE UNIVERZE V LJUBLJANI

Zaloška 4
1000 Ljubljana

Številka: 090-77/2020/2
Datum: 3. 12. 2020

Zadeva: Zahteva za dostop do informacij javnega značaja – odstop zadeve

S strani prosilca, [redacted] smo prejeli e-sporočilo, v katerem le-ta zahteva določene informacije javnega značaja, s katerimi na Ministrstvu za zdravje ne razpolagamo, in se nanašajo na več strokovnih področij. Menimo, da vprašanja prosilca pod zaporednimi številkami od 1 - 7 sodijo v delovno področje vaše institucije. Vprašanja so naslednja:
1) Mi lahko pošljete ali usmerite na papir ali študijo, kjer se točno vidi, da so izolirali virus(SARS-CoV-2)? Naredili pet Kochovih postavk?
2) Mi lahko poveste na koliko ciklov kopiranja(Ct) je dr. Christian Drosten določil zlati standard, ko je prvi naredil protokol odkrivanje virusa s RT-PCR testi? Je to 25 , 27, 30, 35,40 ali več ciklov?
3) Koliko ciklov kopiranja(Ct) je priporočilo proizvajalcev teh PCR testov?
4) Koliko ciklov kopiranja RNA vzorcev se uporablja v naših laboratorijih?
5) Ali se je spreminjalo število ciklov kopiranja med prvim valom korone, po prvem valu, in zdaj ko smo v drugem valu corone?
6) Mi lahko pokažete reference, kjer se točno vidi, da so ti PCR testi primerni za klinično diagnozo s katero lahko 99,9% ugotovimo, da je človek okužen s točno določenim virusom(SARS-CoV-2)?
7) Mi lahko uradno potrdite, da so ti testi 99,9% natančni in seveda, mi zato predložite dokaze?

Zato vam kot pristojni instituciji e-sporočilo z dne 30. 11. 2020 oziroma vprašanja pod zaporednimi številkami od 1 - 7 odstopamo v reševanje.

Pri odgovoru na naš dopis se, prosimo, sklicujte na številko tega dopisa.

Lepo pozdravljeni.

po sklepu ministra:
št. 1001-182/2020/2 z dne 16. 10. 2020
Anita Tomc
višja svetovalka II

Priloga:
- E-sporočilo z dne 30. 11. 2020

Poslati:
- Inštitut za mikrobiologijo in imunologijo Medicinske fakultete Univerze v Ljubljani, Zaloška 4, 1000 Ljubljana, e-naslov: imi.info@mf.uni-lj.si – po e-pošti

V vednost:
- [redacted] – po e-pošti

PRILOGA:

Pošiljatelj: [redacted]
Datum: 30.11.2020 14:14:40
Prejemnik: gp.mz@gov.si
V vednost:
Zadeva: informacije javnega značaja

Pozdravljeni,

Pišem vam email, ker bi rad imel nekaj odgovorov na določena vprašanja glede PCR testov in samega " virusa" (SARS-CoV-2), ki naj bi povzročal bolezen COVID-19.

1) Mi lahko pošljete ali usmerite na papir ali študijo, kjer se točno vidi, da so izolirali virus(SARS-CoV-2)? Naredili pet Kochovih postavk?

2) Mi lahko poveste na koliko ciklov kopiranja(Ct) je dr. Christian Drosten določil zlati standard, ko je prvi naredil protokol odkrivanje virusa s RT-PCR testi? Je to 25 , 27, 30, 35,40 ali več ciklov?

3) Koliko ciklov kopiranja(Ct) je priporočilo proizvajalcev teh PCR testov?

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5) Ali se je spreminjalo število ciklov kopiranja med prvim valom korone, po prvem valu, in zdaj ko smo v drugem valu corone?

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7) Mi lahko uradno potrdite, da so ti testi 99,9% natančni in seveda, mi zato predložite dokaze?

8) Mi lahko pokažete študije, ki dokazujejo, da nošenje mask preprečuje okužbo?

9) Mi lahko pokažete študijo, da asimptomični (brez simptomov) ljudje prenašajo virus?

Na ta vprašanja bi želel odgovor, ker so to informacije javnega značaja in kot del ljudstva iz katerega izhaja vlada, jih moram dobiti. Ukrepe ste tudi naredil po priporočilih vaših strokovnjakov, ki so vam morali predložili strokovne študije, da res obstaja virus(izoliran) in, da ga lahko s RT-PCR testi 99,9% odkrijemo Kar pomeni, da vam bo lahko odgovoriti in poslati reference, ki dajo odgovor na moja vprašanja.

V primeru, da ne dobim odgovora ali , da me boste usmerjali na druge ustanove, bom smatral, da iščete izgovore, kar bo postavilo en velik vprašaj na celotno epidemijo.

V naprej se vam zahvaljujem za odgovore in vam želim vse najboljše.

S spoštovanjem

[redacted]

Dekanat
UL Medicinske fakultete

Univerza *v Ljubljani*
Medicinska fakulteta

Vrazov trg 2
1000 Ljubljana
T: dekanat@mf.uni-lj.si

Št. 094-1/2021-2
Ljubljana, 3. februar 2021

UL Medicinska fakulteta izdaja na podlagi drugega odstavka 22. člena Zakona o dostopu do informacij javnega značaja (Uradni list RS, št. 51/06 – uradno prečiščeno besedilo, 117/06 – ZDavP-2, 23/14, 50/14, 19/15 – odl. US, 102/15 in 7/18), v nadaljevanju: ZDIJZ in skladno s 15. členom ZDIJZ v upravni zadevi presoje utemeljenosti zahteve prosilca [redacted] za dostop do informacij javnega značaja

ODLOČBO

1. Zahteva prosilca [redacted] za dostop do informacij javnega značaja se zavrne v delu, ki se nanaša na naslednje točke:

»1) Mi lahko pošljete ali usmerite na papir ali študijo, kjer se točno vidi, da so izolirali virus(SARS-CoV-2)? Naredili pet Kochovih postavk?

2) Mi lahko poveste na koliko ciklov kopiranja(Ct) je dr. Christian Drosten določil zlati standard, ko je prvi naredil protokol odkrivanje virusa s RT-PCR testi? Je to 25 , 27, 30, 35,40 ali več ciklov?

4) Koliko ciklov kopiranja RNA vzorcev se uporablja v naših laboratorijih? RNA se kopira IMI

6) Mi lahko pokažete reference, kjer se točno vidi, da so ti PCR testi primerni za klinično diagnozo s katero lahko 99,9% ugotovimo, da je človek okužen s točno določenim virusom(SARS-CoV-2)?

7) Mi lahko uradno potrdite, da so ti testi 99,9% natančni in seveda, mi zato predložite dokaze?

8) Mi lahko pokažete študije, ki dokazujejo, da nošenje mask preprečuje okužbo?

9) Mi lahko pokažete študijo, da asimptomični (brez simptomov) ljudje prenašajo virus?«

2. Stroški postopka niso nastali.

Obrazložitev:

Organ je dne 1. 2. 2021 s strani Informacijskega pooblaščenca prejel poziv, vezan na dostop do informacij javnega značaja go. [redacted] Skladno s 4. členom ZDIJZ je informacija javnega značaja tista informacija, ki izvira iz delovnega področja organa, nahaja pa se v obliki dokumenta, zadeve, dosjeja, registra, evidence ali drugega dokumentarnega gradiva (v nadaljevanju: dokument), ki ga je organ izdelal sam, v sodelovanju z drugim organom, ali pridobil od drugih oseb. Iz navedene določbe izhajajo trije osnovni pogoji, ki morajo biti kumulativno izpolnjeni, da lahko govorimo o obstoju informacije javnega značaja, in sicer:

1. informacija mora izvirati iz delovnega področja organa,
2. organ mora z njo razpolagati in
3. nahajati se mora v neki materializirani obliki.

Prosilec v točkah 1., 2., 4. in 6. – 9. zahteva uvodoma navedene podatke. Organ z zahtevanimi dokumenti ne razpolaga oz. ne izvirajo iz delovnega področja organa, zaradi česar je bilo potrebno glede teh točk zahteve odločiti, kot izhaja iz izreka tega sklepa.

Glede točke 1):
UL MF Inštitut za mikrobiologijo in imunologijo znanstvene študije, ki bi izpeljala dokaz o izolaciji virusa Sars-Cov-2 v skladu s Kochovimi postulati, ni izvajal. Organ tako z zahtevanim dokumentom ne razpolaga.

Glede točke 2):
Dr. Christian Drosten zlatega standarda, ko naj bi naredil protokol odkrivanje virusa s RT-PCR testi, ni določal v okviru UL MF Inštituta za mikrobiologijo in imunologijo, tako da informacija ne izvira iz delovnega področja organa.

Glede točke 4):
UL MF Inštitut za mikrobiologijo in imunologijo ne izvaja kopiranja RNA. Zahtevana informacija tako ne izvira iz delovnega področja organa.

Glede točke 6):
Reference v zvezi s primernostjo PCR testov so objavljene na spletu, referenc prav tako ni določal UL MF Inštitut za mikrobiologijo in imunologijo. Zahtevana informacija tako ne izvira iz delovnega področja organa.

Glede točke 7):
UL MF Inštitut za mikrobiologijo in imunologijo dokaza o učinkovitosti testa ni izpeljal. Zahtevana informacija tako ne izvira iz delovnega področja organa.

Glede točke 8):
UL MF Inštitut za mikrobiologijo in imunologijo ni izvedel znanstvene študije, ki bi dokazovala vzročno zvezo med nošenjem mask in preprečevanjem okužbe. Organ tako z zahtevanim dokumentom ne razpolaga, zaradi česar je bilo potrebno glede 8. točke zahteve odločiti, kot izhaja iz izreka tega sklepa.

Glede točke 9):
UL MF Inštitut za mikrobiologijo in imunologijo ni izvedel znanstvene študije, ki bi dokazovala, ali asimptomični (brez simptomov) ljudje prenašajo virus. Organ tako z zahtevanim dokumentom ne razpolaga.

Glede 3. in 5. točke zahteve prosilcu sporočamo, da je priporočeno število ciklov kopiranja 40. Med prvim valom, po prvem valu in v drugem valu epidemije se to število ni spreminjalo.

V zvezi z izdajo te odločbe niso nastali posebni stroški. Ta odločba je v skladu s 30. točko 28. člena Zakona o upravnih taksah (Ur. l. RS, št. 106/10 – uradno prečiščeno besedilo, 14/15 – ZUUJFO, 84/15 – ZZelP-J, 32/16 in 30/18) oproščena plačila upravne takse.

Pouk o pravnem sredstvu:
Zoper to odločbo je v zavrnilnem delu dovoljena pritožba Informacijskemu pooblaščencu RS, Zaloška 59, 1000 Ljubljana v roku 15 dni od dne prejema te odločbe. Pritožba se vloži pisno ali ustno na zapisnik pri UL Medicinski fakulteti, Vrazov trg 2, 1000 Ljubljana ali pošije priporočeno po pošti na ta isti naslov. V tem roku se lahko stranka pravici do pritožbe tudi odpove. Pritožba je takse prosta.

S spoštovanjem,

Prof. dr. Igor Švab, dr. med.
dekan

UNIVERZA V LJUBLJANI
Medicinska fakulteta
Ljubljana

Poslati:
[redacted]
- Informacijski pooblaščenec

univerzitetni klinični center ljubljana
University Medical Centre Ljubljana
v.d. generalnega direktorja Jože Golobič
Zaloška cesta 2
1525 Ljubljana
E: joze.golobic@kclj.si
W www.kclj.s
Twitter: @ukcl

Številka: ZDIJZ-2021-20
Izhodna številka dokumenta: 045-0020/2021/0002

Ljubljana, 9. 7. 2021

SKLEP

Univerzitetni klinični center Ljubljana (v nadaljevanju organ) po v. d. generalnega direktorja, Jožetu Golobič, na podlagi drugega odstavka 22. člena Zakona o dostopu do informacij javnega značaja (Uradni list RS, št. 51/06 - uradno prečiščeno besedilo, 117/06 - ZDavP-2, 23/14, 50/14, 72/14 - skl. US, 19/15 - odl. US in 7/18; v nadaljevanju: ZDIJZ) v zvezi z zahtevo prosilca gospoda [redacted]

ODLOČBO

Zahtevi gospoda [redacted] za dostop do informacije javnega značaja, vloženi dne 14. 6. 2021 se delno ugodi tako, da se mu posreduje naslednje informacije:

K vprašanju pod zaporedno številko 1 se posreduje povezavo:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7095418/

K vprašanju pod zaporedno številko 2 se posreduje povezavo:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7095418/
in pojasnilo: genetski zapis SARS-CoV-2 je soroden drugim koronavirusom in je škodljiv.

K vprašanju pod zaporedno številko 3 se posreduje povezavo:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7184405/pdf/ciaa325.pdf
In pojasnilo: podajamo referenco, iz katere je razvidno, da SARS-CoV-2 izpolnjuje Kochove postulate. Vlagatelju ob tem pojasnjujemo, da je Koch s svojim sodelavcem Henlejem postulate objavil, precej preden so bili odkriti virusi. Kasneje so, predvsem v luči spoznanj virologije, Kochovi postulati bili prilagojeni novim odkritjem. Ne vemo sicer, kaj vlagatelj pojmuje pod pojmom "papir", domnevamo, da gre za neposrečen prevod angleškega izraza "paper", ki v tem primeru pomeni članek.

K vprašanju pod zaporedno številko 4 se posreduje povezavo:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7184405/pdf/ciaa325.pdf

K vprašanju pod zaporedno številko 5 se posreduje napotilo na:
https://pubmed.ncbi.nlm.nih.gov/12748632/
elektronski vir: Nature 2003 May 15;423(6937):240.

K vprašanju pod zaporedno številko 6 se posreduje povezavo:
10.1016/0035-9203(52)90043-6.

K vprašanju pod zaporedno številko 7 se posreduje povezavo:
https://www.eurosurveillance.org/docserver/fulltext/eurosurveillance/25/3/eurosurv-25-3-5.pdf?expires=1624872204&id=id&accname=guest&checksum=8D3EF216634EF95158095FEABA7CCA1C
In pojasnilo: Corman et.al (2020) mejo med pozitivnim in negativnim rezultatom ne podajo s CT vrednostjo, temveč na osnovi limite detekcije (slika 3), ki predstavlja najnižjo količino/koncentracijo analita (v tem primeru kopije virusne dednine) v vzorcu, ki jo je mogoče detektirati (za E gen in RdRp gen so ugotovili limite 5.2 oz 3.8 kopij virusne dednine na reakcijo).

K vprašanju pod zaporedno številko 8 se posreduje povezavo:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/926410/Understanding_Cycle_Threshold__Ct__in_SARS-CoV-2_RT-PCR_.pdf
in pojasnilo: v primeru, da je za RT-PCR po validaciji ugotovljeno, da je test negativen nad 39CT, za takšen zaključek ni potrebno testa izvajati do 45CT.

K vprašanju pod zaporedno številko 10 se posreduje povezavo:
Https://www.qiagen.com/us/resources/resourcedetail?id=8d610767-ec01-4ec8-afc6-119f9f28fefd&lang=en
In pojasnilo: meja ni arbitrarna, temveč je določena glede na podatke validacije testa RT-PCR. ter internih validacijskih analiz posameznega laboratorija.

K vprašanju pod zaporedno številko 11 in 14 se posreduje napotilo na:
Specifičnost vezave začetnih oligonukleotidov v članku Corman et.al. (2020) avtorji pojasnijo sami v odstavku: "Specificity testing".

K vprašanju pod zaporedno številko 12 se posreduje napotilo na:
pojasnila avtorjev študije Corman et.al. (2020), ki so sekvence pridobili v skladu s prakso iz javno dostopnih baz: "We downloaded all complete and partial (if > 400 nt) SARS-related virus sequences available in GenBank by 1 January 2020. The list (n = 729 entries) was manually checked and artificial sequences (laboratory-derived, synthetic, etc), as well as sequence duplicates were removed, resulting in a final list of 375 sequences. These sequences were aligned and the alignment was used for assay design (Supplementary Figure S1). Upon release of the first 2019-nCoV sequence at virological.org, three assays were selected based on how well they matched to the 2019-nCoV genome (Figure 1). The alignment was complemented by additional sequences released independently on GISAID (https://www.gisaid.org), confirming the good matching of selected primers to all sequences. Alignments of primer binding domains with 2019-nCoV, SARS-CoV as well as selected bat-associated SARS-related CoV are shown in Figure 2."

K vprašanju pod zaporedno številko 13 se posreduje povezavo:
https://www.qiagen.com/us/resources/resourcedetail?id=8d610767-ec01-4ec8-afc6-119f9f28fefd&lang=en

K vprašanju pod zaporedno številko 15 se posreduje povezavo na:
European Commission. (2020) Current performance of COVID-19 test methods and devices and proposed performance criteria. 16 April 2020. https://ec.europa.eu/docsroom/documents/40805
p.5: "The RNA contained in this virus is generally detectable in respiratory specimens during the early and acute phases of infection. Whilst positive results are indicative of the presence of SARS-CoV-2 RNA, a clinical correlation with the patient history and other diagnostic information is necessary to determine the infection status of the patient."

K vprašanju pod zaporedno številko 16 se posreduje pojasnilo:
Z RT-PCR metodo se ugotavlja prisotnost/odsotnost virusne dednine.

K vprašanju pod zaporedno številko 17 se posreduje povezavo na:
Https://www.qiagen.com/us/resources/resourcedetail?id=8d610767-ec01-4ec8-afc6-119f9f28fefd&lang=en
In napotilo na: specifičnost vezave začetnih oligonukleotidov na "sorodne koronaviruse" v članku Corman et.al. (2020) avtorji pojasnijo v odstavku: "Cross-reactivity with other coronaviruses".

K vprašanju pod zaporedno številko 18 se posreduje pojasnilo, da lahko RT-PCR najde viralne delce iz preteklih okužb.

K vprašanju pod zaporedno številko 19 se posreduje pojasnilo, da je lahko vzorec pri 40Ct pozitiven in potem negativen, če bi mejo med pozitivnim in negativnim spustili na 25Ct.

K vprašanju pod zaporedno številko 20 se posreduje povezave na:
Efficacy of masks and face coverings in controlling outward aerosol particle emission from expiratory activities | Scientific Reports (nature.com)
Effectiveness of Mask Wearing to Control Community Spread of SARS-CoV-2 | Infectious Diseases | JAMA | JAMA Network
Social interaction context shapes emotion recognition through body language, not facial expressions. - PsycNET (apa.org)
Children's emotion inferences from masked faces: Implications for social interactions during COVID-19 (nih.gov)
COVID-19 and re-opening of schools: Opinions with scientific evidence (nih.gov)
Comprehensive and safe school strategy during COVID-19 pandemic (nih.gov)
Verwendung von Masken bei Kindern zur Verhinderung der Infektion mit SARS-CoV-2 (nih.gov)
To mask or not to mask children to overcome COVID-19 (nih.gov)
An evidence review of face masks against COVID-19 | PNAS
Mask-wearing and control of SARS-CoV-2 transmission in the USA: a cross-sectional stu

K vprašanju pod zaporedno številko 22 posreduje napotilo na:
MSphere 2021 May 19;6(3):e00019-21. doi: 10.1128/mSphere.00019-21

K vprašanju pod zaporedno številko 25 se posreduje pojasnilo, da so bili ljudi v letu 2020, ki so umrli v naši ustanovi zaradi virusa večinoma starejši, nad 65 let.

K vprašanju pod zaporedno številko 27 se posreduje povezavo na:
https://www.cdc.gov/vaccines/covid-19/downloads/Information-for-laboratories-COVID-vaccine-breakthrough-case-investigation.pdf

K vprašanju pod zaporedno številko 29 se posreduje Letna poročila UKC Ljubljana iz katerih bodo razvidni želeni podatki.

K vprašanju pod zaporedno številko 30 se posreduje pojasnilo, da pacientov, ki bi potrebovali nujno oskrbo, nismo zavračali, obravnavani so bili glede na epidemiološko anamnezo. Elektivni pacienti, ki niso izpolnjevani zahtevanih pogojev, pa so lahko po presoji zdravnika tudi odloženi.

K vprašanju pod zaporedno številko 31 posreduje povezavi:
https://c19ivermectin.com/
https://c19hcq.com/

Zahteva za dostop do informacije javnega značaja, vložena dne 14. 2. 2021, se v preostalem delu zavrne.

Posebni stroški v tem postopku niso nastali.

Obrazložitev:

Organ je dne 14. 6. 2021 prejel zahtevo gospoda [redacted] v nadaljevanju: prosilec) za dostop do informacij javnega značaja.

V njej prosilec zahteva vso relevantno dokumentacijo in odgovore na sledeča vprašanja:

1. Vlagatelj želi usmeritev na papir in/ali študije na katere se vaša ustanova naslanja pri dokazovanju fizičnega obstoja virusa SARS-CoV-2 in njegovo patogenost?

2. Ali so se v primeru, da se vaše delo o izolaciji in patogenosti virusa, naslanja na gojenju virusov v celični kulturi, opravili potrebni kontrolni eksperimenti, ter bi vlagatelj želel, da se mu posreduje link do teh podatkov:

- **da se izloči** možnost , da ta sekvenčna struktura, i.e. genetski sev, ki je pripisan temu virusu, ne izvira iz drugege genetskega materiala in da je neškodljiv?

- **da se izloči**, da eksperimentalna priprava, i.e. okužba celične kulture (e.g. VeroE6), s katero se je obdelala celična kultura ,ni razlog za citopatični efekt, ki bi se tako pomotoma pripisal virusu?

3. Se lahko vlagatelja, točno napoti do papirja in/ali študije slovenskega, evropskega ali svetovnega laboratorija, ki je dokazal fizični obstoj virusa **tudi** po Kochovih postulatah?

   Slovenski medicinski slovar za Kochove postulate določa, da se sme nekemu mikrobu, med katere sodijo tudi virusi, priznati vzročnost pri določeni bolezni samo, kadar so izpolnjeni naslednji pogoji: (i) mikrob moramo najti pri vsakem primeru bolezni, ne pa tudi pri zdravih osebah, (ii) treba ga je osamiti od bolnika v čisti kulturi, (iii) treba ga je vcepiti zdravim občutljivim živalim, pri katerih mora povzročiti isto bolezen, in (iv) isti mikrob moramo znova osamiti iz okuženih živali.

4. Ali vaša ustanova razpolaga s papirjem in/ali študijo slovenskega, evropskega ali svetovnega laboratorija, ki je dokazal fizični obstoj virusa in njegovo patogenost na naslednji način:

- se je vzel vzorec(kri, slina, pljučna tekočina) iz okužene osebe, ki se je očistil do te mere, da nam ostanejo samo čisti viralni delci in ničesar drugega,
- se vizualizira vzorec pod mikroskopom in slika,
- karakterizira njegova unikatna biokemična struktura,
- se pridobi celotna sekvenca genoma,
- se določi iz katerih beljakovin je sestavljen,
- ter se očiščen virus vstavi v eksperimentalno telo živali ali človeka, ki je nato povzročil bolezen in njej pripadajoče simptome

5. Se lahko vlagatelja natančno napoti do papirjev in/ali študij slovenskega, evropskega ali svetovnega laboratorija, ki je dokazal fizični obstoj virusov iz družine koronvirusov (**229E, OC43, SARS-CoV-2003, NL63, HKU1, MERS-CoV**) po Kochovih postulatah ali na način opisan pod zaporedno številko 4?

6. Se lahko vlagatelja točno napoti do papirjev in/ali študij slovenskega, evropskega ali svetovnega laboratorija,ki je dokazal fizični obstoj virusa **Ebola, Zika, H1N1** ali **HIV** po Kochovih postulata ali na način opisan pod zaporedno številko 4?

7. Pri katerem ciklu pomnoževanje je Corman-Drosten protokol določil mejo med pozitivnim in negativnim vzorcem?

8. Zakaj se je v Sloveniji uporabljalo 40 ciklov pomnoževanje, ko pa Corman-Drosten protokol navaja 45 Ct?

9. Zakaj se je v Sloveniji v letu 2020 uporabljalo 40Ct, namesto priporočenih 25Ct?

10. Na podlagi katerih znanstvenih dokazov se lahko uporablja test za diagnostiko okuženosti, ki ni binaren(kot test za nosečnost), temveč je arbitraren, kar pomeni, da lahko vsak laboratorij oz država postavi svojo mejo Ct, ki loči med pozitivnim ali negativnim vzorcem?

11. Ali obstaja možnost, da se iniciatorji in geni uporabljeni v Corman-Drosten protokolu, vežejo na sekvence človeškega genoma in mikrobov? V primeru da ne, bi vlagatelj referenco ali link do teh podatkov, ki to dokazujejo.

12. Se lahko vlagatalje usmeri na dokumente,ki pojasnijo, kako je dr. Christian Drosten v protokolu določil sekvence obeh oligonukleotidov, ter E,N in RdRP genov, ki naj bi bili specifični za SARS-CoV-2, če priznava v svojem papirju, da ni imel na voljo izoliranega referenčnega vzorca virusa?

"We aimed to develop and deploy robust diagnostic methodology for use in public health laboratory settings without having virus material available." [1]

13. Se lahko vlagatelja usmeri na papir(validacija testa),kjer je razvidno, da je RT-PCR test občutljiv, specifičen in reproduktiven samo na viralne RNA sekvence virusa?

14. Ali obstaja možnost, da se iniciatorji in geni uporabljeni v Corman-Drosten protokolu, vežejo na sekvence človeškega genoma in mikrobov? V primeru da ne, bi vlagatelj referenco ali link do teh podatkov, ki to dokazujejo.

15. Ali lahko RT-PCR test loči med aktivnim in neaktivnim virusom? V primeru, da lahko, bi vlagatelj link do teh podatkov.

16. Ali lahko RT-PCR test ugotovi , da je viralna RNA sekvenca patogena? V primeru, da lahko, bi vlagatelj link do teh podatkov

17. Ali lahko RT-PCR test ugotovi sorodne koronaviruse? V primeru, da ne more, bi vlagatelj link do teh podatkov.

18. Ali lahko RT-PCR najde viralne delce iz preteklih okužb? Če ne more, bi vlagatelj link do teh podatkov, ki to potrjujejo.

19. Je lahko vzorec pri 40Ct pozitiven in potem negativen, če bi mejo med pozitivnim in negativnim spustili na 25Ct?

20. Se lahko vlagatelju napoti do RCT študij in ne priporočil, ki brez dvoma dokazujejo, da nošenje mask zaustavi širjenje virusov?

21. Vlagatelj želi tudi reference do RCT varnostnih študij izven kontroliranih območij(zdravstvene ustanove, laboratoriji itd), da nošenje mask v vsakdanjem življenju ne škoduje zdravju?

22. Se lahko vlagatelja napoti do RCT študij in ne računalniških modelov,ki brez dvoma dokazujejo, da zdravi ljudje lahko širijo virus?

23. Koliko ljudi je v vaši ustanovi umrlo v letu 2020, ki so imeli samo pozitive RT-PCR test in bili brez vsake življensko nevarne pridružene bolezni?

24. Koliko ljudi je v vaši ustanovi umrlo v letu 2020, ki so bili poslani iz DSO-jev in koliko ostalih?

25. Koliko je bila povprečna starost ljudi v letu 2020, ki so umrli v vaši ustanovi zaradi virusa?

26. Koliko ljudi v letu 2021 je bilo pozitivnih na RT-PCR testu ob prihodu v vašo ustanovo, kljub temu, da so že prejeli priporočene odmerke cepiva?

27. Zakaj se zdaj za »cepljene« ljudi priporoča izvajanje RT-PCR testov pri 28 Ct ali pa sploh ne, ko za vse druge velja, da se izvaja RT-PCR test med 40Ct? Zakaj dvojna merila, ki s tem ustvarjajo velik sum in dokazuje, da se lahko manipulira število okuženih s številom pomnožitev pri RT-PCR testih?

https://www.cdc.gov/vaccines/covid-19/downloads/Information-for-laboratories-COVID-vaccine-breakthrough-case-investigation.pdf

28. Koliko ljudi ste v letu 2021 zdravili ali so umrli zaradi stranskih učinkov cepiv za C-19?

29. Se lahko vlagatelju pošlje dokumentacija zasedenosti vseh vaših bolnišničnih postelj za leto 2017, 2018, 2019 in 2020?

30. Ali se bo izvedla zdravstvena storitev zdravemu pacientu, ki bi prišel v vašo ustanovo zaradi zloma noge in ne želi, da se ga kakorkoli testira?

31. Zakaj se v vaši ustanovi ne ponuja drugih varnih in učinkovitih terapij, kot je HQC in Ivermectin ,ter se samo ponuja popolnoma eksperimentalno injekcijo genske terapije, kot edini način zdravljenja C19 bolezni?
https://c19ivermectin.com/
https://c19hcq.com/

Prvenstveno je organ v skladu s prvim odstavkom 4. člena ZDIJZ presojal ali zahtevane informacije ustrezajo zakonski opredelitvi informacije javnega značaja in ali organ razpolaga z zahtevanimi informacijami. Po prvem odstavku 4. člena ZDIJZ je informacija javnega značaja informacija, ki izvira iz delovnega področja organa, nahaja pa se v obliki dokumenta, zadeve, dosjeja, registra, evidence ali drugega dokumentarnega gradiva (v nadaljevanju: dokument), ki ga je organ izdelal sam, v sodelovanju z drugim organom ali pridobil od drugih oseb. Iz navedene določbe izhajajo trije osnovni pogoji, ki morajo biti kumulativno izpolnjeni, da lahko govorimo o obstoju informacije javnega značaja, in sicer:

1. informacija mora izvirati iz delovnega področja organa,
2. organ mora z njo razpolagati in
3. nahajati se mora v materializirani obliki.

Upoštevajoč navedeno informacijo javnega značaja predstavlja dokument, ki že obstaja, je ustvarjen oziroma tisti dokument, ki ga je organ v okviru svojega delovnega področja že izdelal oziroma pridobil in ga ni dolžan ustvariti šele na podlagi zahteve.

Organ pojasnjuje, da je kot zavezanec po ZDIJZ prosilcu dolžan omogočiti dostop le do že obstoječih (materializiranih) informacij in ni dolžan odgovarjati na vprašanja oziroma podajati pojasnila na način, da bi posebej tvoril stavke, ki bi predstavljali odgovore na vprašanja, niti ni dolžan ustvariti dokumente ali jih pridobivati od drugih subjektov, da bi zadostil zahtevi. Iz odločbe IP, št. 090-277/2020/4 z dne 17.12.2020 izhaja, da na primer vloga, s katero se zahteva, da organ odgovori na vprašanja oz. pripravi pojasnilo, obrazložitev ipd. ne predstavlja zahteve za dostop do informacij javnega značaja. IP v odločbi pojasnjuje, da ZDIJZ ne omogoča oziroma predvideva pravice do odgovorov in pojasnil ter podobnega. Takšno stališče izhaja tudi iz sodbe Upravnega sodišča RS, št. I U 1351/2010-12 z dne 25. 5. 2011. Prosilec ima namreč po ZDIJZ pravico zahtevati dokumente, s katerimi organi zavezanci že razpolagajo, ne more pa prisiliti organa, da posebej na zahtevo prosilca ustvari določen dokument (npr. pripravi odgovore na vprašanja, poda pojasnilo, obrazložitve ipd.)

Organ po preučitvi zahteve ugotavlja, da v zvezi z vprašanji pod zaporednimi številkami 9, 21, 23, 24, 26 ter 28 prosilec od organa zahteva podajo odgovorov in pojasnil, ki ne predstavljajo zahteve za dostop do informacij javnega značaja po 4. členu ZDIJZ. Poleg tega organ z informacijami ne razpolaga v obliki dokumenta, zadeve, dosjeja, registra ali evidence oziroma drugega dokumentarnega gradiva oziroma da se dokumenti, iz katerih bi izhajali odgovori na navedena vprašanja.

Glede na navedeno upoštevajoč dejstvo, da organ ni dolžan ustvariti novih dokumentov oziroma podajati odgovorov in pojasnil, ni izpolnjen pogoj, ki ga za informacijo javnega značaja določa prvi odstavek 4. člena ZDIJZ, zato je potrebno prosilčevo zahtevo upoštevaje določilo 4. člena ZDIJZ v tem delu zavrniti.

Kljub temu je organ za ostala vprašanja pripravil in predložil vire podatkov, povezave na vire podatkov in pri nekaterih kratka pojasnila, kot je razvidno iz izreka te odločbe. V tem delu organ šteje, da je zahtevi delno ugodil.

Organ mora ob izdaji odločbe odločiti tudi o posebnih stroških, ki so nastali v zvezi z odločanjem v upravnem postopku. V predmetnem postopku posebni stroški postopka niso nastali, zato je organ odločil kot izhaja iz 3. točke izreka te odločbe.

POUK O PRAVNEM SREDSTVU:

Zoper to odločbo je dovoljena pritožba v roku 15 dni od dneva vročitve na Informacijskega pooblaščenca, Zaloška 59, 1000 Ljubljana, in je prosta plačila upravne takse. Pritožba se vloži v pisni (fizični ali elektronski) obliki ali ustno na zapisnik pri organu. Če je pritožba poslana priporočeno po pošti, se šteje, da je pravočasna, če je oddana na pošto zadnji dan pritožbenega roka. O pritožbi odloča Informacijski pooblaščenec.

Univerzitetni klinični center Ljubljana
v.d. generalnega direktorja
Jože Golobič

p. p. št. 100-0012/2020/0007
Petra Mrhar Slak, univ. dipl. prav.

UNIVERZITETNI KLINIČNI CENTER LJUBLJANA 3

Vročiti:
- prosilcu
- spis.

Translation provided by FOI submitter

QUESTIONS AND THE ANSWERS PROVIDED UKCLJ (UNIVERSITY MEDICAL CENTRE LJUBLJANA), SLOVENIA:

1) The applicant wants a link to the studies that your institution relies on in proving the physical existence of the SARS-CoV-2 virus and its pathogenicity?

ANSWER :
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7095418/

2) In the event that your work on virus isolation and its pathogenicity relies on the cultivation of viruses in cell culture, the necessary control experiments have been carried out, and the applicant would like to be provided with a link to this information:

- to rule out the possibility that this sequence structure i.e. the genetic strain attributed to this virus does not originate from other genetic material and is harmless?

- to exclude that experimental preparation, i.e. is the cell culture infection (VeroE6) treated with the cell culture not the reason for the cytopathic effect that would so mistakenly be attributed to the virus?

ANSWER:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7095418/
The genetic code of SARS-CoV-2 is related to other coronaviruses and is harmful

3) Can the applicant be referred exactly to the studies of a Slovenian, European or world laboratory, which proved the physical existence of the virus even according to Koch's postulates?

ANSWER:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7184405/pdf/ciaa325.pdf
We give a reference which shows that SARS-CoV-2 meets Koch's postulates. We explain to the applicant that Koch and his colleague Henle published the postulates before viruses were discovered. Later, mainly in the light of virology findings, Koch's postulates were adapted to the new discoveries.

4) Does your institution have an article or study from a Slovenian, European or world laboratory that has proven its physical existence and pathogenicity in the following way:
- a sample (blood, saliva, lung fluid, etc.) was taken from the infected person, which was cleaned to such an extent that only pure viral particles and nothing else remained
-the sample is visualized under the microscope and the image of the virus is taken
-characterized by its unique biochemical structure
-the entire genome sequence is obtained

-determines which proteins it is composed of
-and then an isolated and purified sample is inserted into the experimental body of the animal or human who then caused the disease and its associated symptoms

ANSWER: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7184405/pdf/ciaa325.pdf

5) Can the applicant be referred to the studies of a Slovenian, European or world laboratory that has proven the physical existence of viruses from the coronavirus family (229E, OC43, SARS-CoV-2003, NL63, HKU1, MERS-CoV) according to Koch's postulates or in the manner described under serial number 4?

ANSWER:
https://pubmed.ncbi.nlm.nih.gov/12748632/

6) Can the applicant be specifically referred to the studies of a Slovenian, European or world laboratory that has proven the physical existence of Ebola, Zika, H1N1 or HIV viruses according to Koch's postulates or in the manner described under serial number 4?

ANSWER:
DOI: 10.1016/0035-9203(52)90043-6
https://pubmed.ncbi.nlm.nih.gov/12995441/
https://academic.oup.com/trstmh/article-abstract/46/5/521/1896900?redirectedFrom=fulltext

7) By which multiplication cycle did the Corman-Drosten protocol define the boundary between the positive and negative sample?

ANSWER:
https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.25.3.2000045

Explanation: Corman et al (2020) does not specify the boundary between a positive and a negative sample with a Ct value, but on the basis of a detection limit (Figure 3) representing the lowest amount / concentration of analyte (in this case a copy of viral inheritance) can be detected (limits of 5.2 and 3.8 copies of viral inheritance per reaction were found for E gene and RdRP gene, respectively).

8) Why was 40 ct used in Slovenia, if Corman et al states 45 Ct?

ANSWER:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/926410/Understanding_Cycle_Threshold__Ct__in_SARS-CoV-2_RT-PCR_.pdf
Explanation: In the event that the RT-PCR is found to be negative above 39CT after validation, it is not necessary to perform a test up to 45Ct for such completion.
9) Why was 40Ct used in Slovenia instead of the recommended 25 Ct?

ANSWER: Refused to answer

10) On the basis of which scientific evidence can a test be used to diagnose an infection that is not binary (as a pregnancy test) but arbitrary, which means that each laboratory or country can set its own Ct limit that separates when a sample is positive or negative?

ANSWER:
http://www.giagen.com/us/resources/resourcedetail?id=8d610767-ec01-4ec8-afc6-119f9f28fefd&lang=en
Explanation: The limit is not arbitrary, but is determined on the validation data of the RT-PCR test, and internal validation analyzes of each laboratory

11) Is there a possibility that the initiators and genes used in the Corman et al protocol bind to sequences of the human genome and microbes? If not, the applicant wants a reference or link to this data to prove this?

ANSWER:
The specificity of the binding of the initial oligonucleotides in the article by Corman et al (2020) is explained by the authors themselves in the paragraph: "Specificity testing"

12) Can the applicant be directed to documents that explain how dr. Christian Drosten determined the sequences of both oligonucleotides, and the E, N and RdRP genes that are supposed to be specific for SARS-CoV-2, if he admits in his study that he did not have an isolated reference sample of the virus?

ANSWER:
Explanations of the authors of the studies Corman et al (2020), who obtained the sequences in accordance with the practice from publicly available databases.
On the page 2 you have the rest of the answer in english third pragraph from the bottom up

13) Can the applicant be referred to a study (test validation) where the RT-PCR test is shown to be sensitive, specific and reproducible only to viral RNA sequences of the virus?

ANSWER:
http://www.giagen.com/us/resources/resourcedetail?id=8d610767-ec01-4ec8-afc6-119f9f28fefd&lang=en

14) Almost the same question as under number 11. My mistake. Same answer as under number 11

15) Can RT-PCR distinguish between active and inactive virus? In case it can, the applicant wants a link to this information

ANSWER:
https://ec.europa.eu/docsroom/documents/40805
The remaining answer is in English in the last paragraph on page 2

16) Can an RT-PCR test determine that a viral RNA sequence is pathogenic? In case it can, the applicant wants a link to this information

ANSWER:
With RT-PCR method we detect the presence/absence of viral inheritance

17) Can an RT-PCR test detect related coronaviruses? In case it does not, the applicant wants a link to this data.

ANSWER:
https://www.qiagen.com/us/resources/resourcedetail?id=8d610767-ec01-4ec8-afc6-119f9f28fefd&lang=en

In reference to: the specificity of the binding of the initial oligonucleotides to "related coronaviruses" in Corma et.al. (2020) the authors explain in paragraph: "Cross - reactivity with other coronaviruses"

18) Can an RT-PCR test find viral particles from past infections? If he cannot, the applicant wants a link to this information

ANSWER: RT-PCR test can find viral particles from past infections

19) Can a sample at 40Ct be positive and then negative if we lower the boundary between positive and negative to 25 Ct?

ANSWER: Yes, it can

20) Can the applicant be directed to RCT studies and not recommendations that unequivocally prove that wearing a mask prevents the spread of the virus?

ANSWER:

https://www.nature.com/articles/s41598-020-72798-7
https://jamanetwork.com/journals/jama/fullarticle/2776536
https://psycnet.apa.org/record/2020-02994-001
https://pubmed.ncbi.nlm.nih.gov/33362251/

https://pubmed.ncbi.nlm.nih.gov/33362251/
https://pubmed.ncbi.nlm.nih.gov/33422089/
https://link.springer.com/article/10.1007/s00112-020-01090-99m
https://pubmed.ncbi.nlm.nih.gov/32388722/
https://www.pnas.org/content/118/4/e2014564118
https://pubmed.ncbi.nlm.nih.gov/33483277/

21) The applicant also wants references to RCT safety studies outside the controlled areas (medical facilities, laboratories, etc.) that wearing a mask in everyday life is not harmful to health?

ANSWER: Refused to answer

22) Can an applicant be referred to RTC studies rather than computer models that unequivocally prove that a healthy person can spread the virus?

ANSWER:
https://journals.asm.org/doi/10.1128/mSphere.00019-21

23) How many people died in your institution in 2020 who had only a positive RT-PCR test and were free of any life-threatening associated disease?

ANSWER: Refused to answer

24) How many people died in your institution in 2020 who were sent from nursing homes and how many others?

ANSWER: Refused to answer

25) What was the average age of people in 2020 who died in your institution from the virus?

ANSWER: the people who died were mostly from the age of 65 onwards

26) How many people tested positive for RT-PCR tests in 2021 upon arrival at your facility, even though they had already received the recommended doses of vaccines?

ANSWER: Refused to answer

27) Why is it now recommended for vaccinated people to perform the RT-PCR test at 28Ct or not at all, when for all others it is considered that the RT-PCR test is performed at 40Ct? Why double standards, which create a lot of suspicion and prove that the number of infected people can be manipulated by the number of aids in the RT-PCR test?

ANSWER: Information-for-laboratories-COVID-vaccine-breakthrough-case-investigation.pdf

28) How many people have you treated or died from the side effects of COVID-19 vaccines in 2021?

ANSWER: Refused to answer

29) Can the applicant be sent the occupancy documentation of all your hospital beds for 2017, 2018, 2019 and 2020?

ANSWER: I got the annual report for 2019 and 2020

30) Will a medical service be provided to a healthy patient who would come to your facility due to a broken leg and does not want to be tested in any way?

31) Why is there no other safe and effective therapies like HQC and Ivermectin offered in your facility, but only a fully experimental gene therapy injection is offered as the only way to treat COVID-19 disease?

ANSWER:
https://c19ivermectin.com/
https://c19hcq.com/
they put my links in this answer

IN THE HIGH COURT OF SOUTH AFRICA
(WESTERN CAPE DIVISION)

CASE NO: 5852/21

In the Matter between:

RICARDO MAARMAN	APPLICANT
AND	
THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	FIRST RESPONDENT
AND	
THE MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS	SECOND RESPONDENT
AND	
PROFESSOR SALIM ABDOOL KARIM on behalf of the GOVERNMENTAL COVID 19 ADVISORY COMMITTEE	THRID RESPONDENT

NOTICE OF MOTION
(Interim urgent interdict)

TAKE NOTICE THAT;

The Respondent are hereby called upon to show cause, if any, to this Honourable Court, sitting at Cape Town on the day of ***20 April 2021, at 10H00***, or so soon thereafter as the matter may be heard, why an order should not be issued in the following terms:

1. That this Application is heard as a matter of urgency and that the Applicant's failure to comply with the time limits imposed by the Rules of this Honourable Court be condoned in terms of Rule 6 (12).

2. That the respondent produces the isolated and purified physical SARS-CoV-2-virus (not a culture isolate or any mixture within in which the supposed virus is, nor a photograph or the RNA-sequence only), to the applicant at the place and in terms of its security measures of choice, within 14 days.

3. Further or alternative relief.

4. Cost of the application if opposed.

TAKE NOTICE FURTHER THAT, the affidavit of, ***RICARDO MAARMAN***, the Applicant herein, annexed hereto, will be used in the support of this Application.

TAKE NOTICE FURTHER THAT if you intend opposing this application you are required; to notify the applicant in writing on or before ***12 April 2021*** of your intention to oppose.

To file your answering affidavit, if any on or before ***12April 2021.***

And further that you are required to appoint in such notification an address referred to in rule 6(5)(d)(i) of the rules of this Honourable Court at which you will accept notice and service of all documents in these proceedings, such an address (not being a post office box) to be one within 15 (Fifteen) kilometres of the office of the registrar.

The applicant consents to exchange taking place via email to carlo@victorlegal.co.za or tammy@victorlegal.co.za

TAKE NOTICE FURTHER; that the Applicant has appointed ***T VICTOR AND ASSOCIATES, 24*** Viola Road, Bloubergstrand, Cape Town, ***C/O ROB GREEN*** Attorneys, Room 305 Benzal House, 3 Barrack Street, Cape Town as its attorney of record and his service address as the address at which the Applicant will accept service of all process in these proceedings.

KINDLY PLACE THE MATTER ON THE ROLL ACCORDINGLY.

DATED AT CAPE TOWN ON THIS THE 18th DAY OF MARCH 2021.

T VICTOR AND ASSOCIATES

24 Viola Road

Bloubergstrand

Cape Town

TEL 074 707 8168

FAX 086 294 5204

EMAIL victorlegalinfo@gmail.com

C/O

ROB GREEN Attorneys,

Room 305 Benzal House,

3 Barrack Street, Cape Town)

TO: THE REGISTRAR CAPE TOWN HIGH COURT

AND TO; ALL THREE THE RESPONDENTS

Served at the office of the State Advocate Cape Town

IN THE HIGH COURT OF SOUTH AFRICA
(WESTERN CAPE DIVISION)

In the Matter between: CASE NO:

RICARDO MAARMAN

Applicant

And

THE MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS

Respondent

FOUNDING AFFIDAVIT

I, the undersigned

RICARDO MAARMAN
820531 5257 086

Hereby state under oath:

1. The facts set out within this affidavit are within my personal knowledge and expertise with reference. To the best of my knowledge, all the facts are correct. In certain aspects, I have relied on documentary evidence, of which relevant portions are attached as annexures, whilst others are easily obtainable from our very own government websites.

THE PARTIES.

2. The Applicant is an adult male, Ricardo Maarman, who holds an MA International Politics obtained at the University of Leicester in the UK. he specialized in the Post-Cold War World Order, International Security, Intelligence and Security and US Foreign Policy, his service address for the purposes of this application is Rob Green Attorneys, Room 305 Benzal House, 3 Barrack Street, Cape Town, as the address at which the Applicant will accept service of all process in these proceedings.

3. The Respondent is the Minister of Cooperative Governance and Traditional Affairs who is cited herein in her official capacity as the Minister mandated in terms of the provisions of the Disaster Management Act, 57 of 2002 ("the DMA") and whose Cape Town office is situated at the State Attorney 4th Floor, 22 Long Street, Cape Town, and whose full and further details are unknown to me.

NATURE OF THE APPLICATION.

This is an application for an order as follows.

4. That this Application is heard as a matter of urgency and that the Applicant's failure to comply with the time limits imposed by the Rules of this Honourable Court be condoned in terms of Rule 6 (12).

5. That the respondent produces the isolated and purified physical SARS-CoV-2-virus (not a culture isolate or any mixture within in which the supposed virus is, nor a photograph or the RNA-sequence only), to the applicant at the place of his choice and under the security measures as preferred by the respondent, within 14 days.

6. Further or alternative relief.

7. Cost of the application if opposed.

URGENCY.

8. I respectfully submit that this matter cannot wait to be dealt with in the ordinary course, as such I ask the Court to dispense with the forms and service provided for in the Rules and to indulge in my non-adherence with the normal rules of procedure as set out in Rule 6.

9. This matter is of such urgency that it simply cannot wait for the normal procedures to be complied with.

10. I respectfully submit that this Application should be heard other than in the normal course, otherwise the relief which we seek will be rendered ineffective.

DETAIL OF THE CIRCUMSTANCES WHICH MAKE THE MATTER URGENT.

11. Currently the Entire State is under Lockdown level one, which is a serious violation of the citizens Fundamental rights.

12. There is a massive nationwide roll out of a vaccine claimed by the respondent that must be used in the prevention of being infected by the alleged virus.

13. This vaccine-roll-out has begun in other countries and it has resulted in deaths and vaccine injuries, ***RM1.***

14. The national disaster has been declared and is in ongoing for almost a year affecting the entire nation with dire consequences.

15. There is no end in sight in the foreseeable future to this pandemic.

16. It is an urgent matter of national concern.

17. The outcome of the order could very well mean a quick recovery to normal circumstances for the entire nation.

18. In South Africa, there is vast unemployment and poverty as such, the questioning of the very cause that threatens to drastically increase the already desperate circumstances must at least be thoroughly investigated and with utmost haste.

19. On 6 May 2020 Africa's Medical Media Digest reported that Pandemic Data and Analytics (Panda), a multidisciplinary initiative co-ordinated by actuary Nick Hudson reported that If South Africa's present economically restrictive lockdown measures are not discontinued immediately, they may cause 29 times more deaths than the measures aim to prevent the spread. And each week of continuing lockdown will, in the long run, cause more loss of life than the virus itself. ***RM2***

REASONS WHY RELIEF CANNOT BE OBTAINED IN THE ORDINARY COURSE.

20. If this matter is heard in the normal course, the relief sought would be of no use, since it is critical for the entire nation.

21. Attached hereto and marked ***RM3*** is a medico legal report from.... stating that the virus has not yet been proven to exist.

HIGH DEGREE

22. I respectfully submit that this application carries a High Degree of urgency in that we are faced with the imminent impoverishment, deuteriation of the wellbeing of the entire nation and their constitutional fundamental right infringements.

TIMETABLE FOR THE FILING OF DOCUMENTS.

23. I propose the following timetable for the processes in this matter which will allow this matter to return to Court in the shortest possible time and which will also allow the respondents reasonably enough time to respond.

24. The matter to be heard on 9 April 2021.

25. Filing of respondents Heads on 6 April 2021.

26. Filing of applicants Heads on 4 April 2021.

27. Applicants replying affidavit on 1 April 2021.

28. Respondents' Notice of opposition and answering affidavit on 29 March 2021.

29. Service on respondent on 26 March 2021.

THE APPLICANT'S LOCUS STANDI

30. The applicant brings this application by virtue of section 38(a) of the Constitution by acting in his own interest and in accordance with its own objectives directed at the protection of his Constitutional Rights and financial sustainability.

31. The Applicant also brings the application in the public interest of all South Africans as a whole and in terms of section 38(d) of the Constitution, with the objective of the protection of their Constitutional Rights and financial sustainability.

THE LEGAL AND CONSTITUTIONAL PRINCIPLES INVOLVED

32. The Constitution provides that the Republic of South Africa is a sovereign, democratic state founded, inter alia, on the following values: Life, Human dignity, the achievement of equality and the advancement of human rights and freedoms and the Rule of Law.

33. The Constitution, provides that "All spheres of government and all organs of state within each sphere must be loyal to the Constitution, the Republic and its people; respect the constitutional status and not assume any power or function except those conferred on them in terms of the Constitution."

34. The Bill of Rights applies to all law, and binds the legislature, the executive, the judiciary and all organs of state.

35. Everyone has inherent dignity and the right to have their dignity respected and protected.

36. Everyone has the right to life, bodily and psychological integrity; To make decisions concerning the security and control over their body; Freedom to practice their trade, Freedom of movement, occupation and profession; Not to be treated in a cruel, inhuman or degrading way; Their right to have access to health care services; Just administrative action.

37. Every citizen has the right to administrative action that is lawful, reasonable, and procedurally fair.

38. These abovementioned rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality, and freedom, taking into account all relevant factors, including the nature of the right; the importance of the purpose of the limitation; the nature and extent of the limitation; the relation between the limitation and its purpose; and less restrictive means to achieve the purpose.

39. No law including the DMA, may limit any right entrenched in the Bill of Rights.

40. It is therefore submitted that, in so far as the Regulations or any Direction Purportedly issued pursuant thereto, that will violate the above-mentioned fundamental rights will be inconsistent with the Constitution, and therefore illegal and void if the SARS-CoV-2-virus is not proven to exist.

41. Furthermore, the rights in the Bill of Rights cannot be infringed upon or limited in any way save in terms of the provisions of section 36 or 37.

42. The national state of disaster, announced in terms of the DMA, has been called on the mere allegation of the existence of the SARS-CoV-2-virus, and the applicant stands on his Fundamental right to test whether the violation of his and the entire nation's Constitutional rights have been based on the existence of the SARS-CoV-2-virus

THE STATE MAY NOT INTERFERE WITH THOSE FREEDOMS, EXCEPT UNDER SECTION 36 OF THE CONSTITUTION.

43. My respectful submission is that until the Respondent has produced the SARS-CoV-2-virus to be tested by independent experts in the appropriate circumstances that the Limitation of the rights of the Applicant and the Nation's rights to freedom of movement is not justified in terms of Section 36. (1) of the Constitution.

44. According to Section 36. (1) The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors.

45. We are not asking this honourable Court to do the Section 36 test in this matter, or to decide on the existence of the SARS-CoV-2-virus we are simply asking that the respondent produces the isolated and purified physical SARS-CoV-2-virus (not a

culture isolate or any mixture within in which the supposed virus is, nor a photograph or the RNA-sequence only), to the applicant at the place of his choice and under the security measures as preferred by the respondent, within 14 days, in order for us to test whether these extremely harsh disaster enforced on the nation is in fact based on the existence of the SARS-CoV-2-virus.

46. The nature of the rights here being limited are fundamental rights in terms of chapter two; the right to bodily and psychological integrity; The right to make decisions concerning the security and control over their own bodies; Freedom to practice their trade, freedom of movement, occupation, and profession; Not to be treated in a cruel, inhuman or degrading way; Their right to have access to health care services; the right to just administrative action.

47. These are fundamental rights that cannot be limited if there are no evidence of the existence of the SARS-CoV-2-virus.

RULE 16 A

48. A Rule 16 A notice will be issued together with the issuing of this application ***(See Attached copy of the notice marked RM4).***

BACKGROUND.

49. During January 2020, the world became aware of the so-called Corona Virus.

50. At the writing of this affidavit the reported South African statistical information of the so-called Virus are as follows; 1 404 839 cases have been reported. Attached hereto and marked ***RM5***, see the latest coronavirus world report.

51. Of the 1 404 839 reported South African cases 1 217 492 have recovered.

52. Currently 150 800 people in South Africa have the so-called Virus of which namely 546 are in a serious or critical condition thus 0.31% of infected people are in a serious condition.

53. 40 574 out of 1 404 839 who contracted the so-called Virus in South Africa to date has died, namely 1.38%.

54. On 15 March 2020, Dr Mmaphaka Tau, the Head of the National Disaster Management Centre in the Department of Cooperative Governance gave notice that the Covid-19 pandemic was declared as a National Disaster.

55. Also, on 15 March 2020, the respondent issued a declaration of a National State of Disaster and published the declaration in the Government Gazette of that date and on subsequently monthly declarations continued with the declaration and publications of the regulations relating to the National disaster. Attach hereto as Annexure ***RM6*** a copy of the notice to that effect in the Government Gazette.

RATIONALITY

56. To pass the rational basis test, the statute or ordinance must have a legitimate state interest, and there must be a rational connection between the regulations means and goals.

57. The national lockdown severely restricts the movement and choices of people. The result is a severe disruption of business and wellbeing and freedom of movement.

58. This is done under the over broad provision in s 27(2)(n) of the DMA the question that arises is whether this disruption meets the rationality and constitutionality test in terms of South African law.

59. Some disruption of life may be necessary to save lives if we are assured beyond doubt of the existence of the SARS-CoV-2-virus on which the Restrictions are based.

60. This applicant has a reasonable suspicion about the existence of SARS-CoV-2-virus.

61. It is respectfully submitted that this Honourable Court must at least agree that the South African nation is at least entitled to know beyond any doubt that all the damages and restrictions and violations of their rights is based on a virus that is proven to exist.

62. To date it has simply been assumed that the SARS-CoV-2-virus does exist, without question.

63. The respondent has alleged that the SARS-CoV-2-virus does exist as such, she needs to prove it.

64. This can easily be done by the respondent since it should already be in possession of the SARS-CoV-2 virus.

65. The supposed existence of **SARS-CoV-2 virus** has not been established, an RNA-sequence obtained through an RNA-sequencing device RT-PCR test, a DNA or RNA-sequence, does not prove anything without a standard to measure it against, that standard can only be the physical virus.

66. If the virus has not been proven to exist then it follows that no link can be established between the supposed non-existent virus and a disease, no experiments have been presented in which the virus is isolated without any cultures or other substances, and then injected into healthy organisms producing a particular disease, and repeated, without this there can be no link between a virus and a disease.

67. If the virus does not exist, thus no link to a disease can be proven and then no reasonable and justifiable remedy or countermeasures can be devised.

68. There is no evidence existence of the SARS-CoV-2 virus.

69. There is no evidence of the existence of the SARS-Cov-2 virus, its link to Coviid-19 disease.

70. The PCR test are unreliability.

SECTION 39 OF THE CONSTITUTION AND ITS RELEVANCE TO THE FACTS PRESENTED

71. With regards to the nature of the matter, Section 39 (1)(a) and (b) respectively, have to be cited, as it is part and parcel of the fabric of our society, that this section be included here, which states that:

(1) When interpreting the Bill of Rights, a court, tribunal or forum-

(a) must promote the values that underlie an open and democratic society Based on human dignity , equality and freedom;

(b), must consider international law; and

(c), must consider a foreign law

72. Its relevance, that the court should in accordance with the above be open the facts presented below, which in turn sheds light on the Portuguese Judgment (***please find attached hereto marked RM7***), The Court here concludes that:

"Any diagnostic test must be interpreted in the context of the actual possibility of the disease, which existed before its realization. For Covid-19, this decision to perform the test depends on the previous assessment of the existence of symptoms, previous medical history of Covid 19 or presence of antibodies, any potential exposure to this disease and no likelihood of another possible diagnosis." "One of the potential reasons for presenting positive results may lie in the prolonged shedding of viral RNA, which is known to extend for weeks after recovery, in those who were previously exposed to SARS-CoV-2. However, and more relevantly, there is no scientific data to suggest that low levels of viral RNA by RT-PCR equate to infection, unless the presence of infectious viral particles have been confirmed by a laboratory. In summary, Covid-19

tests that show false positives are increasingly likely, in the current epidemiological climate panorama in the United Kingdom, with substantial personal, health and social system consequences."

73. To prove the existence of something especially when it is mixed or incorporated with other things is to first separate or isolate it, then to measure it, to determine its parameters and to determine its qualities. An RNA or DNA sequence is not proof of existence, e.g., having the DNA sequence of a person does not mean that the person exist, to prove the person exists the DNA sequence must be matched to a DNA sequence obtained verifiably directly from the physical person.

74. Here follows explanations regarding the supposed isolation of SARS-CoV-2: as described in an article entitled ***The Genetic Sequence, Origin, Diagnosis of SARS-CoV-2,*** written by Huihui Wang et al.***RM7***

- "Confirmed cases with SARS-CoV-2 were identified as a positive result of a high-throughput sequencing or an RT-PCR assay for respiratory specimens including nasal and pharyngeal swab"

- "Airway epithelial cells from infected patients were used to isolate a novel coronavirus, temporarily named 2019-nCoV, but later, the Coronavirus Research Group of the International Committee for the Classification of viruses found that the new coronavirus is related to the SARS-virus" The International Committee for the Classification of viruses is affiliated to the International

Council of Sciences, which in turn has a formal relationship with UNESCO since 1947, which in turn is a specialised agency of the UN.

- "In addition, the World Health Organisation has named the disease caused by SARS-CoV-2 as coronavirus disease 2019 (Covid-19)".

- "After the SARS-CoV-2 was isolated from the lower respiratory tract specimen, a diagnostic RT-PCR test was developed. RT-PCR tests based on the RNA-dependent RNA polymerase (RdRp) gene of the ORF1ab sequence, E gene, N gene and S gene of the SARS-CoV-2 genome"

- "The genome of coronaviruses, ranging from 26 to 32 kilobases in length, includes a variable number"

- "The SARS-CoV-2 genome was reported to possess 14 ORF's encoding 27 proteins"

75. From scientific article: ***SARS-CoV-2 isolation and propagation from Turkish Covid-19 patients***, as published in the Turkish journal of Biology 44 (3) 192, 2020:

- "Samples were collected from the nasopharyngeal and oropharyngeal cavity of Covid-19 positive diagnosed patients according to their real-time PRC analysis"
- "Next, SARS-CoV-2 specific RT-PCR was performed"

76. From: CDC website in the US, ***Sever Acute Respiratory Syndrome Coronavirus 2 from Patient with Coronavirus Disease***, *United States of America* (viewed on the 16 February 2021):***RM8***

- "We isolated virus from nasopharyngeal and oropharyngeal specimens from this patient and characterised the viral sequence, replication properties, and cell culture tropism"

- "Confirmed PCR-positive specimens were aliquoted and frozen until virus isolation was initiated"

- "we performed confirmatory testing by using real-time reverse transcription PCR (CDC) and full-genome sequencing"

- "We extracted nucleic acid from the isolates and amplified by using the 37 individual nested PCRs"

- "A nearly full-length viral contig obtained in each sample had 100% identity to the 2019-nCoV/USA-WA1/2020 strain (GeneBank accession no. MN985325.1)"

77. From the Australian claim of isolation of the virus, ***Isolation and rapid sharing of the 2019 novel coronavirus (SARS-CoV-2) from the first patient diagnosed with COVID-19 in Australia***, we get the following telling statement:***RM8***

- "In consultation with the World Health Organization, the viral isolate was shared with domestic and international reference laboratories within 24 hours, and lodgement with major North American and European culture collections for further distribution is underway".

78. These claims of isolation at best are based on the matching of one sequence of RNA with another sequence, without producing the actual virus. The NCID of SA on its website has a picture of what it calls the virus, "culture isolate" this is highly deceptive wording, a culture is a soup or a mixture of biological material, they admit it is green monkey cells, within which the virus supposedly is mixed, yet they claim a photo of the virus "culture isolate". It is the responsibility of those who make the claim to produce the proof, the government claims the existence of the SARS-CoV-2 virus, there is reasonable suspicion of this claim, therefore it is reasonable that they be ordered to provide adequate proof.

A REASONABLE SUSPICION THAT THE VIRUS CANNOT BE LINKED TO THE DISEASE

79. To link the virus to the disease, the virus must first be shown to exist, then it must be purified from other elements and then introduced to a healthy organism and it must be shown to cause a disease or illness. This experiment must be conducted several times over a period of time. Lastly, these experiments must be independently reviewed, only then can it be said that a link has been established between a virus and a disease.

80. This is the timeline of events, source, article **SARS-CoV-2: an Emerging coronavirus that causes a global threat**, by Zeng, published on 2020/03/15, in the *International Journal of Biological Sciences*:***RM9***

a. 29th December 2019 the first cases linked to the Huanan Seafood marketplace emerge.

b. 30th December 2019 China CDC was reported to about the pneumonia of unknown ethology.

c. 31st December 2019 WHO CDC was informed of the pneumonia of unknown ethology by China CDC.

d. 6th January 2020 Chinese CDC activated Level 2 emergency response.

e. 7th January 2020, SARS-CoV-2 was isolated by China.

f. 10th January 2020, first genome sequence of SARS-CoV-2 was released.

g. 23rd January 2020 Wuhan City was locked down.

h. 30th January 2020, WHO declared a "public health emergency of international concern".

81. The entire processes of isolating the virus, linking the virus to a disease and then imposing countermeasures occurred within one month and the World Health Organisation was instrumental and co-ordinating matters from the very beginning of the process, even before the Chinese supposedly isolated the virus. The processes of linking the virus to the disease has not been

demonstrated by the Chinese and by WHO, in fact the Chinese say it is WHO that linked the SARS-CoV-2 with the Covid-19 disease.

82. It is generally known that the symptoms of Covid-19 are virtually indistinguishable from cold and or flu symptoms, which is another cause for concern.

83. It can be argued that reasonable suspicion persists whether the SARS-CoV-2 virus can be linked to the Covid-19 disease, those who make the claim must produce the proof. The Court should therefore grant the order, that would compel the government to provide such proof to the satisfaction of the Court.

THE SUSPICIOUS AND FLAWED EPIDEMIOLOGICAL-MATHEMATICAL MODELS, INFECTION RATES AND DEATHS ATTRIBUTED TO COVID-19

84. The epidemiological models have been challenged and proven to be inaccurate and had to be revised, modelling in itself cannot form the cornerstone of any reasonable decision to impose such harsh and devastating measures such as the lockdown, especially not in the case of a novel virus and new disease, for which there would not exist much data to do adequate modelling.

85. The infection rates were determined purely by a NON-VALIDATED RT-PCR test which selects a particular RNA-sequence amongst many that appear.

86. Higher test frequency would inevitably also lead to higher positive tests thus increase in cases.

87. The policy that all people testing positive and subsequently dying, should be classified as death as a result of Covid-19, without conducting autopsies is also wrong and completely unreliable, in addition the media reports these deaths, as "deaths due to Covid related complications" which is meaningless. This even in cases where there exist co-morbidities. This would not have been possible if public health officials, the Executive and the Legislature did not allow and put through such changes in protocol.

88. The PCR tests is at the heart of the reasoning and justification of the Lockdown and there is ample clear proof that these tests are unreliable. Modelling has been a great part of the reasoning and justifications to impose the Lockdown measures as well, even though not much previous data exists, the models have been refuted and modelling is inherently flawed and cannot be the sole arbiter of reasonable justification.

SARS-COV-2 IS SUPPOSEDLY A NOVEL VIRUS AND COVID-19 A NOVEL DISEASE

89. In the face of a novel virus and a novel disease sufficient time should have been allowed to isolate the virus, link it to a disease, to conduct experimentations to determine effective treatments and cures. There is no proof that this has been done.

90. Without the abovementioned having been done over a reasonable time period and with independent reviews, any treatment is nothing other than a medical experiment, the difference is that these experiments are being conducted on the entire human-race.

91. This request should be easily accomplished considering that there are over a million reported Covid-19 cases and a new variant in South Africa.

92. Lockdowns have never been done in the history of South Africa and by extension never in the entire globe, it is unprecedented, hence a bio-medical experiment.

93. It amounts to an unconscionable experiment with human life, if the virus has never been isolated and linked to a disease, and therefore no treatment related to the disease can be claimed, except as a mass scientific fraud.

94. This arguably presents clear evidence of the conduct of a bio-medical experiment upon the entire population of South Africa.

THE LOCKDOWN MEASURES ARE UNREASONABLE, HARMFUL AND DEADLY

95. If there is no virus and no link to a disease, then these measures are unreasonable, unjustifiable, and extremely dangerous.

96. Declaring the pandemic itself is traumatizing and greatly imposes on the rights and freedoms of people.

97. The restrictions on trade and movement, is devastating to the economy, to social life, education et cetera.

98. In the absence of a physically verifiable virus, there is no way to determine the effectiveness of the mandatory masks policies, there is a vast body of science that proves that masks are not effective and that they are potentially deadly.

99. The policy of not treating "non-urgent" matters in public health facilities and prioritising Covid-19, is potentially fatal.

100. The policy of prescribing diagnostic techniques to medical professionals and then a subsequent treatment protocol from which they cannot veer, is potentially deadly, as misdiagnosis and wrong treatments could be fatal.

100. The Lockdown measures whether reasonable and justified or not, pose an existential threat and harm to the entire nation of South Africa.

THE WEARING OF CLOTH FACE-MASKS ARE PARTICULARLY HARMFUL

101. The following is extracted from a book written by Dr Vernon Coleman MB ChB DSc FRSA (Title: ***Proof That Face Masks Do More Harm Than Good) RM10***

102. Wearing a mask for hours at a time could cause pulmonary fibrosis.

103. People who cough and sneeze into their mask increase the risk of a build-up of fungi and bacteria – which can lead to dangerous chest infections.

104. Moisture retention, reuse of cloth masks and poor filtration may result in increased risk of infection as a precautionary measure, cloth masks should not be recommended for health care workers, particularly in high-risk situation.

British Medical Journal published a paper entitled, *A Cluster Randomised Trial of Cloth Masks Compared with Medical Masks in Healthcare Workers*, 2015

105. Pregnant women should not wear a mask, this is risky both to not themselves and to their unborn child. There is a real risk that the baby will be stillborn or in some way damaged or poorly developed at birth.

106. According to a dentist, Marc Sclafani, (told the New York Post) 'gum disease, or periodontal disease, will eventually lead to strokes and an increased risk of heart attacks.' The fact that face coverings increase mouth dryness and contribute to a build-up of bad bacteria as people tend to breath through their mouth instead of nose when wearing a mask.

107. A man suffered a collapsed lung after running 2.5 miles while wearing a face mask due to high pressure in his lungs.

108. Wearing masks reduce oxygen levels and increase levels of carbon dioxide. The side effects of excess carbon dioxide (hypercapnia) are headaches, dizziness, drowsiness, nausea, vomiting and a tight feeling in the chest.

109. According to Dr Margarite Griesz-Brisson MD PhD is a leading European neurologist and neurophysiologist, masks causes brain damage due to lower oxygen levels. When the oxygen deprivation becomes chronic, the symptoms disappear because the body gets used to them. However, efficiency remains impaired and the damage to the brain continues.

110. In March 2020, Dr Jenny Harries, Deputy Chief Medical Officer in the UK, warned that it is possible to trap the virus in a mask and start breathing it in. She said that wearing a mask was not a good idea.

111. Face mask use was found not to be protective against the common cold. *Use of surgical face masks to reduce the incidence of the common cold among health workers in Japan: a randomized clinical trial* was published in the *American Journal of Infection Control* in June 2009.

112. Neither surgical nor cotton masks effectively filtered SARS-CoV-2 during coughs by infected patients'. *Annals Internal Medicine* 2020. The title of their paper was, *Effectiveness of surgical and cotton masks in blocking SARS CoV 2: A controlled comparison in 4 patients.*

113. It is likely that anyone who wears a face mask for long periods will have a damaged immune system – and be more susceptible to infection.

114. There is increase in dry eye symptoms among mask wearers. *Ophthalmology and Therapy* (published in September 2020), written by Majid Moshirfar, William B. West Jr and Douglas P. Marx .

115. The World Health Organisation recommends that disposable masks should be discarded after one use. However few people can afford this, so masks are frequently worn more than once. This massively increases the risk of a chest infection developing.

116. Reports are suggesting that the bacterial pneumonias are on the rise due to face masks. Dr James Meehan.

117. If mask wearing were a science, the rules would be constant – but they are not. It is clear, therefore, that there is no science behind mask wearing.

118. Small children are more likely to develop a weakened immune system if they wear a mask. I would strongly advise parents not to use any form of face covering for their baby,' said Dr Rebecca Fletcher, chair of Bury, Rochdale and Oldham Child Death Overview Panel.

119. Masks have no significant preventative impact against any known pathogenic microbes, specifically, regarding covid-19, we have shown...that mask use is not correlated with lower death rates nor with lower positive PCR tests. Masks have also been demonstrated historically to contribute to increased infections within the respiratory tract' ...'the use of face masks will contribute to far more morbidity and mortality than has occurred due to covid-19.' *Masks, false safety and real dangers, Part 2: Microbial challenges from masks.* Boris Borovoy, Colleen Huber and Maris Crisler.

120. The wearing of cloth-masks over the mouth and nose, is extremely harmful and even deadly.

THE SUPPOSED COVID-19 VACCINES

121. If the virus has not been isolated nor a link established to a disease, then there can't be any remedy, much less a vaccine.

122. Not only has multiple vaccines been developed in the absence of proving the above-mentioned but these vaccines have been developed in unprecedented short period of time, even skipping animal trials.

123. These vaccines possess so-called new vaccine technology that have never been tried on humans before and some of them contain foetal tissue and chimpanzee cells, which many people would find objectionable.

124. Not only are these vaccines unprecedented but the idea of vaccinating the entire human-race has also never been done.

125. The early rollouts of vaccines in other countries have not only seen fatalities and injuries, but the process has not been stopped at all.

126. The CDC website cites a number of vaccine recipients who have reported some adverse reactions within 0 to 7 days of having been ***RM11*** vaccinated. Reactions and Adverse Events of the Pfizer-BioNTech COVID-19 Vaccine | CDC and https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html

127. In the United Kingdom, various Covid 19 Vaccine Adverse Reactions per type of vaccine (e.g. Pfizer, Astrazeneca etc) are recorded in the weekly report Coronavirus vaccine - weekly summary of Yellow Card reporting . They include Blindness, Lymphadenopathy, Death, Diarrhoea, Pyrexia, Hepatic, Myalgia Bell's palsy etc. Vaccine Analysis Profile - Pfizer/BioNTech Vaccine Analysis Profile - Oxford University/AstraZeneca Vaccine Analytics Profile - brand unspecified

128. The vaccines have never been developed at such a fast pace, some of these technologies are new untested, never before have we vaccinated the greater part of our entire population with such a new technology, the vaccines contain objectionable ingredients and many injuries and deaths have already been reported linked to these new vaccines. Arguably this constitutes, bio-

medical experimentation on an entire population, using a harmful bio-chemical compound with known risks to health and life.

PRIMA FACIE RIGHT.

129. The applicant, and the public have the following undisputable prima facie rights.

a. To Human dignity.

b. Life.

c. Bodily and psychological integrity.

d. To make decisions concerning the security and control over their body.

e. Freedom to practice their trade, occupation and profession.

f. Not to be treated in a cruel, inhuman or degrading way.

g. The right to have access to health care services.

h. Freedom of movement.

i. Just administrative action.

130. Not to have limitations imposed on their rights entrenched in the Bill of Rights and if so that it must be restrictively interpreted, so as to impose a minimum limitation on those rights, in accordance with section 36 of the Constitution.

131. That the Bill of Rights be applied to all law including the DMA.

132. The Applicant has a right to access to information in terms of Section 32 of our Constitution, and that is what he is essentially requesting here.

133. From the above it is clear that a strong case has been made by the applicant and those it is acting on behalf of, have at least one prima facie right.

REASONABLE APPREHENSION OF IRREPARABLE AND IMMINENT HARM.

134. I submit that harm is apparent in this instance, as set out throughout this founding affidavit.

135. Without the relief sought to prevent further harm the applicant and the rest of South Africa will continue to suffer irreparable financial, material, physical and psychological harm.

136. The public further stands to be severely prejudiced with the arbitrary infringements of their fundamental rights should the respondents continue to ignore their rights.

137. At the current rate the South African Government will run out of money to pay the salaries of state employees, it is submitted that If South Africa's present economically restrictive lockdown measures are not discontinued immediately, the respondents may cause 29 times more deaths with the measures aim to prevent the spread than the virus itself.

138. From the above it is clear that a strong case has been made by the applicant and those it is acting on behalf of the existence of the reasonable apprehension of irreparable and imminent harm.

BALANCE OF CONVENIENCE.

139. The balance of convenience favours the granting of the interdict.

140. I submit that on weighing up the consequences of the prejudice that each party would suffer if this Interdict is not granted, it would be immeasurably more detrimental towards the applicant than it would be for the respondent if it is not granted.

RESPONDENTS PERCEIVED PREJUDICE.

141. None, I am simply asking that the respondents produce to me on its terms something that it has in its possession, in order for me to verify its existence.

IS IT TOO RISKY?

142. The respondent is welcome to provide the purified physical SARS-CoV-2-virus to me for verification under whatever security measures they prefer, and I am willing to indemnify them from any damages or risk during the period of verification.

NO OTHER REMEDY.

142. We have written to the respondent in this regard which has simply been ignored. ***(See Annexure RM12).***

143. At this stage in time the public has no other adequate remedy available, to prevent imminent and irreparable harm befalling them.

IN THESE PREMISES, I respectfully pray for an Order in terms of the Notice of Motion prefixed hereto.

_____

D E P O N E N T

RICARDO MAARMAN

820531 5257 086

I CERTIFY that the deponent has acknowledged that he knows and understands the contents of this affidavit which was signed and sworn to before me at Cape Town on this the _____ day of March 2021.

_____

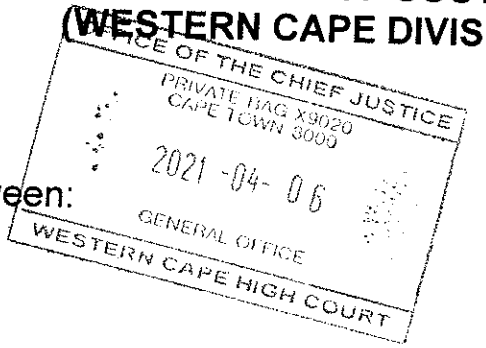
COMMISSIONER OF OATHS

FULL NAMES:

BUSINESS ADDRESS:

DESIGNATION:

IN THE HIGH COURT OF SOUTH AFRICA
(WESTERN CAPE DIVISION)



CASE NO: 5852/21

In the Matter between:

RICARDO MAARMAN — APPLICANT

AND

THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA — FIRST RESPONDENT

AND

THE MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS — SECOND RESPONDENT

AND

PROFESSOR SALIM ABDOOL KARIM on behalf of the GOVERNMENTAL COVID 19 ADVISORY COMMITTEE — THRID RESPONDENT

NOTICE OF MOTION
(Interim urgent interdict)

TAKE NOTICE THAT;

The Respondent are hereby called upon to show cause, if any, to this Honourable Court, sitting at Cape Town on the day of ***20 April 2021, at 10H00***, or so soon thereafter as the matter may be heard, why an order should not be issued in the following terms:

1. That this Application is heard as a matter of urgency and that the Applicant's failure to comply with the time limits imposed by the Rules of this Honourable Court be condoned in terms of Rule 6 (12).

2. That the respondents produce the isolated and purified physical SARS-CoV-2-virus (not a culture isolate or any mixture within in which the supposed virus is, nor a photograph or the RNA-sequence only), to the applicant at the place and in terms of their security measures of choice, within 7 days.

3. Further or alternative relief.

4. Cost of the application if opposed.

TAKE NOTICE FURTHER THAT, the affidavit of, ***RICARDO MAARMAN***, the Applicant herein, annexed hereto, will be used in the support of this Application.

TAKE NOTICE FURTHER THAT if you intend opposing this application you are required; to notify the applicant in writing on or before ***13 April 2021*** of your intention to oppose.

To file your answering affidavit, if any on or before ***13 April 2021***

And further that you are required to appoint in such notification an address referred to in rule 6(5)(d)(i) of the rules of this Honourable Court at which you will accept notice and service of all documents in these proceedings, such an address (not being a post office box) to be one within 15 (Fifteen) kilometres of the office of the registrar.

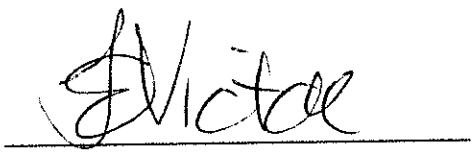
The applicant consents to exchange taking place via email to

carlo@victorlegal.co.za

TAKE NOTICE FURTHER; that the Applicant has appointed ***VICTOR AND ASSOCIATES, 24*** Viola Road, Bloubergstrand, Cape Town, ***C/O ROB GREEN*** Attorneys, Room 305 Benzal House, 3 Barrack Street, Cape Town as its attorney of record and his service address as the address at which the Applicant will accept service of all process in these proceedings.

KINDLY PLACE THE MATTER ON THE ROLL ACCORDINGLY.

DATED AT CAPE TOWN ON THIS THE 18th DAY OF MARCH 2021.



T VICTOR AND ASSOCIATES

24 Viola Road

Bloubergstrand

Cape Town

TEL 074 707 8168

FAX 086 294 5204

EMAIL victorlegalinfo@gmail.com

C/O

ROB GREEN Attorneys,

Room 305 Benzal House, 3 Barrack Street, Cape Town)

TO: **THE REGISTRAR CAPE TOWN HIGH COURT**

AND TO; **THE FIRST RESPONDENT**

Tuynhuys, Plein St,

Cape Town.

AND TO; **THE SECOND RESPONDENT**

The Minister of Cooperative Governance and Traditional Affairs

Good Hope Building, 1st Floor, Room 1,

Plein Street, Cape Town.

AND TO: **THE THIRD RESPONDENT**

Professor SALIM ABDOOL KARIM on behalf of the

Governmental Covid 19 Advisory Committee

ALL RESPONDENTS SERVED AT THE OFFICE OF THE STATE ADVOCATE CAPE TOWN

IN THE HIGH COURT OF SOUTH AFRICA
(WESTERN CAPE DIVISION)

CASE NO:

In the Matter between:

RICARDO MAARMAN	APPLICANT
AND	
THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	FIRST RESPONDENT
AND	
THE MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS	SECOND RESPONDENT
AND	
PROFESSOR SALIM ABDOOL KARIM on behalf of the GOVERNMENTAL COVID 19 ADVISORY COMMITTEE	THRID RESPONDENT

FOUNDING AFFIDAVIT

I, the undersigned

RICARDO MAARMAN
820531 5257 086

Hereby state under oath:

1. The facts set out within this affidavit are within my personal knowledge and expertise with reference. To the best of my knowledge, all the facts are correct. In certain aspects, I have relied on documentary evidence, of which

RM

relevant portions are attached as annexures, whilst others are easily obtainable from our very own government websites.

THE PARTIES.

2. The Applicant is an adult male, Ricardo Maarman, who holds an MA International Politics obtained at the University of Leicester in the UK. he specialized in the Post-Cold War World Order, International Security, Intelligence and Security and US Foreign Policy, his service address for the purposes of this application is Rob Green Attorneys, Room 305 Benzal House, 3 Barrack Street, Cape Town, as the address at which the Applicant will accept service of all process in these proceedings.

3. The first respondent is the President of the Republic of South Africa who is cited herein in his official capacity and whose Cape Town office is situated at Tuynhuys, Plein St, Cape Town and whose full and further details are unknown to me.

4. The second respondent is the Minister of Cooperative Governance and Traditional Affairs who is cited herein in her official capacity as the Minister mandated in terms of the provisions of the Disaster Management Act, 57 of 2002 ("the DMA") and whose Cape Town office is situated at the State Attorney 4th Floor, 22 Long Street, Cape Town, and whose full and further details are unknown to me.

RM

5. The third respondent is Professor Salim Abdool Karim who is cited herein in his official capacity as the head of the Governmental Covid 19 Advisory Committee and whose Cape Town office is situated at the State Attorney 4th Floor, 22 Long Street, Cape Town, and whose full and further details are unknown to me.

NATURE OF THE APPLICATION.

This is an application for an order as follows.

6. That this Application is heard as a matter of urgency and that the Applicant's failure to comply with the time limits imposed by the Rules of this Honourable Court be condoned in terms of Rule 6 (12).

7. That the respondents produce the isolated and purified physical SARS-CoV-2-virus (not a culture isolate or any mixture within in which the supposed virus is, nor a photograph or the RNA-sequence only), to the applicant at the place of their choice and under the security measures as preferred by the respondents, within 7 days.

8. Further or alternative relief.

9. Cost of the application if opposed.

RM

URGENCY.

10. I respectfully submit that this matter cannot wait to be dealt with in the ordinary course, as such I ask the Court to dispense with the forms and service provided for in the Rules and to indulge in my non-adherence with the normal rules of procedure as set out in Rule 6.

11. This matter is of such urgency that it simply cannot wait for the normal procedures to be complied with.

12. I respectfully submit that this Application should be heard other than in the normal course, otherwise the relief which we seek will be rendered ineffective.

DETAIL OF THE CIRCUMSTANCES WHICH MAKE THE MATTER URGENT.

13. Currently the Entire State is under Lockdown level one, which is a serious violation of the citizens Fundamental rights. To date, the Minister of Health has uttered and there are circulating discussions that the Lockdown measures will be tightened, which begs for these measures to be scrutinised. Accordingly, this has been stated in the following sources:

https://www.timeslive.co.za/news/south-africa/2021-03-25-level-2-on-the-cards-for-easter-here-are-some-major-changes-that-could-be-in-place-before-the-holiday/;https://www.iol.co.za/news/politics/mkhize-says-move-to-level-2-during-easter-will-prevent-super-spreader-events-a5f88b6b-63a1-4b1c-95d8-a841099bd415 (***see annexed hereto marked as annexure RM 1)***

RM

14. There is a massive nationwide roll out of a vaccine claimed by the respondent that must be used in the prevention of being infected by the alleged virus.

15. This vaccine-roll-out has begun in other countries and it has resulted in deaths and vaccine injuries, ***RM2.***

16. The national disaster has been declared and is in ongoing for almost a year affecting the entire nation with dire consequences.

17. There is no end in sight in the foreseeable future to this pandemic.

18. It is an urgent matter of national concern.

19. The outcome of the order could very well mean a quick recovery to normal circumstances for the entire nation.

20. In South Africa, there is vast unemployment and poverty as such, the questioning of the very cause that threatens to drastically increase the already desperate circumstances must at least be thoroughly investigated and with utmost haste.

21. On 6 May 2020 Africa's Medical Media Digest reported that Pandemic Data and Analytics (Panda), a multidisciplinary initiative co-ordinated by actuary Nick Hudson reported that If South Africa's present economically restrictive lockdown measures are not discontinued immediately, they may cause 29 times more deaths

RM

than the measures aim to prevent the spread. And each week of continuing lockdown will, in the long run, cause more loss of life than the virus itself. ***RM3***

REASONS WHY RELIEF CAN NOT BE OBTAINED IN THE ORDINARY COURSE.

22. If this matter is heard in the normal course, the relief sought would be of no use, since it is critical for the entire nation.

23. Attached hereto and marked ***RM4*** is a medico legal report stating that the virus has not yet been proven to exist.

HIGH DEGREE

24. I respectfully submit that this application carries a High Degree of urgency in that we are faced with the imminent impoverishment, deterioration of the wellbeing of the entire nation and their constitutional fundamental right infringements.

TIMETABLE FOR THE FILING OF DOCUMENTS.

25. I propose the following timetable for the processes in this matter which will allow this matter to return to Court in the shortest possible time and which will also allow the respondents reasonably enough time to respond.

26. The matter to be heard on 20 April 2021.

27. Filing of respondents Heads on 16 April 2021.

KM

28. Filing of applicants Heads on 15 April 2021.

29. Applicants replying affidavit on 14 April 2021.

30. Respondents' Notice of opposition and answering affidavit on 13 April 2021.

31. Service on respondent on 9 April 2021.

THE APPLICANT'S LOCUS STANDI

32. The applicant brings this application by virtue of section 38(a) of the Constitution by acting in his own interest and in accordance with its own objectives directed at the protection of his Constitutional Rights and financial sustainability.

33. The Applicant also brings the application in the public interest of all South Africans as a whole and in terms of section 38(d) of the Constitution, with the objective of the protection of their Constitutional Rights and financial sustainability.

THE LEGAL AND CONSTITUTIONAL PRINCIPLES INVOLVED

34. The Constitution provides that the Republic of South Africa is a sovereign, democratic state founded, inter alia, on the following values: Life, Human dignity, the achievement of equality and the advancement of human rights and freedoms and the Rule of Law.

35. The Constitution, provides that "All spheres of government and all organs of state within each sphere must be loyal to the Constitution, the Republic and its people;

KM

respect the constitutional status and not assume any power or function except those conferred on them in terms of the Constitution."

36. The Bill of Rights applies to all law, and binds the legislature, the executive, the judiciary and all organs of state.

37. Everyone has inherent dignity and the right to have their dignity respected and protected.

38. Everyone has the right to life, bodily and psychological integrity; To make decisions concerning the security and control over their body; Freedom to practice their trade, Freedom of movement, occupation and profession; Not to be treated in a cruel, inhuman or degrading way; Their right to have access to health care services; Just administrative action.

39. Every citizen has the right to administrative action that is lawful, reasonable, and procedurally fair.

40. These abovementioned rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality, and freedom, taking into account all relevant factors, including the nature of the right; the importance of the purpose of the limitation; the nature and extent of the limitation; the relation between the limitation and its purpose; and less restrictive means to achieve the purpose.

RM

41. No law including the DMA, may limit any right entrenched in the Bill of Rights.

42. It is therefore submitted that, in so far as the Regulations or any Direction Purportedly issued pursuant thereto, that will violate the above-mentioned fundamental rights will be inconsistent with the Constitution, and therefore illegal and void if the SARS-CoV-2-virus is not proven to exist.

43. Furthermore, the rights in the Bill of Rights cannot be infringed upon or limited in any way save in terms of the provisions of section 36 or 37.

44. The national state of disaster, announced in terms of the DMA, has been called on the mere allegation of the existence of the SARS-CoV-2-virus, and the applicant stands on his Fundamental right to test whether the violation of his and the entire nation's Constitutional rights have been based on the existence of the SARS-CoV-2-virus

THE STATE MAY NOT INTERFERE WITH THOSE FREEDOMS, EXCEPT UNDER SECTION 36 OF THE CONSTITUTION.

45. My respectful submission is that until the Respondent has produced the SARS-CoV-2-virus to be tested by independent experts in the appropriate circumstances that the Limitation of the rights of the Applicant and the Nation's rights to freedom of movement is not justified in terms of Section 36. (1) of the Constitution.

46. According to Section 36. (1) The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable

RM

and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors.

47. We are not asking this honourable Court to do the Section 36 test in this matter, or to decide on the existence of the SARS-CoV-2-virus we are simply asking that the respondent produces the isolated and purified physical SARS-CoV-2-virus (not a culture isolate or any mixture within in which the supposed virus is, nor a photograph or the RNA-sequence only), to the applicant at the place of his choice and under the security measures as preferred by the respondent, within 7 days, in order for us to test whether these extremely harsh disaster enforced on the nation is in fact based on the existence of the SARS-CoV-2-virus.

48. The nature of the rights here being limited are fundamental rights in terms of chapter two; the right to bodily and psychological integrity; The right to make decisions concerning the security and control over their own bodies; Freedom to practice their trade, freedom of movement, occupation, and profession; Not to be treated in a cruel, inhuman or degrading way; Their right to have access to health care services; the right to just administrative action.

49. These are fundamental rights that cannot be limited if there are no evidence of the existence of the SARS-CoV-2-virus.

RULE 16 A

50. A Rule 16 A notice will be issued together with the issuing of this application ***(See Attached copy of the notice marked RM5).***

RM

BACKGROUND.

51. During January 2020, the world became aware of the so-called Corona Virus.

52. At the writing of this affidavit the reported South African statistical information of the so-called Virus are as follows; 1 404 839 cases have been reported. Attached hereto and marked ***RM6***, see the latest coronavirus world report.

53. Of the 1 404 839 reported South African cases 1 217 492 have recovered.

54. Currently 150 800 people in South Africa have the so-called Virus of which namely 546 are in a serious or critical condition thus 0.31% of infected people are in a serious condition.

55. 40 574 out of 1 404 839 who contracted the so-called Virus in South Africa to date has died, namely 1.38%.

56. On 15 March 2020, Dr Mmaphaka Tau, the Head of the National Disaster Management Centre in the Department of Cooperative Governance gave notice that the Covid-19 pandemic was declared as a National Disaster.

57. Also, on 15 March 2020, the respondent issued a declaration of a National State of Disaster and published the declaration in the Government Gazette of that date and on subsequently monthly declarations continued with the declaration and publications of the regulations relating to the National disaster. Attach hereto as Annexure ***RM7*** a copy of the notice to that effect in the Government Gazette.

RM

RATIONALITY

58. To pass the rational basis test, the statute or ordinance must have a legitimate state interest, and there must be a rational connection between the regulations means and goals.

59. The national lockdown severely restricts the movement and choices of people. The result is a severe disruption of business and wellbeing and freedom of movement.

60. This is done under the over broad provision in s 27(2)(n) of the DMA the question that arises is whether this disruption meets the rationality and constitutionality test in terms of South African law.

61. Some disruption of life may be necessary to save lives if we are assured beyond doubt of the existence of the SARS-CoV-2-virus on which the Restrictions are based.

62. This applicant has a reasonable suspicion about the existence of SARS-CoV-2-virus.

63. It is respectfully submitted that this Honourable Court must at least agree that the South African nation is at least entitled to know beyond any doubt that all the damages and restrictions and violations of their rights is based on a virus that is proven to exist.

RM

64. To date it has simply been assumed that the SARS-CoV-2-virus does exist, without question.

65. The respondent has alleged that the SARS-CoV-2-virus does exist as such, she needs to prove it.

66. This can easily be done by the respondent since it should already be in possession of the SARS-CoV-2 virus.

67. The supposed existence of **SARS-CoV-2 virus** has not been established, an RNA-sequence obtained through an RNA-sequencing device RT-PCR test, a DNA or RNA-sequence, does not prove anything without a standard to measure it against, that standard can only be the physical virus.

68. If the virus has not been proven to exist then it follows that no link can be established between the supposed non-existent virus and a disease, no experiments have been presented in which the virus is isolated without any cultures or other substances, and then injected into healthy organisms producing a particular disease, and repeated, without this there can be no link between a virus and a disease.

69. If the virus does not exist, thus no link to a disease can be proven and then no reasonable and justifiable remedy or countermeasures can be devised.

70. There is no evidence existence of the SARS-CoV-2 virus.

70. There is no evidence of the existence of the SARS-Cov-2 virus, its link to Coviid-19 disease.

71. The PCR test are unreliability.

SECTION 39 OF THE CONSTITUTION AND ITS RELEVANCE TO THE FACTS PRESENTED

72. With regards to the nature of the matter, Section 39 (1)(a) and (b) respectively, have to be cited, as it is part and parcel of the fabric of our society, that this section be included here, which states that:

(1) When interpreting the Bill of Rights, a court, tribunal or forum-

(a) must promote the values that underlie an open and democratic society Based on human dignity , equality and freedom;

(b), must consider international law; and

(c), must consider a foreign law

73. Its relevance, that the court should in accordance with the above be open the facts presented below, which in turn sheds light on the Portuguese Judgment (***please find attached hereto marked RM8***), The Court here concludes that:

"Any diagnostic test must be interpreted in the context of the actual possibility of the disease, which existed before its realization. For Covid-19, this decision to perform the test depends on the previous assessment of the existence of symptoms, previous medical history of Covid 19 or presence of antibodies, any potential exposure to this disease and no likelihood of another possible diagnosis." "One of the potential reasons for presenting positive results may lie in the prolonged shedding of viral RNA, which is known to extend for weeks after recovery, in those who were previously exposed to SARS-CoV-2. However, and more relevantly, there is no scientific data to suggest that low levels of viral RNA by RT-PCR equate to infection, unless the presence of

RM

infectious viral particles have been confirmed by a laboratory. In summary, Covid-19 tests that show false positives are increasingly likely, in the current epidemiological climate panorama in the United Kingdom, with substantial personal, health and social system consequences."

74. To prove the existence of something especially when it is mixed or incorporated with other things is to first separate or isolate it, then to measure it, to determine its parameters and to determine its qualities. An RNA or DNA sequence is not proof of existence, e.g., having the DNA sequence of a person does not mean that the person exist, to prove the person exists the DNA sequence must be matched to a DNA sequence obtained verifiably directly from the physical person.

75. Here follows explanations regarding the supposed isolation of SARS-CoV-2: as described in an article entitled ***The Genetic Sequence, Origin, Diagnosis of SARS-CoV-2,*** written by Huihui Wang et al.***RM9***

- "Confirmed cases with SARS-CoV-2 were identified as a positive result of a high-throughput sequencing or an RT-PCR assay for respiratory specimens including nasal and pharyngeal swab"

- "Airway epithelial cells from infected patients were used to isolate a novel coronavirus, temporarily named 2019-nCoV, but later, the Coronavirus Research Group of the International Committee for the Classification of viruses found that the new coronavirus is related to the SARS-virus" The International Committee for the Classification of viruses is affiliated to the International

RM

Council of Sciences, which in turn has a formal relationship with UNESCO since 1947, which in turn is a specialised agency of the UN.

- "In addition, the World Health Organisation has named the disease caused by SARS-CoV-2 as coronavirus disease 2019 (Covid-19)".

- "After the SARS-CoV-2 was isolated from the lower respiratory tract specimen, a diagnostic RT-PCR test was developed. RT-PCR tests based on the RNA-dependent RNA polymerase (RdRp) gene of the ORF1ab sequence, E gene, N gene and S gene of the SARS-CoV-2 genome"

- "The genome of coronaviruses, ranging from 26 to 32 kilobases in length, includes a variable number"

- "The SARS-CoV-2 genome was reported to possess 14 ORF's encoding 27 proteins"

76. From scientific article: ***SARS-CoV-2 isolation and propagation from Turkish Covid-19 patients***, as published in the Turkish journal of Biology 44 (3) 192, 2020:

- "Samples were collected from the nasopharyngeal and oropharyngeal cavity of Covid-19 positive diagnosed patients according to their real-time PRC analysis"
- "Next, SARS-CoV-2 specific RT-PCR was performed"

RM

77. From: CDC website in the US, ***Sever Acute Respiratory Syndrome Coronavirus 2 from Patient with Coronavirus Disease***, *United States of America* (viewed on the 16 February 2021):***RM10***

- "We isolated virus from nasopharyngeal and oropharyngeal specimens from this patient and characterised the viral sequence, replication properties, and cell culture tropism"

- "Confirmed PCR-positive specimens were aliquoted and frozen until virus isolation was initiated"

- "we performed confirmatory testing by using real-time reverse transcription PCR (CDC) and full-genome sequencing"

- "We extracted nucleic acid from the isolates and amplified by using the 37 individual nested PCRs"

- "A nearly full-length viral contig obtained in each sample had 100% identity to the 2019-nCoV/USA-WA1/2020 strain (GeneBank accession no. MN985325.1)"

78. From the Australian claim of isolation of the virus, ***Isolation and rapid sharing of the 2019 novel coronavirus (SARS-CoV-2) from the first patient diagnosed with COVID-19 in Australia***, we get the following telling statement:***RM11***

- "In consultation with the World Health Organization, the viral isolate was shared with domestic and international reference laboratories within 24 hours, and lodgement with major North American and European culture collections for further distribution is underway".

79. These claims of isolation at best are based on the matching of one sequence of RNA with another sequence, without producing the actual virus. The NCID of SA on its website has a picture of what it calls the virus, "culture isolate" this is highly deceptive wording, a culture is a soup or a mixture of biological material, they admit it is green monkey cells, within which the virus supposedly is mixed, yet they claim a photo of the virus "culture isolate". It is the responsibility of those who make the claim to produce the proof, the government claims the existence of the SARS-CoV-2 virus, there is reasonable suspicion of this claim, therefore it is reasonable that they be ordered to provide adequate proof.

A REASONABLE SUSPICION THAT THE VIRUS CANNOT BE LINKED TO THE DISEASE

80. To link the virus to the disease, the virus must first be shown to exist, then it must be purified from other elements and then introduced to a healthy organism and it must be shown to cause a disease or illness. This experiment must be conducted several times over a period of time. Lastly, these experiments must be independently reviewed, only then can it be said that a link has been established between a virus and a disease.

KM

81. This is the timeline of events, source, article **SARS-CoV-2: an Emerging coronavirus that causes a global threat**, by Zeng, published on 2020/03/15, in the *International Journal of Biological Sciences*:**RM16**

a. 29th December 2019 the first cases linked to the Huanan Seafood marketplace emerge.
b. 30th December 2019 China CDC was reported to about the pneumonia of unknown ethology.
c. 31st December 2019 WHO CDC was informed of the pneumonia of unknown ethology by China CDC.
d. 6th January 2020 Chinese CDC activated Level 2 emergency response.
e. 7th January 2020, SARS-CoV-2 was isolated by China.
f. 10th January 2020, first genome sequence of SARS-CoV-2 was released.
g. 23rd January 2020 Wuhan City was locked down.
h. 30th January 2020, WHO declared a "public health emergency of international concern".

82. The entire processes of isolating the virus, linking the virus to a disease and then imposing countermeasures occurred within one month and the World Health Organisation was instrumental and co-ordinating matters from the very beginning of the process, even before the Chinese supposedly isolated the virus. The processes of linking the virus to the disease has not been

RM

demonstrated by the Chinese and by WHO, in fact the Chinese say it is WHO that linked the SARS-CoV-2 with the Covid-19 disease.

83. It is generally known that the symptoms of Covid-19 are virtually indistinguishable from cold and or flu symptoms, which is another cause for concern.

84. It can be argued that reasonable suspicion persists whether the SARS-CoV-2 virus can be linked to the Covid-19 disease, those who make the claim must produce the proof. The Court should therefore grant the order, that would compel the government to provide such proof to the satisfaction of the Court.

THE SUSPICIOUS AND FLAWED EPIDEMIOLOGICAL-MATHEMATICAL MODELS, INFECTION RATES AND DEATHS ATTRIBUTED TO COVID-19

85. The epidemiological models have been challenged and proven to be inaccurate and had to be revised, modelling in itself cannot form the cornerstone of any reasonable decision to impose such harsh and devastating measures such as the lockdown, especially not in the case of a novel virus and new disease, for which there would not exist much data to do adequate modelling.

RM

86. The infection rates were determined purely by a NON-VALIDATED RT-PCR test which selects a particular RNA-sequence amongst many that appear.

87. Higher test frequency would inevitably also lead to higher positive tests thus increase in cases.

88. The policy that all people testing positive and subsequently dying, should be classified as death as a result of Covid-19, without conducting autopsies is also wrong and completely unreliable, in addition the media reports these deaths, as "deaths due to Covid related complications" which is meaningless. This even in cases where there exist co-morbidities. This would not have been possible if public health officials, the Executive and the Legislature did not allow and put through such changes in protocol.

89. The PCR tests is at the heart of the reasoning and justification of the Lockdown and there is ample clear proof that these tests are unreliable. Modelling has been a great part of the reasoning and justifications to impose the Lockdown measures as well, even though not much previous data exists, the models have been refuted and modelling is inherently flawed and cannot be the sole arbiter of reasonable justification.

KM

SARS-COV-2 IS SUPPOSEDLY A NOVEL VIRUS AND COVID-19 A NOVEL DISEASE

90. In the face of a novel virus and a novel disease sufficient time should have been allowed to isolate the virus, link it to a disease, to conduct experimentations to determine effective treatments and cures. There is no proof that this has been done.

91. Without the abovementioned having been done over a reasonable time period and with independent reviews, any treatment is nothing other than a medical experiment, the difference is that these experiments are being conducted on the entire human-race.

92. This request should be easily accomplished considering that there are over a million reported Covid-19 cases and a new variant in South Africa.

93. Lockdowns have never been done in the history of South Africa and by extension never in the entire globe, it is unprecedented, hence a bio-medical experiment.

94. It amounts to an unconscionable experiment with human life, if the virus has never been isolated and linked to a disease, and therefore no treatment related to the disease can be claimed, except as a mass scientific fraud.

RM

95. This arguably presents clear evidence of the conduct of a bio-medical experiment upon the entire population of South Africa.

THE LOCKDOWN MEASURES ARE UNREASONABLE, HARMFUL AND DEADLY

96. If there is no virus and no link to a disease, then these measures are unreasonable, unjustifiable, and extremely dangerous.

97. Declaring the pandemic itself is traumatizing and greatly imposes on the rights and freedoms of people.

98. The restrictions on trade and movement, is devastating to the economy, to social life, education et cetera.

99. In the absence of a physically verifiable virus, there is no way to determine the effectiveness of the mandatory masks policies, there is a vast body of science that proves that masks are not effective and that they are potentially deadly.

100. The policy of not treating "non-urgent" matters in public health facilities and prioritising Covid-19, is potentially fatal.

101. The policy of prescribing diagnostic techniques to medical professionals and then a subsequent treatment protocol from which they cannot veer, is potentially deadly, as misdiagnosis and wrong treatments could be fatal.

100. The Lockdown measures whether reasonable and justified or not, pose an existential threat and harm to the entire nation of South Africa.

THE WEARING OF CLOTH FACE-MASKS ARE PARTICULARLY HARMFUL

101. The following is extracted from a book written by Dr Vernon Coleman MB ChB DSc FRSA (Title: ***Proof That Face Masks Do More Harm Than Good) RM13***

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102. Wearing a mask for hours at a time could cause pulmonary fibrosis.

103. People who cough and sneeze into their mask increase the risk of a build-up of fungi and bacteria – which can lead to dangerous chest infections.

104. Moisture retention, reuse of cloth masks and poor filtration may result in increased risk of infection as a precautionary measure, cloth masks should not be recommended for health care workers, particularly in high-risk situation. *British Medical Journal* published a paper entitled, *A Cluster Randomised Trial of Cloth Masks Compared with Medical Masks in Healthcare Workers*, 2015

105. Pregnant women should not wear a mask, this is risky both to not themselves and to their unborn child. There is a real risk that the baby will be stillborn or in some way damaged or poorly developed at birth.

106. According to a dentist, Marc Sclafani, (told the New York Post) 'gum disease, or periodontal disease, will eventually lead to strokes and an increased risk of heart attacks.' The fact that face coverings increase mouth dryness and contribute to a build-up of bad bacteria as people tend to breathe through their mouth instead of nose when wearing a mask.

107. A man suffered a collapsed lung after running 2.5 miles while wearing a face mask due to high pressure in his lungs.

108. Wearing masks reduce oxygen levels and increase levels of carbon dioxide. The side effects of excess carbon dioxide (hypercapnia) are headaches, dizziness, drowsiness, nausea, vomiting and a tight feeling in the chest.

109. According to Dr Margarite Griesz-Brisson MD PhD is a leading European neurologist and neurophysiologist, masks causes brain damage due to lower oxygen levels. When the oxygen deprivation becomes chronic, the symptoms

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disappear because the body gets used to them. However, efficiency remains impaired and the damage to the brain continues.

110. In March 2020, Dr Jenny Harries, Deputy Chief Medical Officer in the UK, warned that it is possible to trap the virus in a mask and start breathing it in. She said that wearing a mask was not a good idea.

111. Face mask use was found not to be protective against the common cold. *Use of surgical face masks to reduce the incidence of the common cold among health workers in Japan: a randomized clinical trial* was published in the *American Journal of Infection Control* in June 2009.

112. Neither surgical nor cotton masks effectively filtered SARS-CoV-2 during coughs by infected patients'. *Annals Internal Medicine* 2020. The title of their paper was, *Effectiveness of surgical and cotton masks in blocking SARS CoV 2: A controlled comparison in 4 patients.*

113. It is likely that anyone who wears a face mask for long periods will have a damaged immune system – and be more susceptible to infection.

114. There is increase in dry eye symptoms among mask wearers. *Ophthalmology and Therapy* (published in September 2020), written by Majid Moshirfar, William B. West Jr and Douglas P. Marx .

115. The World Health Organisation recommends that disposable masks should be discarded after one use. However few people can afford this, so masks are frequently worn more than once. This massively increases the risk of a chest infection developing.

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116. Reports are suggesting that the bacterial pneumonias are on the rise due to face masks. Dr James Meehan.

117. If mask wearing were a science, the rules would be constant – but they are not. It is clear, therefore, that there is no science behind mask wearing.

118. Small children are more likely to develop a weakened immune system if they wear a mask. I would strongly advise parents not to use any form of face covering for their baby,' said Dr Rebecca Fletcher, chair of Bury, Rochdale and Oldham Child Death Overview Panel.

119. Masks have no significant preventative impact against any known pathogenic microbes, specifically, regarding covid-19, we have shown...that mask use is not correlated with lower death rates nor with lower positive PCR tests. Masks have also been demonstrated historically to contribute to increased infections within the respiratory tract' ...'the use of face masks will contribute to far more morbidity and mortality than has occurred due to covid-19.' *Masks, false safety and real dangers, Part 2: Microbial challenges from masks.* Boris Borovoy, Colleen Huber and Maris Crisler.

120. The wearing of cloth-masks over the mouth and nose, is extremely harmful and even deadly.

THE SUPPOSED COVID-19 VACCINES

121. If the virus has not been isolated nor a link established to a disease, then there can't be any remedy, much less a vaccine.

122. Not only has multiple vaccines been developed in the absence of proving the above-mentioned but these vaccines have been developed in unprecedented short period of time, even skipping animal trials.

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123. These vaccines possess so-called new vaccine technology that have never been tried on humans before and some of them contain foetal tissue and chimpanzee cells, which many people would find objectionable.

124. Not only are these vaccines unprecedented but the idea of vaccinating the entire human-race has also never been done.

125. The early rollouts of vaccines in other countries have not only seen fatalities and injuries, but the process has not been stopped at all.

126. The CDC website cites a number of vaccine recipients who have reported some adverse reactions within 0 to 7 days of having been ***RM14*** vaccinated. Reactions and Adverse Events of the Pfizer-BioNTech COVID-19 Vaccine | CDC and https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html

127. In the United Kingdom, various Covid 19 Vaccine Adverse Reactions per type of vaccine (e.g. Pfizer, Astrazeneca etc) are recorded in the weekly report Coronavirus vaccine - weekly summary of Yellow Card reporting . They include Blindness, Lymphadenopathy, Death, Diarrhoea, Pyrexia, Hepatic, Myalgia Bell's palsy etc. Vaccine Analysis Profile - Pfizer/BioNTech Vaccine Analysis Profile - Oxford University/AstraZeneca Vaccine Analytics Profile - brand unspecified

128. The vaccines have never been developed at such a fast pace, some of these technologies are new untested, never before have we vaccinated the greater part of our entire population with such a new technology, the vaccines contain objectionable ingredients and many injuries and deaths have already been reported linked to these new vaccines. Arguably this constitutes, bio-

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medical experimentation on an entire population, using a harmful bio-chemical compound with known risks to health and life.

PRIMA FACIE RIGHT.

129. The applicant, and the public have the following undisputable prima facie rights.

a. To Human dignity.

b. Life.

c. Bodily and psychological integrity.

d. To make decisions concerning the security and control over their body.

e. Freedom to practice their trade, occupation and profession.

f. Not to be treated in a cruel, inhuman or degrading way.

g. The right to have access to health care services.

h. Freedom of movement.

i. Just administrative action.

130. Not to have limitations imposed on their rights entrenched in the Bill of Rights and if so that it must be restrictively interpreted, so as to impose a minimum limitation on those rights, in accordance with section 36 of the Constitution.

131. That the Bill of Rights be applied to all law including the DMA.

132. The Applicant has a right to access to information in terms of Section 32 of our Constitution, and that is what he is essentially requesting here.

133. From the above it is clear that a strong case has been made by the applicant and those it is acting on behalf of, have at least one prima facie right.

REASONABLE APPREHENSION OF IRREPARABLE AND IMMINENT HARM.

134. I submit that harm is apparent in this instance, as set out throughout this founding affidavit.

135. Without the relief sought to prevent further harm the applicant and the rest of South Africa will continue to suffer irreparable financial, material, physical and psychological harm.

136. The public further stands to be severely prejudiced with the arbitrary infringements of their fundamental rights should the respondents continue to ignore their rights.

137. At the current rate the South African Government will run out of money to pay the salaries of state employees, it is submitted that If South Africa's present economically restrictive lockdown measures are not discontinued immediately, the respondents may cause 29 times more deaths with the measures aim to prevent the spread than the virus itself.

138. From the above it is clear that a strong case has been made by the applicant and those it is acting on behalf of the existence of the reasonable apprehension of irreparable and imminent harm.

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BALANCE OF CONVENIENCE.

139. The balance of convenience favours the granting of the interdict.

140. I submit that on weighing up the consequences of the prejudice that each party would suffer if this Interdict is not granted, it would be immeasurably more detrimental towards the applicant than it would be for the respondent if it is not granted.

RESPONDENTS PREJUDICE.

141. None, I am simply asking and praying to this Honourable Court that the respondents produce to me on its terms and merits, a mere sample or prototypical example that it has in its possession in terms of my rights, for me to verify its existence.

THE RISKS INVOLVED

142. The respondents are welcome to provide the purified physical SARS-CoV-2-virus to me for verification under whatever security measures they prefer, and I am willing to indemnify them from any damages or risk during the period of verification.

NO OTHER REMEDY.

143. We have written to the respondent in this regard which has simply been ignored. ***(See Annexure RM15).***

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KM 147 At this stage in time the public has no other adequate remedy available, to prevent imminent and irreparable harm befalling them.

IN THESE PREMISES, I respectfully pray for an Order in terms of the Notice of Motion prefixed hereto.

D E P O N E N T

RICARDO MAARMAN

820531 5257 086

I CERTIFY that the deponent has acknowledged that he knows and understands the contents of this affidavit which was signed and sworn to before me at Cape Town on this the 21 day of March 2021.

Malvleke ks
CST
266915

COMMISSIONER OF OATHS

FULL NAMES: Katekani Malvleke

BUSINESS ADDRESS: 263 Royal park Drive Mondeor

DESIGNATION: CST

SOUTH AFRICAN POLICE SERVICE
MONDEOR SAPS
21 MAR 2021
CLIENT SERVICE CENTRE
SOUTH AFRICAN POLICE SERVICE

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NEWS / POLITICS

National Minister of Health Zwelini Mkhize Photograph :Phando Jikelo/african News Agency (ANA)

Mkhize says move to level 2 during Easter will prevent super spreader events

By Se-Anne Rall Mar 25, 2021

DURBAN – Health Minister Dr Zweli Mkhize has warned that strict precautionary measures will be undertaken during the Easter weekend to prevent potential super spreader events.

Mkhize's warning comes in the wake of experts' advice for the government to upgrade the country to level 2 in anticipation of the third wave which is set to hit South Africa next month.

"This is a sensitive period of the Easter period where there is the vulnerability and the chance of the risk that we could have a super spreading event, with all the festivities and activities that go with the Easter long weekend. So the advisory was for a temporary increase in restrictions over this period of time," he said.

Harder lockdown looms for Easter weekend eNCA

With the Easter weekend coming up, and the temperatures dipping, A COVID-19 infection surge seems inevitable. But will we slip into another lockdown for that weekend? Courtesy #DStv403

Speaking to the SABC, Mkhize said discussions on the implementation of stricter lockdown regulations were still in progress.

"There have been recommendations given about imposing a stricter lockdown but others are calling for some regulations to be relaxed so there is still consultation around the matter. The consultation process takes into account the advice given the ministerial advisory committee as well as the concerns of the various sectors of the economy including social, churches and business sectors," he said.

Mkhize said the decision is also guided by scientific research.

"We have to balance the MAC's advice and look at hunger, unemployment and economic activities and we expect that after the consultation we will come up with something. This is not an easy

As per the latest from the Health Ministry, SA has a cumulative count of 1 540 009 Covid cases. The total death count is at 52 372.

Related Video:

'No indication of COVID-19 third wave' eNCA

The former co-chair of the Ministerial Advisory Committee on COVID-19 says he'll still work on the virus. But his priority is HIV research and other commitments. Professor Salim Abdool Karim is stepping down a year after serving on the committee. He says there are no indications yet that we're heading for a third...

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COVID-19 3RD WAVE LOCKDOWN

The Vaccine Adverse Event Reporting System (VAERS) Results

MODERNA

Messages:

- **VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.**
- **These results are for 645 total events.**
- **When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.**
- **Click on a VAERS ID to see a report containing detailed information for the event.**

Some measures are hidden, use Quick or More Options above to restore them.

Serious	Vaccine Type	VAERS ID	Adverse Event Description
Yes	COVID19 VACCINE (COVID19)	0909095-1	on 12/24/2020 the resident was sleepy and stayed in bed most of the shift. He stated he was doing okay but requested pain medication for his legs at 250PM. At 255AM on 12/25/2020 the resident was observed in bed lying still, pale, eyes half open and foam coming from mouth and unresponsive. He was not breathing and with no pulse
Yes	COVID19 VACCINE (COVID19)	0910363-1	Patient had mild hypotension, decreased oral intake, somnolence starting 3 days after vaccination and death 5 days after administration. He did have advanced dementia and was hospice eligible based on history of aspiration pneumonia.
Yes	COVID19 VACCINE (COVID19)	0913733-1	My grandmother died a few hours after receiving the moderna covid vaccine booster 1. While I don?t expect that the events are related, the treating hospital did not acknowledge this and I wanted to be sure a report was made.
Yes	COVID19 VACCINE (COVID19)	0914621-1	Resident in our long term care facility who received first dose of Moderna COVID-19 Vaccine on 12/22/2020, only documented side effect was mild fatigue after receiving. She passed away on 12/27/2020 of natural causes per report. Has previously been in & out of hospice care, resided in nursing home for 9+ years, elderly with dementia. Due to proximity of vaccination we felt we should report the death, even though it is not believed to be related.
Yes	COVID19 VACCINE (COVID19)	0915880-1	Patient died within 12 hours of receiving the vaccine.
Yes	COVID19 VACCINE (COVID19)	0917117-1	After vaccination, patient tested positive for COVID-19. Patient was very ill and had numerous chronic health issues prior to vaccination. Facility had a number of patients who had already tested positive for COVID-19. Vaccination continued in an effort to prevent this patient from contracting the virus or to mitigate his risk. This was unsuccessful and patient died.
Yes	COVID19 VACCINE (COVID19)	0917790-1	At the time of vaccination, there was an outbreak of residents who had already tested positive for COVID 19 at the nursing home where patient was a resident. About a week later, patient tested positive for COVID 19. She had a number of chronic, underlying health conditions. The vaccine did not have enough time to prevent COVID 19. There is no evidence that the vaccination caused patient's death. It simply didn't have time to save her life.
Yes	COVID19 VACCINE (COVID19)	0917793-1	Prior to the administration of the COVID 19 vaccine, the nursing home had an outbreak of COVID-19. Patient was vaccinated and about a week later she tested positive for COVID-19. She had underlying thyroid and diabetes disease. She died as a result of COVID-19 and her underlying health conditions and not as a result of the vaccine.
Yes	COVID19 VACCINE (COVID19)	0918065-1	1/1/2020: Residents was found unresponsive. Pronounced deceased at 6:02pm
Yes	COVID19 VACCINE (COVID19)	0918487-1	Two days post vaccine patient went into cardiac arrest and passed away.
Yes	COVID19 VACCINE (COVID19)	0918518-1	syncopal episode - arrested - CPR - death
Yes	COVID19 VACCINE (COVID19)	0919537-1	Resident exhibited no adverse events during 30 minute monitoring following vaccine administration. Resident found without pulse at 1900.
Yes	COVID19 VACCINE (COVID19)	0920326-1	Redness and warmth with edema to right side of neck and under chin. Resident was on Hospice services and expired on 1.1.21
Yes	COVID19 VACCINE (COVID19)	0920368-1	12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics
Yes	COVID19 VACCINE (COVID19)	0920815-1	Found deceased in her home, unknown cause, 6 days after vaccine.
Yes	COVID19 VACCINE	0921547-1	DEATH ON 1/4/2021, RESIDENT RECIEVED VACCINE ON 1/2/20

			Moderna COVID-19 Vaccine.; Reporter's Comments: This case concerns a 91-year old female patient. The medical history and concomitant medication is not provided. The patient experienced Death. The event occurred approximately one day after receiving their first of two planned doses of mRNA-1273 (Lot unknown). Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the onset of the event, a causal relationship cannot be excluded and the event is considered possibly related to the vaccine.; Reported Cause(s) of Death: Unknown Cause of Death
Yes	COVID19 VACCINE (COVID19)	1002187-1	PATIENT WAS IN CLINIC FOR 1ST CLINIC. WAS DISCHARGED BEFORE OUR 2ND CLINIC. HE CAME BACK TO OBTAIN HIS 2ND SHOT. WE WENT OUT TO THE CAR GAVE SHOT. THE NEXT DAY TO MY KNOWLEDGE, HE STARTED CODING AT HOME. AMBULANCE WAS CALLED AND HE CONTINUED TO CODE. THE AMBULANCE CREW TRIED CPR FOR 30 MINS WITH NO LUCK. PATIENT PASSED 2-3-21.
Yes	COVID19 VACCINE (COVID19)	1002229-1	spontaneous death, found unresponsive in cell after normal morning activities
Yes	COVID19 VACCINE (COVID19)	1002813-1	Patient was seen at 0710 he was sleeping but at normal cognitive behavior Patient was again assessed at 0720 where he was noted to be unresponsive, BP 180/100s, HR 230s, he was a DNR therefore not CPR was administered. EMS arrived at facility patient was noted to be in full cardiac and respiratory arrest. Time of death 0735
Yes	COVID19 VACCINE (COVID19)	1002840-1	Client lives alone and had dinner at his home with family members after the 4:40 appointment. Client stated that in general he did not feel well but did not give any specific symptom. Family states they asked the client to go to the ER and the client refused. Family states they helped the client to his chair in the living room and then left to go home. Family states that the client was found in his bedroom the next morning at 7:54 a.m. deceased.
Yes	COVID19 VACCINE (COVID19)	1002931-1	CARDIAC ARREST, DEATH Narrative: The patient presents to the emergency department in cardiopulmonary arrest. CPR was continued upon arrival. The Combi tube was removed and an endotracheal tube was placed without complications. ROSC was obtained multiple times but the patient continued to go into PEA. The patient was seen in the emergency department by both critical care and Cardiology. EKG shows ST elevations, but the patient was unstable to go to catheterization. The patient had 1 episode of asystole. Despite best efforts and multiple attempts we were unable to resuscitate the patient. Time of death 1253 on 1/24/21.
Yes	COVID19 VACCINE (COVID19)	1003390-1	On 2/1/2021, the patients daughter, who claims is a nurse, reported this incident to me. She stated that the evening after the patient received the vaccine, she felt some mild injection site pain. The morning after, the patient reported severe abdominal pain, diarrhea and vomiting. The patients daughter then called her physician to report these symptoms and attributed them as an adverse reaction to the vaccine at that time. These symptoms were intermittent for one week and no other adverse reactions were noted. In the early morning hours of 1/27/2021, the patient was toileting and had expired while doing so. An ambulance was called and cause of death was not found. An autopsy was not performed.
Yes	COVID19 VACCINE (COVID19)	1004206-1	"Death; A spontaneous report was received from a nurse concerning a 91-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and died two days later. The patient's medical history included dementia. Concomitant medications reported included paracetamol. On 21 Jan 2021, approximately two days prior to her death, the patient received the first of two planned doses of mRNA-1273, intramuscularly for prophylaxis of COVID-19 infection. On 23 Jan 2021, the patient died. The nurse reporting the event stated that the patient's death was considered as due to ""natural causes"" and that she was not aware of any new-onset symptoms of illness prior to the patient's death. The patient was described as ""fragile"" and was under hospice care at the time of her death. An autopsy was not performed. Action taken with the drug in response to the event is not applicable. The patient died on 23 Jan 2021. The cause of death was natural cause of death related to dementia. Autopsy was not performed.; Reporter's Comments: This case concerns a 91-years-old female patient, with medical history of dementia, who experienced a serious unexpected event of death. This event occurred 2 days after first dose of mRNA-1273, lot # unknown. At the time of death, the subject was very fragile and was in hospice care. Concomitant medication included Tylenol. Treatment details were not provided. The doctor considered that the death was due to natural causes. However, autopsy was not performed. Very limited information regarding this event has been provided at this time. Based on the limited information available, it is difficult to assess a cause and effect relationship. The benefit-risk relationship of Moderna's COVID-19 vaccine is not affected by this report.; Reported Cause(s) of Death: Natural cause of death related to dementia"
Yes	COVID19 VACCINE (COVID19)	1004811-1	On 1/23/21 the patient had a single-car accident, slid off icy road into snowbank. She was seen in our ER, diagnosed w/ trauma and L4 compression fracture. She was transported to Hospital for further trauma workup. We believe she was treated and released. On 1/31/21 the patient had a headache but did not seek medical attention. In the morning of 2/1 she became unresponsive and was pronounced dead on the scene when EMS arrived. Autopsy showed a left temporal subdural hematoma.
Yes	COVID19 VACCINE (COVID19)	1004956-1	Wife reported patient expired on 2/3/2021
Yes	COVID19 VACCINE (COVID19)	1005130-1	Report of patient expired on 2/3/2021
Yes	COVID19 VACCINE (COVID19)	1005217-1	Nursing home called 911 for decline in condition. Patient transported to ER where she was admitted to inpatient care and expired 1/30 at 16:13
Yes	COVID19 VACCINE (COVID19)	1005276-1	chills 1 day after vaccine administration; found dead by family 1/18/2021 Narrative: Per patient family report, patient said the next day after vaccination that he didn't feel well because of chills. Patient was found dead at home by his family on January 18th. He was a 74yo man with castrate resistant prostate cancer and liver and bone metastases with rising PSA, status post intravenous chemotherapy 1/7/21
Yes	COVID19 VACCINE (COVID19)	1005377-1	"Significant other reported patient expired ""a week before 2nd vaccine was due""."
Yes	COVID19 VACCINE (COVID19)	1005455-1	We don't know what happened. 25 hours after the shot, he started gagging and stopped breathing. He was pronounced at OSF at 8:07pm after we took him off life support.
Yes	COVID19 VACCINE (COVID19)	1005568-1	Pt. deceased.
Yes	COVID19 VACCINE (COVID19)	1006216-1	Notes of the checks/events with resident: 18:36 2/2/21 Resident had no complaint of pain, swelling, redness or warmth to vaccine site. No signs and symptoms of fever, chills, tiredness or headache. T 97.2 02:50 2/3/2021 Resident received 2nd COVID vaccine. No complaint of pain, swelling, redness or warmth to vaccine site. No signs and symptoms of fever, chills, tiredness or headache. T 98.1 07:15 2/3/2021 Resident was observed not breathing. 911 was contacted along with the doctor. Resident was confirmed having passed away.
Yes	COVID19 VACCINE (COVID19)	1006228-1	2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient POA determined that this would not be her sister's wishes and made the decision to make patient comfort care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.
Yes	COVID19 VACCINE (COVID19)	1006289-1	death- 2/1/2021
Yes	COVID19 VACCINE (COVID19)	1006303-1	death- 2/1/2021
Yes	COVID19 VACCINE	1006316-1	death- 2/2/2021

	(COVID19)		
Yes	COVID19 VACCINE (COVID19)	1046613-1	patient passed away within 60 days of receiving a COVID vaccine
Yes	COVID19 VACCINE (COVID19)	1046698-1	patient passed away within 60 days of receiving a COVID vaccine
Yes	COVID19 VACCINE (COVID19)	1046795-1	Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127
Yes	COVID19 VACCINE (COVID19)	1046845-1	Deceased 02/18/2021 with an unknown cause of death
Yes	COVID19 VACCINE (COVID19)	1046881-1	Code blue called at 11:00pm. Patient had code status of Do Not Resuscitate.
Yes	COVID19 VACCINE (COVID19)	1047183-1	Pt had expired before second dose was delivered.
Yes	COVID19 VACCINE (COVID19)	1047197-1	death
Yes	COVID19 VACCINE (COVID19)	1047282-1	Patient felt fine on Friday afternoon and evening after shot. Felt fine on Saturday until the afternoon when she started feeling fatigued and chilled. Decided to take a warm bath at about 6pm. Was found dead in bathtub at approximately 7pm with blisters on arms, legs, and face.
Yes	COVID19 VACCINE (COVID19)	1047326-1	According to patient's caregiver, patient presented with symptoms of fever (101.6 F) and purple blotches all over the body within an hour. Since patient was in hospice , caregiver called Hospice and a pharmacy and was told to give patient Benadryl and Tylenol. Patient was given both medications and the fever subsided in a few days but the purple blotches never went away. Patient passed away at the facility a week later.
Yes	COVID19 VACCINE (COVID19)	1048786-1	"Was given vaccine around 1:30Pm on 2-11-2021. He and his wife waited in the building for 15 minutes and then left. he denied complaint. (He was waiting to have both Covid shots before he went to cardiologist Re: CAD.) He had an alarm going off in his house, was going to basement to check it out. Police officer heard alarm, came into house, & heard a thud when Doc fell. He was in PEA (Pulseless Electrical Activity) when brought into ER. Given 5 ""rounds of Epinephrine with no response."
Yes	COVID19 VACCINE (COVID19)	1048882-1	Vaccine was administered 2/1/2021 at approximately 9am. Due to self reporting of allergic reaction (hives) to Augmentin, patient was monitored on site for 30 minutes. After the monitoring period, she was cleared to go with no issues reported at the time. We were later informed that the patient passed away from a pulmonary embolism on 2/12/2021.
Yes	COVID19 VACCINE (COVID19)	1048947-1	Patient experienced an episode of emesis and loss of consciousness several hours after vaccine on 2/16/21. He was taken by EMS to the hospital and was noted to be hypoxic and hypotensive. He was admitted to the hospital and subsequently intubated. He was also found to have a small bowel obstruction and a nasogastric tube was placed to decompress the bowel. He required pressor support as well. He expired on 2/17/21.
Yes	COVID19 VACCINE (COVID19)	1049012-1	Patient was given vaccine on friday, one week later she passed away. The family called the pharmacy to inform us on Saturday, Feb 20, 2021. After the phone call was over, we saw in her pharmacy profile that she had received the vaccine one week prior
Yes	COVID19 VACCINE (COVID19)	1049389-1	Patient passed away Saturday at 14:04pm. Patient's wife reports his death was sudden, he passed away sitting in his chair his heart just stopped she said. They tried to perform CPR, 911 was called and paramedics arrived at the scene and he was given medication but never had any return of vital signs and so his death was called at the scene. Wife reports he was not ill, did not have any symptoms prior to the event. They are not going to be doing a autopsy. She wanted us to know based on timing that there may be some possible correlation with his COVID19 vaccine. He obtained the vaccine on 02/09/2021 - wife reports he had no symptoms, not even arm soreness after the vaccine. Had no fever, shortness of breath. Did not complain of chest pain. We can update chart to reflect the patient is deceased and lets make a card for the family.
Yes	COVID19 VACCINE (COVID19)	1049406-1	Patient rcvd 1st covid 19 vaccine on 1/26/2021. Patient had house guests on 1/30/21. Those house guests tested positive for covid on 2/1/2021. Patient started getting symptoms on 02/2/2021. Patient tested postivie on 2/4/2021. Patient was hospitalized 2/7/2021. Patient passed away on 2/21/21.
Yes	COVID19 VACCINE (COVID19)	1049648-1	I was notified on 2/22/21 that this patient passed away over the weekend. I do not know the details, nor can I confirm anything beyond what I was told. I believe the death occurred on 2/20/21 due to a massive stroke.
Yes	COVID19 VACCINE (COVID19)	1049852-1	When calling to get billing information we were notified that patient had passed away. Patient's daughter said patient was having cvd a/s on 2.1.2021 got vaccine 2.2.2021 and passed away 2.5.2021. Cardiologist said not related
Yes	COVID19 VACCINE (COVID19)	1049963-1	Found lying face down without respiration or pulse, believed to be within 5 minutes of event. ACLS procedures unsuccessful. Unable to get autopsy. Believed to be heart attack secondary to COVID infection, but unconfirmed. Relative contribution of recent vaccination unknown.
Yes	COVID19 VACCINE (COVID19)	1049997-1	Vaccine was administered at Nursing Facility. Patient is an 89-year-old female with prior medical history of CVA with dysphagia, history of possible dementia, GERD, hyperlipidemia, and a pacemaker. She is a resident from town. She was sent for hypotension with a blood pressure of 90/52, tachypnea respirations of 54, possible aspiration pneumonia. Status post Covid vaccine earlier today. History is limited as patient is nonverbal on my exam. Death within 24 hours of vaccination
Yes	COVID19 VACCINE (COVID19)	1050137-1	Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).
Yes	COVID19 VACCINE (COVID19)	1050172-1	Individual developed severe body aches, severe shoulder discomfort, high fevers (documented max temp. 103.7 F). Daughter reported that she became non-responsive with high fevers, and when the fevers decreased she was more lucid. Her condition rapidly progressed to nausea vomiting, diarrhea and patient died on 2/9/2021.
Yes	COVID19 VACCINE (COVID19)	1050201-1	Died 7 days after receiving 2nd dose of Moderna vaccine. Had underlying hx Lung CA w/mets.
Yes	COVID19 VACCINE (COVID19)	1050281-1	Per family, patient has been feeling sick since he was vaccinated, patient went to ER on 02/15/2021, and after few hours at ER patient passed away.
Yes	COVID19 VACCINE (COVID19)	1050431-1	Since I was not with my husband I can only tell you what was told to me. He walked out of the store toward our car. Someone watched him, concerned, because he was walking very slowly (normally has a slow gait because of leg braces and toe amputations so I don't know if it was unusually slow). The woman saw him fall and she ran to help- administered CPR immediately-and told me he died instantly. Medics tried to resuscitate and failed to bring a pulse. (My husband left our home around 11:15 to drop a package off at store. The store is one mile from our home. At around 12:30 a deputy came to my door and when I saw him my knees buckled. I knew something horrible

Yes	COVID19 VACCINE (COVID19)	1078246-1	Death. Ruptured myocardial infarct.
Yes	COVID19 VACCINE (COVID19)	1078352-1	Developed fatigue, body aches, headache 1 day after vaccination on 3/3. The morning of 3/5 complained of chest pain. Took Tylenol at 8:30 am. At 10:30 am his family found him unresponsive. EMS was called and he was pronounced dead in the home.
Yes	COVID19 VACCINE (COVID19)	1079251-1	Patient died the day after she received her vaccine
Yes	COVID19 VACCINE (COVID19)	1079904-1	SUBJECT WAS FOUND DECEASED ON 22 FEB 2021 AT AROUND 11:30 PM
Yes	COVID19 VACCINE (COVID19)	1079958-1	Pt found down and pulseless in home by husband. EMS called, Pt found to be in PEA arrest. Pt achieved ROSC with CPR and Epinephrin. Pt Passed away on 09/07/2021 at 1330. Pt was in multisystem organ failure.
Yes	COVID19 VACCINE (COVID19)	1079976-1	12/23/20 (Moderna #1) - Malaise, cough on 12/24, went to walk-in on 12/25 c/o cough, malaise, rx'd Augmentin x14d, Rapid covid negative (and PCR resulted negative). 12/27 slept all day, 12/28 back to work. 1/12/21 metallic taste in mouth, severe GI sx, malaise, aches, headache. 1/14 seen at walk-in and covid swabbed Negative. 1/21/21 exposed to parents who found out they were covid + on 1/22/21. 1/25/21 (Moderna #2) - Continued with persistent cough and GI sx. Then also developed urinary frequency and urgency. Seen at urgent care 2/1 c/o cough, dx URI, rx'd augmenting. Woke up morning of 2/2/21 abruptly, stood up, said something was wrong, and collapsed. CPR attempted immediately, EMS brought him to ER where he was pronounced dead.
Yes	COVID19 VACCINE (COVID19)	1080425-1	Narrative: Patient with h/o ESRD on HD MWF, HTN presented to ER on 2/20/21 with worsening dyspnea and GI symptoms; tested positive for COVID-19. Patient had received first COVID vaccination approx. 9 days prior. Patient admitted to ICU for treatment of COVID+ PNA. During admission, patient often could not tolerate removal of fluid during HD d/t tachycardia. He received dexamethasone, convalescent plasma for COVID. Patient underwent TTE which was notable for septal wall motion abnormalities and grossly reduced EF. Admission also c/b acute liver injury, possible cholecystitis, thrombocytopenia, SVT, encephalopathy. Patient then developed progressive shock and hemodynamic instability on 3/2 and passed away on 3/2/21.
Yes	COVID19 VACCINE (COVID19)	1080429-1	DEATH Narrative: no documentation regarding any immediate reaction after vaccine administration. 83 y.o. male with pmh severe pulmonary hypertension, s/p TAVR last year, severe asbestos related lung disease on chronic oxygen, recently started on palliative care. Was found by daugher deceased on the morning of 2/11/2021. Autopsy declined by family.
Yes	COVID19 VACCINE (COVID19)	1080430-1	Death Narrative: Death was not determined to be related to COVID vaccination. COVID vaccination (dose 1) occurred on 1/27/21 with no noted side effects. Death occurred on 2/14/21.
Yes	COVID19 VACCINE (COVID19)	1080431-1	Narrative: 67 year-old male received his 1st COVID vaccine dose at a clinic on 2/25/21 at ~ 11:45am. No known prior COVID infection. No history of vaccine allergies or allergies to any component of the COVID vaccine. Does have history of allergic reactions including hives, angioedema or anaphylaxis to some medications (neomycin, Neosporin, bacitracin) and environmental allergens (yellow jackets, fir trees). Patient reported previously daily use of diphenhydramine (2 caps every morning) and kept an epi-pen on hand. The afternoon of 2/26/21, patient presented to his neighbor's house requesting assistance with an epi-pen. Neighbor reported significant swelling around tongue and lips, and ability to faintly speak. Neighbor administered epi-pen, but unsure if it worked, so administered a 2nd epi-pen. Within a minute or two after the 2nd dose, patient slumped over and became non-responsive. EMS was called and neighbor began CPR. EMS reported that patient was non-responsive upon arrival. A King airway was placed and a Lucas device used for chest compressions. Three rounds of epinephrine were administered during transport to the local emergency room. Patient remained unresponsive with evidence of PEA during transport. Arrival at the ER occurred ~ 4:25pm. On arrival patient noted to be unresponsive with CPR in progress. Dose of epinephrine administered ~ 3 minutes after arrival in ER. No femoral pulse palpable, cardiac monitor did show some electrical activity. Evaluation of oral cavity showed significant swelling of tongue. Additional dose of epinephrine given. Patient remained with no palpable central pulse and showed continued evidence of PEA. Patient was estimated to have been down > 45 minutes. Patient pronounced deceased at 4:59pm.
Yes	COVID19 VACCINE (COVID19)	1080433-1	unknown cardiovascular event
Yes	COVID19 VACCINE (COVID19)	1080434-1	Death Narrative: Patient passed away on 3-2-21, patient received the vaccine on 2-24-21. Patient was obese and had several co-morbid conditions.
Yes	COVID19 VACCINE (COVID19)	1080671-1	Patient received vaccine 1/26/2021, complained of fever and chills post vaccine. Daughter reported worsening symptoms to confusion, decreased appetite, N/V and chest pain. Dry cough and SOB. Patient admitted to facility for Chest pain, AMS on 2/2/2021. Expired 2/2/2021.
Yes	COVID19 VACCINE (COVID19)	1081009-1	there were no signs of adverse reaction at the time of injections and she waited 15 minutes at the site to watch for side effects. and none were evident or reported. We were notified that she passed away on Saturday, March 6.
Yes	COVID19 VACCINE (COVID19)	1081033-1	Patient expired 2 days after receiving the vaccination. Patient had other signs of deterioration over the course of the previous month with worsening edema and difficulty breathing. Unlikely to be related according to our assessments, but wanted to err on the side of caution.
Yes	COVID19 VACCINE (COVID19)	1081155-1	Pt died on 3/6/2021. Received Vaccine on 2/12/2021. Unknown cause of death.
Yes	COVID19 VACCINE (COVID19)	1081304-1	patient passed away within 60 days of receiving a COVID vaccine
Yes	COVID19 VACCINE (COVID19)	1081305-1	Sudden death approximately 24 hours after receiving 2nd COVID vaccine - symptoms unknown - autopsy revealed cardiac disease as the cause of death
Yes	COVID19 VACCINE (COVID19)	1081547-1	NO IMMEDIATE ADVERSE EVENTS PRESENT FOLLOWING IMMUNIZATION. RESIDENT WAS ALERT, RESPONSIVE, TALKATIVE, WITHOUT COMPLAINTS, AND ENGAGING IN NORMAL ACTIVITIES AFTER IMMUNIZATION, AS WELL AS THE FOLLOWING DAY. HE WAS FOUND IN BED THE SECOND MORNING AFTER VACCINATION (AT 6:25AM) WITHOUT VITAL SIGNS AND HAD EXPIRED PEACEFULLY IN HIS SLEEP. HE WAS A DNR, NO LIFE SUSTAINING MEASURES WERE PERFORMED.
Yes	COVID19 VACCINE (COVID19)	1082467-1	Pt passed away on 3/6/21.
Yes	COVID19 VACCINE (COVID19)	1082707-1	death
Yes	COVID19 VACCINE (COVID19)	1082717-1	Patient dropped dead 24 hours after receiving the vaccine. The vaccine killed her. She received the vaccine 2/16/2021 and died 2/17/2021
Yes	COVID19 VACCINE (COVID19)	1082759-1	Death
Yes	COVID19 VACCINE	1082787-1	Death on 3/7/21

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COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021
Data Lock Date: 07-Mar-2021 19:00:03

All UK spontaneous reports received up to and including 07/03/21 for COVID-19 vaccines where the brand has not been specified.

Rm
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Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
Lymphatic system disorders NEC		
Lymphadenopathy	3	0
Blood disorders SOC TOTAL	3	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac signs and symptoms NEC		
Palpitations	2	0
Ischaemic coronary artery disorders		
Myocardial infarction	1	1
Supraventricular arrhythmias		
Atrial fibrillation	1	0
Cardiac disorders SOC TOTAL	4	1

Rm 2

45

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	1	0
Ear pain	2	0
Inner ear signs and symptoms		
Tinnitus	2	0
Vertigo	4	0
Ear disorders SOC TOTAL	9	0

RM2

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Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Eye disorders		
Lacrimation disorders		
Lacrimation increased	1	0
Lid, lash and lacrimal infections, irritations and inflammations		
Swelling of eyelid	1	0
Ocular disorders NEC		
Eye pain	2	0
Eye swelling	1	0
Ocular infections, inflammations and associated manifestations		
Eye pruritus	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal haemorrhage	1	0
Retinal structural change, deposit and degeneration		
Retinal toxicity	1	0
Visual disorders NEC		
Diplopia	2	0
Vision blurred	1	0
Visual impairment and blindness (excl colour blindness)		
Blindness transient	1	0
Visual impairment	1	0
Eye disorders SOC TOTAL	13	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Anal and rectal pains		
Proctalgia	1	0
Dental pain and sensation disorders		
Toothache	1	0
Diarrhoea (excl infective)		
Diarrhoea	9	0
Dyspeptic signs and symptoms		
Dyspepsia	1	0
Faecal abnormalities NEC		
Abnormal faeces	1	0
Faeces discoloured	1	0
Gastritis (excl infective)		
Gastritis	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain upper	6	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	4	0
Nausea and vomiting symptoms		
Nausea	35	0
Vomiting	20	0
Vomiting projectile	1	0
Oral dryness and saliva altered		
Dry mouth	1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	1	0
Lip pain	1	0
Oral pain	1	0
Oral soft tissue swelling and oedema		
Lip swelling	2	0
Stomatitis and ulceration		
Mouth ulceration	2	0
Gastrointestinal disorders SOC TOTAL	89	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021
Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders		
Application and instillation site reactions		
Application site burn	1	0
Asthenic conditions		
Asthenia	10	0
Fatigue	55	0
Malaise	21	0
Death and sudden death		
Death	4	4
Febrile disorders		
Pyrexia	54	0
Feelings and sensations NEC		
Chills	43	0
Feeling abnormal	3	0
Feeling cold	12	0
Feeling hot	4	0
Feeling of body temperature change	4	0
Thirst	1	0
Gait disturbances		
Gait disturbance	4	0
Gait inability	1	0
General signs and symptoms NEC		
Condition aggravated	2	0
Illness	3	0
Influenza like illness	8	0
Peripheral swelling	6	0
Swelling	8	0
Swelling face	5	0
Injection site reactions		
Injection site inflammation	1	0
Injection site mass	1	0
Injection site pain	1	0
Pain and discomfort NEC		
Axillary pain	1	0
Chest discomfort	4	0
Chest pain	3	0
Discomfort	1	0
Facial pain	1	0
Pain	27	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	2	0
Vaccination site reactions		
Vaccination site bruising	2	0
Vaccination site erythema	7	0
Vaccination site induration	1	0
Vaccination site inflammation	2	0
Vaccination site mass	1	0
Vaccination site pain	8	0
Vaccination site papule	1	0
Vaccination site pruritus	2	0
Vaccination site rash	1	0
Vaccination site swelling	5	0
Vaccination site vesicles	1	0
Vaccination site warmth	2	0

RMC

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Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name		Total	Fatal
General disorders	General disorders cont'd		
General disorders SOC TOTAL		324	4

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Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021
Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Hepatic disorders		
Bile duct infections and inflammations		
Biliary colic	1	0
Hepatic disorders SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Hypersensitivity	1	0
Allergies to foods, food additives, drugs and other chemicals		
Drug hypersensitivity	1	0
Immune system disorders SOC TOTAL	2	0

RM2
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Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 06-Feb-2020
Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
Coronavirus infections		
COVID-19	1	0
Herpes viral infections		
Herpes zoster	1	0
Oral herpes	1	0
Influenza viral infections		
Influenza	4	0
Lower respiratory tract and lung infections		
Pneumonia	2	1
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Sepsis	1	0
Urinary tract infections		
Cystitis	1	0
Viral infections NEC		
Gastroenteritis viral	1	0
Sweating fever	1	0
Infections SOC TOTAL	13	1

RM2

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Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries		
Exposures associated with pregnancy, delivery and lactation		
Exposure via breast milk	1	0
Medication errors, product use errors and issues NEC		
Wrong technique in product usage process	1	0
Non-site specific injuries NEC		
Fall	2	0
Non-site specific procedural complications		
Incision site pain	1	0
Injection related reaction	1	0
Skin injuries NEC		
Contusion	1	0
Injuries SOC TOTAL	7	0

RM2

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Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021
Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
Coagulation and bleeding analyses		
Fibrin D dimer increased	1	0
International normalised ratio increased	1	0
Heart rate and pulse investigations		
Heart rate increased	1	0
Physical examination procedures and organ system status		
Body temperature abnormal	1	0
Body temperature decreased	2	0
Body temperature increased	1	0
Therapeutic drug monitoring analyses		
Anticoagulation drug level below therapeutic	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure increased	4	0
Investigations SOC TOTAL	**12**	**0**

RML

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Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021
Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	27	0
Hypophagia	2	0
Hyperglycaemic conditions NEC		
Hyperglycaemia	1	0
Metabolic disorders SOC TOTAL	**30**	**0**

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Bone related signs and symptoms		
Bone pain	1	0
Cartilage disorders		
Costochondritis	1	0
Joint related signs and symptoms		
Arthralgia	18	0
Joint stiffness	1	0
Joint swelling	1	0
Muscle pains		
Myalgia	23	0
Muscle related signs and symptoms NEC		
Muscle fatigue	1	0
Muscle spasms	2	0
Muscle tightness	2	0
Muscle twitching	1	0
Muscle weakness conditions		
Muscular weakness	3	0
Musculoskeletal and connective tissue conditions NEC		
Mobility decreased	1	0
Musculoskeletal stiffness	4	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	3	0
Neck pain	1	0
Pain in extremity	24	0
Muscle & tissue disorders SOC TOTAL	87	0

AML
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Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
Acute polyneuropathies		
Guillain-Barre syndrome	2	0
Coordination and balance disturbances		
Balance disorder	3	0
Dysstasia	2	0
Disturbances in consciousness NEC		
Lethargy	9	0
Somnolence	7	0
Syncope	1	0
Dyskinesias and movement disorders NEC		
Bradykinesia	1	0
Hypokinesia	2	0
Eye movement disorders		
VIth nerve paralysis	1	0
Facial cranial nerve disorders		
Facial paresis	1	0
Headaches NEC		
Headache	87	0
Memory loss (excl dementia)		
Amnesia	2	0
Mental impairment (excl dementia and memory loss)		
Disturbance in attention	2	0
Migraine headaches		
Migraine	8	0
Retinal migraine	1	0
Neurological signs and symptoms NEC		
Dizziness	26	0
Dizziness postural	3	0
Neurological symptom	1	0
Paraesthesias and dysaesthesias		
Burning sensation	2	0
Hypoaesthesia	1	0
Paraesthesia	8	0
Paralysis and paresis (excl cranial nerve)		
Paralysis	1	0
Seizures and seizure disorders NEC		
Convulsions local	1	0
Seizure	1	0
Sensory abnormalities NEC		
Dysgeusia	2	0
Sensory disturbance	1	0
Sleep disturbances NEC		
Poor quality sleep	1	0
Transient cerebrovascular events		
Transient ischaemic attack	1	0
Tremor (excl congenital)		
Tremor	21	0
Nervous system disorders SOC TOTAL	199	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	1	0
Anxiety symptoms		
Anxiety	1	0
Nervousness	1	0
Stress	1	0
Confusion and disorientation		
Confusional state	7	0
Disorientation	4	0
Disturbances in initiating and maintaining sleep		
Insomnia	1	0
Emotional and mood disturbances NEC		
Irritability	1	0
Hallucinations (excl sleep-related)		
Hallucination	1	0
Mood alterations with depressive symptoms		
Depressed mood	1	0
Panic attacks and disorders		
Panic attack	1	0
Perception disturbances NEC		
Autoscopy	1	0
Sleep disorders NEC		
Sleep disorder	2	0
Thinking disturbances		
Bradyphrenia	1	0
Psychiatric disorders SOC TOTAL	24	0

Rm 2
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Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Dysuria	1	0
Urinary incontinence	2	0
Renal lithiasis		
Nephrolithiasis	1	0
Urinary abnormalities		
Haematuria	1	0
Urine odour abnormal	1	0
Urinary tract signs and symptoms NEC		
Renal pain	2	0
Renal & urinary disorders SOC TOTAL	8	0

RML

60

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Menstruation with increased bleeding		
Polymenorrhoea	1	0
Reproductive & breast disorders SOC TOTAL	1	0

RML

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Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 06-Feb-2020
Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	9	1
Bronchospasm and obstruction		
Asthma	1	0
Chronic obstructive pulmonary disease	1	0
Coughing and associated symptoms		
Cough	5	0
Haemoptysis	1	0
Nasal congestion and inflammations		
Nasal congestion	1	0
Nasal disorders NEC		
Epistaxis	2	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	1	1
Respiratory tract disorders NEC		
Lung disorder	1	0
Upper respiratory tract signs and symptoms		
Oropharyngeal pain	2	0
Rhinorrhoea	2	0
Respiratory disorders SOC TOTAL	26	2

RM1

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Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021
Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders		
Apocrine and eccrine gland disorders		
Cold sweat	2	0
Hyperhidrosis	9	0
Night sweats	2	0
Dermal and epidermal conditions NEC		
Dry skin	1	0
Skin burning sensation	1	0
Skin discolouration	2	0
Skin swelling	1	0
Erythemas		
Erythema	8	0
Exfoliative conditions		
Skin exfoliation	1	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	1	0
Pruritus NEC		
Pruritus	11	0
Rashes, eruptions and exanthems NEC		
Rash	9	0
Rash erythematous	2	0
Rash pruritic	4	0
Urticarias		
Urticaria	3	0
Skin disorders SOC TOTAL	57	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Social circumstances		
Disability issues		
Bedridden	1	0
Social circumstances SOC TOTAL	1	0

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Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Mar-2021 Data Lock Date: 07-Mar-2021 19:00:03
Earliest Reaction Date: 06-Feb-2020 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Vascular disorders		
Haemorrhages NEC		
Haematoma	1	0
Non-site specific vascular disorders NEC		
Vascular rupture	1	0
Peripheral vascular disorders NEC		
Flushing	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	1	0
Vascular hypertensive disorders NEC		
Hypertension	3	0
Vascular disorders SOC TOTAL	7	0
TOTAL REACTIONS FOR DRUG	**917**	**8**
TOTAL REPORTS	**281**	
TOTAL FATAL OUTCOME REPORTS		8

MEDICAL Brief
Africa's Medical Media Digest

Deaths may top 88,000 but lockdown disaster dwarfs CO\ SA actuaries

MAY 6TH, 2020 SOUTH AFRICA

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Daily Maverick reports that is the stark message in a report delivered to President Cyril Ramaphosa by **Pande (Panda),** a multidisciplinary initiative co-ordinated by actuary Nick Hudson, CEO of private equity firm, **SANA F** itself as a concerned group of professionals and comprises actuaries, an economist, lawyers, a medical doct a statistics lecturer.

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Actuarial analysis could help provide "improved, data-led" decision-making. This would go beyond quantifying the virus, and look at the impact of a longer-term humanitarian disaster: this would require the "next best acti

*The death toll from **South Africa**'s coronavirus outbreak this year could range between 46,000 and 88,000,* acco model from the **Actuarial Society of SA (Assa)**. ***Business Day*** reports that the outputs vary depending on the about the percentage of people who are asymptomatic, how infectious people are, and how effective the lock

The Assa model's output is broadly in line with government projections, and has been provided to Assa's men actuaries in their work advising clients in the insurance industry. Life assurance companies in particular, need projections to assess their mortality expectations and stress test capital requirements, said Assa president L

The report says the model itself is still a work in progress and will only be provided to actuaries at a later stag local data at present, because South Africa's epidemic was still in its early stages, and new information was c about SARS-CoV-2, the coronavirus that causes **COVID-19**.

Assa has provided the industry with a range of scenarios that predict the number of symptomatic patients wi and September, at between 588,000 and 2.3m people. The demand for hospital beds when the outbreak is at between 69,400 and 125,000, while intensive care unit bed demand ranges between 10,700 and 19,200, accor

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Letter

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Statement on Virus Isolation (SOVI)

***Isolation**: "The action of isolating; the fact or condition of being isolated or standing alone; separation from other things or persons; solitariness."*
—From the Oxford English Dictionary

The controversy over whether the SARS-CoV-2 virus has ever been isolated or purified continues. However, using the above definition, common sense, the laws of logic and the dictates of science, any unbiased person must come to the conclusion that the SARS-CoV-2 virus has *never* been isolated or purified. As a result, no confirmation of the virus' existence can be found. The logical, common sense, and scientific consequences of this fact are:

- the structure and composition of something not shown to exist can't be known, including the presence, structure, and function of any hypothetical spike or other proteins;
- the genetic sequence of something that has never been found can't be known;
- "variants" of something that hasn't been shown to exist can't be known;
- it's impossible to demonstrate that SARS-CoV-2 causes a disease called Covid-19.

In as concise terms as possible, here's the proper way to isolate, characterize and demonstrate a new virus. First, one takes samples (blood, sputum, secretions) from many people (e.g. 500) with symptoms which are unique and specific enough to characterize an illness. Without mixing these samples with ANY tissue or products that also contain genetic material, the virologist macerates, filters and ultracentrifuges i.e. *purifies* the specimen. This common virology technique, done for decades to isolate

bacteriophages[1] and so-called giant viruses in every virology lab, then allows the virologist to demonstrate with electron microscopy thousands of identically sized and shaped particles. These particles are the isolated and purified virus.

These identical particles are then checked for uniformity by physical and/or microscopic techniques. Once the purity is determined, the particles may be further characterized. This would include examining the structure, morphology, and chemical composition of the particles. Next, their genetic makeup is characterized by extracting the genetic material directly from the purified particles and using genetic-sequencing techniques, such as Sanger sequencing, that have also been around for decades. Then one does an analysis to confirm that these uniform particles are exogenous (outside) in origin as a virus is conceptualized to be, and not the normal breakdown products of dead and dying tissues.[2] (As of May 2020, we know that virologists have no way to determine whether the particles they're seeing are viruses or just normal break-down products of dead and dying tissues.)[3]

If we have come this far then we have fully isolated, characterized, and genetically sequenced an exogenous virus particle. However, we still have to show it is causally related to a disease. This is carried out by exposing a group of healthy subjects (animals are usually used) to this isolated, purified virus in the manner in which the disease is thought to be transmitted. If the animals get sick with the same disease, as confirmed by clinical and autopsy findings, one has now shown that the virus actually causes a disease. This demonstrates infectivity and transmission of an infectious agent.

None of these steps has even been attempted with the SARS-CoV-2 virus, nor have all these steps been successfully performed for any so-called

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[1] Isolation, characterization and analysis of bacteriophages from the haloalkaline lake Elmenteita, KenyaJuliah Khayeli Akhwale et al, PLOS One, Published: April 25, 2019.
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0215734 -- accessed 2/15/21

[2] "Extracellular Vesicles Derived From Apoptotic Cells: An Essential Link Between Death and Regeneration," Maojiao Li1 et al, Frontiers in Cell and Developmental Biology, 2020 October 2.
https://www.frontiersin.org/articles/10.3389/fcell.2020.573511/full -- accessed 2/15/21

[3] "The Role of Extraellular Vesicles as Allies of HIV, HCV and SARS Viruses," Flavia Giannessi, et al, Viruses, 2020 May

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pathogenic virus. Our research indicates that a single study showing these steps does not exist in the medical literature.

Instead, since 1954, virologists have taken unpurified samples from a relatively few people, often less than ten, with a similar disease. They then minimally process this sample and inoculate this unpurified sample onto tissue culture containing usually four to six other types of material — **all of which contain identical genetic material as to what is called a "virus."** The tissue culture is starved and poisoned and naturally disintegrates into many types of particles, some of which contain genetic material. Against all common sense, logic, use of the English language and scientific integrity, this process is called "virus isolation." This brew containing fragments of genetic material from many sources is then subjected to genetic analysis, which then creates in a computer-simulation process the alleged sequence of the alleged virus, a so called *in silico genome*. At no time is an actual virus confirmed by electron microscopy. At no time is a genome extracted and sequenced from an actual virus. This is scientific fraud.

The observation that the unpurified specimen — inoculated onto tissue culture along with toxic antibiotics, bovine fetal tissue, amniotic fluid and other tissues — destroys the kidney tissue onto which it is inoculated is given as evidence of the virus' existence and pathogenicity. This is scientific fraud.

From now on, when anyone gives you a paper that suggests the SARS-CoV-2 virus has been isolated, please check the methods sections. If the researchers used Vero cells or any other culture method, you know that their process was not isolation. You will hear the following excuses for why actual isolation isn't done:

1. There were not enough virus particles found in samples from patients to analyze.

2. Viruses are intracellular parasites; they can't be found outside the cell in this manner.

If No. 1 is correct, and we can't find the virus in the sputum of sick people, then on what evidence do we think the virus is dangerous or even lethal? If No. 2 is correct, then how is the virus spread from person to person? We are told it emerges from the cell to infect others. Then why isn't it possible to find it?

Finally, questioning these virology techniques and conclusions is not some distraction or divisive issue. Shining the light on this truth is essential to stop this terrible fraud that humanity is confronting. For, as we now know, if the virus has never been isolated, sequenced or shown to cause illness, if the virus is imaginary, then why are we wearing masks, social distancing and putting the whole world into prison?

Finally, if pathogenic viruses don't exist, then what is going into those injectable devices erroneously called "vaccines," and what is their purpose? This scientific question is the most urgent and relevant one of our time.

We are correct. The SARS-CoV2 virus does not exist.

Sally Fallon Morell, MA

Dr. Thomas Cowan, MD

Dr. Andrew Kaufman, MD

Please show your support by sharing this document with as many people as you can, and then visit https://www.andrewkaufmanmd.com/sovi to add your name to the list of supporters world wide.

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RESEARCH

Severe Acute Respiratory Syndrome Coronavirus 2 from Patient with Coronavirus Disease, United States

Jennifer Harcourt,[1] Azaibi Tamin,[1] Xiaoyan Lu, Shifaq Kamili, Senthil K. Sakthivel, Janna Murray, Krista Queen, Ying Tao, Clinton R. Paden, Jing Zhang, Yan Li, Anna Uehara, Haibin Wang, Cynthia Goldsmith, Hannah A. Bullock, Lijuan Wang, Brett Whitaker, Brian Lynch, Rashi Gautam, Craig Schindewolf, Kumari G. Lokugamage, Dionna Scharton, Jessica A. Plante, Divya Mirchandani, Steven G. Widen, Krishna Narayanan, Shinji Makino, Thomas G. Ksiazek, Kenneth S. Plante, Scott C. Weaver, Stephen Lindstrom, Suxiang Tong, Vineet D. Menachery,[2] Natalie J. Thornburg[2]

The etiologic agent of an outbreak of pneumonia in Wuhan, China, was identified as severe acute respiratory syndrome coronavirus 2 in January 2020. A patient in the United States was given a diagnosis of infection with this virus by the state of Washington and the US Centers for Disease Control and Prevention on January 20, 2020. We isolated virus from nasopharyngeal and oropharyngeal specimens from this patient and characterized the viral sequence, replication properties, and cell culture tropism. We found that the virus replicates to high titer in Vero-CCL81 cells and Vero E6 cells in the absence of trypsin. We also deposited the virus into 2 virus repositories, making it broadly available to the public health and research communities. We hope that open access to this reagent will expedite development of medical countermeasures.

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A novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has been identified as the source of a pneumonia outbreak in Wuhan, China, in late 2019 (*1*,*2*). The virus was found to be a member of the β coronavirus family, in the same species as SARS-CoV and SARS-related bat CoVs (*3*,*4*). Patterns of spread indicate that SARS-CoV-2 can be transmitted person-to-person, and may be more transmissible than SARS-CoV (*5*–*7*). The spike protein of coronaviruses mediates virus binding and cell entry. Initial characterization of SARS-CoV-2 spike indicates that it binds the same receptor as SARS-CoV angiotensin-converting enzyme, which is expressed in both upper and lower human respiratory tracts (*8*).

The unprecedented rapidity of spread of this outbreak represents a critical need for reference reagents. The public health community requires viral lysates to serve as diagnostic references, and the research community needs virus isolates to test antiviral compounds, develop new vaccines, and perform basic research. In this article, we describe isolation of SARS-CoV-2 from a patient who had coronavirus disease (COVID-19) in the United States and described its genomic sequence and replication characteristics. We have made the virus isolate available to the public health community by depositing it into 2 virus reagent repositories.

[1]These authors contributed equally to this article.

[2]These senior authors contributed equally to this article.

Methods

Specimen Collection

Virus isolation from patient samples was deemed not to be human subjects research by the National Center for Immunizations and Respiratory Diseases, Centers for Disease Control and Prevention (CDC) (research determination no. 0900f3eb81ab4b6e). Clinical specimens from a case-patient who had acquired COVID-19 during travel to China and who was identified in Washington, USA, were collected as described (*1*). Nasopharyngeal (NP) and oropharyngeal (OP) swab specimens were collected on day 3 postsymptom onset, placed in 2–3 mL of viral transport medium, used for molecular diagnosis, and frozen. Confirmed PCR-positive specimens were aliquoted and refrozen until virus isolation was initiated.

Cell Culture, Limiting Dilution, and Virus Isolation

We used Vero CCL-81 cells for isolation and initial passage. We cultured Vero E6, Vero CCL-81, HUH 7.0, 293T, A549, and EFKB3 cells in Dulbecco minimal essential medium (DMEM) supplemented with heat-inactivated fetal bovine serum (5% or 10%) and antibiotics/antimycotics (GIBCO, https://www.thermofisher.com). We used both NP and OP swab specimens for virus isolation. For isolation, limiting dilution, and passage 1 of the virus, we pipetted 50 μL of serum-free DMEM into columns 2–12 of a 96-well tissue culture plate, then pipetted 100 μL of clinical specimens into column 1 and serially diluted 2-fold across the plate. We then trypsinized and resuspended Vero cells in DMEM containing 10% fetal bovine serum, 2× penicillin/streptomycin, 2× antibiotics/antimycotics, and 2× amphotericin B at a concentration of 2.5×10^5 cells/mL. We added 100 μL of cell suspension directly to the clinical specimen dilutions and mixed gently by pipetting. We then grew the inoculated cultures in a humidified 37°C incubator in an atmosphere of 5% CO_2 and observed for cytopathic effects (CPEs) daily. We used standard plaque assays for SARS-CoV-2, which were based on SARS-CoV and Middle East respiratory syndrome coronavirus (MERS-CoV) protocols (*9*,*10*).

When CPEs were observed, we scraped cell monolayers with the back of a pipette tip. We used 50 μL of viral lysate for total nucleic acid extraction for confirmatory testing and sequencing. We also used 50 μL of virus lysate to inoculate a well of a 90% confluent 24-well plate.

Inclusivity/Exclusivity Testing

From the wells in which CPEs were observed, we performed confirmatory testing by using real-time reverse transcription PCR (CDC) and full-genome sequencing (*1*). The CDC molecular diagnostic assay targets 3 portions of the nucleocapsid gene, and results for all 3 portions must be positive for a sample to be considered positive (https://www.cdc.gov/coronavirus/2019-ncov/lab/rt-pcr-detection-instructions.html and https://www.cdc.gov/coronavirus/2019-ncov/lab/rt-pcr-panel-primer-probes.html). To confirm that no other respiratory viruses were present, we performed Fast Track Respiratory Pathogens 33 Testing (FTD Diagnostics, http://www.fast-trackdiagnostics.com).

Whole-Genome Sequencing

We designed 37 pairs of nested PCRs spanning the genome on the basis of the coronavirus reference sequence (GenBank accession no. NC045512). We extracted nucleic acid from isolates and amplified by using the 37 individual nested PCRs. We used positive PCR amplicons individually for subsequent Sanger sequencing and also pooled them for library preparation by using a ligation sequencing kit (Oxford Nanopore Technologies, https://nanoporetech.com), subsequently for Oxford Nanopore MinION sequencing. We generated consensus nanopore sequences by using Minimap version 2.17 (https://github.com) and Samtools version 1.9 (http://www.htslib.org). We generated consensus sequences by Sanger sequencing from both directions by using Sequencher version 5.4.6 (https://www.genecodes.com), and further confirmed them by using consensus sequences generated from nanopore sequencing.

To sequence passage 4 stock, we prepared libraries for sequencing by using the Next Ultra II RNA Prep Kit (New England Biolabs, https://www.neb.com) according to the manufacturer's protocol. In brief, we fragmented ≈70–100 ng of RNA for 15 min, followed by cDNA synthesis, end repair, and adaptor ligation. After 6 rounds of PCR, we analyzed libraries by using an Agilent Bioanalyzer (https://www.agilent.com) and quantified them by using a quantitative PCR. We pooled samples and sequenced samples by using a paired-end 75-base protocol on an Illumina (Illumina, Inc., https://www.illumina.com) MiniSeq instrument and using the High-Output Kit and then processed reads by using Trimmomatic version 0.36 (*11*) to remove low-quality base calls and any adaptor sequences. We used the de novo assembly program ABySS (*12*) to assemble the reads into contigs by using several different sets of reads and kmer values ranging from 20 to 40. We compared contigs >400 bases against the National Center for Biotechnology Information (Bethesda, MD, USA) nucleotide collection using BLAST

(https://blast.ncbi.nlm.nih.gov). A nearly full-length viral contig obtained in each sample had 100% identity to the 2019-nCoV/USA-WA1/2020 strain (GenBank accession no. MN985325.1). All the remaining contigs mapped to either host cell rRNA or mitochondria. We mapped the trimmed reads to the reference sequence by using BWA version 0.7.17 (*13*) and visualized these reads by using the Integrated Genomics Viewer (*14*) to confirm the identity with the USA-WA1/2020 strain.

Electron Microscopy

We scraped infected Vero cells from the flask, pelleted by low-speed centrifugation, rinsed with 0.1 mol/L phosphate buffer, pelleted again, and fixed for 2 h in 2.5% buffered glutaraldehyde. We then postfixed specimens with 1% osmium tetroxide, en bloc stained with 4% uranyl acetate, dehydrated, and embedded in epoxy resin. We cut ultrathin sections, stained them with 4% uranyl acetate and lead citrate, and examined them by using a Thermo Fisher/FEI Tecnai Spirit electron microscope (https://www.fei.com).

Protein Analysis and Western Blotting

We harvested cell lysates by using Laemmli sodium dodecyl sulfate–polyacrylamide gel electrophoresis sample buffer (Bio-Rad, https://www.bio-rad.com) containing 2% SDS and 5% β-mercaptoethanol. We removed the cell lysates from a Biosafety Level 3 Laboratory, boiled them, and loaded them onto a polyacrylamide gel. We subjected the lysates to sodium dodecyl sulfate–polyacrylamide gel electrophoresis, followed by transfer to a polyvinylidene difluoride polyvinylidene fluoride membrane. We then blocked the membrane in 5% nonfat dry milk dissolved in Tris-buffered saline containing 0.1% Tween-20 (TBS-T) for 1 h, followed by a short wash with TBS-T. We incubated the membrane overnight with primary antibody, either rabbit polyclonal serum against the SARS-CoV spike protein (#40150-T52; Sino Biological, https://www.sinobiological.com), β-actin antibody (#4970; Cell Signaling Technology, https://www.cellsignal.com), or a custom rabbit polyclonal serum against SARS-CoV nucleocapsid. We then washed the membrane with 3 times with TBS-T and applied horseradish peroxidase-conjugated secondary antibody for 1 h. Subsequently, we washed the membrane 3 times with TBS-T, incubated with Clarity Western ECL Substrate (#1705060S; Bio-Rad), and imaged with a multipurpose imaging system.

Generation of SARS-CoV Nucleocapsid Antibodies

We used the plasmid pBM302 (*15*) to express SARS-CoV nucleocapsid protein, with a C-terminal His6 tag, to high levels within the inclusion bodies of *Escherichia coli* and the recombinant protein was purified from the inclusion bodies by using nickel-affinity column chromatography under denaturing conditions. We used stepwise dialysis against Tris/phosphate buffer to refold the recombinant SARS-CoV nucleocapsid protein with decreasing concentrations of urea to renature the protein. We then immunized rabbits with the renatured, full-length, SARS-CoV nucleocapsid protein to generate an affinity-purified rabbit anti–SARS-CoV nucleocapsid protein polyclonal antibody.

Results

A patient was identified with confirmed COVID-19 in Washington State on January 22, 2020. CPE was not observed in mock infected cells (Figure 1, panel A). Cycle threshold (C_t) values were 18–20 for NP specimens and 21–22 for OP specimens (*1*). The positive clinical specimens were aliquoted and refrozen inoculated into cell culture on January 22, 2020. We observed CPE 2 days postinoculation and harvested viral lysate on day 3 postinoculation (Figure 1, panels B, C). We used 50 μL of passage 1 viral lysates for nucleic acid extraction to confirm the presence of SARS-CoV-2 by using the CDC molecular diagnostic assay (*1*). The C_t values of 3 nucleic acid extractions were 16.0–17.1 for nucleocapsid portion 1, 15.9–17.1 for nucleocapsid portion 2, and 16.2–17.3 for nucleocapsid portion 3, which confirmed isolation of SARS-CoV-2 (C_t <40 is considered a positive result). We also tested extracts for 33 additional different respiratory pathogens by using the Fast Track 33 Assay. No other pathogens were detected. Identity was additionally supported by thin-section electron microscopy (Figure 1, panel D). We observed a morphology and morphogenesis characteristic of coronaviruses.

We used isolates from the first passage of an OP and an NP specimen for whole-genome sequencing. The genomes from the NP specimen (GenBank accession MT020880) and OP specimen (GenBank accession no. MT020881) showed 100% identity with each other. The isolates also showed 100% identity with the corresponding clinical specimen (GenBank accession no. MN985325).

After the second passage, we did not culture OP and NP specimens separately. We passaged virus isolate 2 more times in Vero CCL-81 cells and titrated by determining the 50% tissue culture infectious dose ($TCID_{50}$). Titers were 8.65×10^6 $TCID_{50}$/mL for the third passage and 7.65×10^6 $TCID_{50}$/mL for the fourth passage.

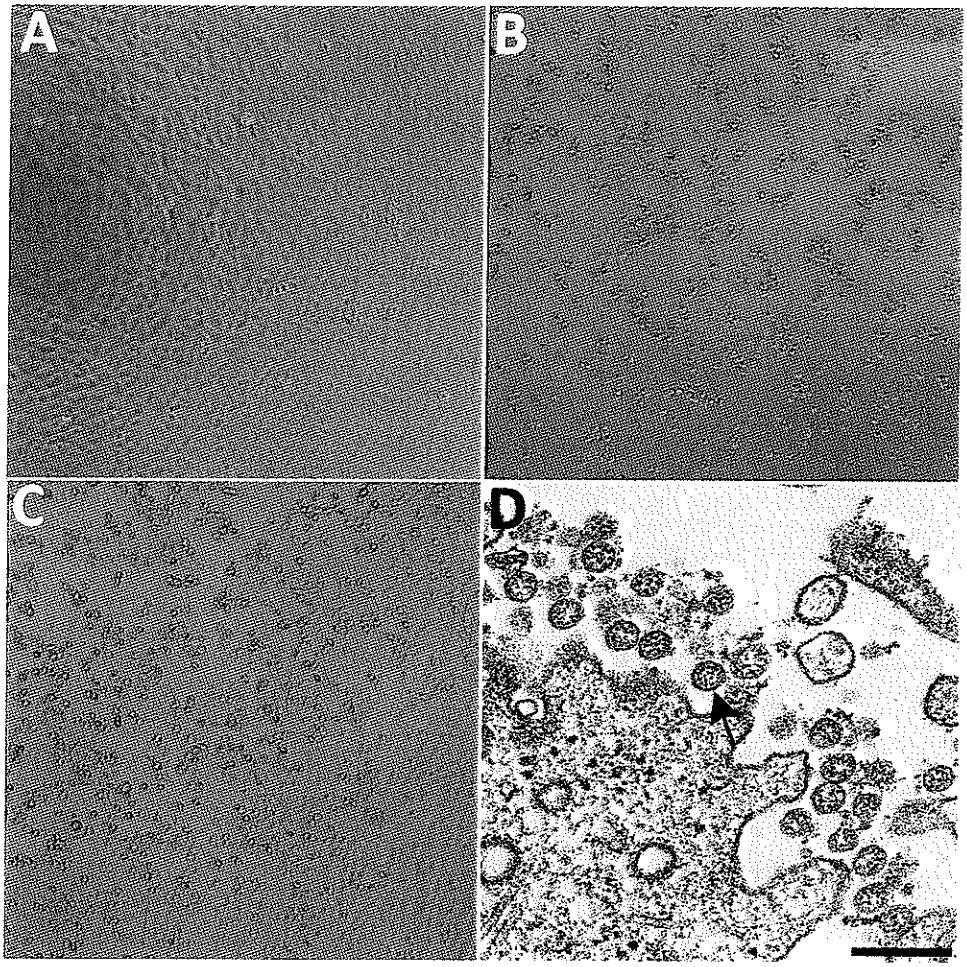

Figure 1. Cytopathic effect caused by severe acute respiratory syndrome coronavirus 2 from patient with coronavirus disease, United States, 2020. A–C) Phase-contrast microscopy of Vero cell monolayers at 3 days postinoculation: A) Mock, B) nasopharyngeal specimen, C) oropharyngeal specimen. Original magnifications ×10). D) Electron microscopy of virus isolate showing extracellular spherical particles with cross-sections through the nucleocapsids (black dots). Arrow indicates a coronavirus virion budding from a cell. Scale bar indicates 200 nm.

We passaged this virus in the absence of trypsin. The spike protein sequence of SARS-CoV-2 has an RRAR insertion at the S1-S2 interface that might be cleaved by furin (*16*). Highly pathogenic avian influenza viruses have highly basic furin cleavage sites at the hemagglutinin protein HA1-HA2 interface that permit intracellular maturation of virions and more efficient viral replication (*17*). The RRAR insertion in SARS-CoV-2 might serve a similar function.

We subsequently generated a fourth passage stock of SARS-CoV-2 on VeroE6 cells, another fetal rhesus monkey kidney cell line. We sequenced viral RNA from SARS-CoV-2 passage 4 stock and confirmed it to have no nucleotide mutations compared with the original reference sequence (GenBank accession no. MN985325). SARS-CoV has been found to grow well on VeroE6 cells and MERS-CoV on Vero CCL81 cells (*18,19*). To establish a plaque assay and determine the preferred Vero cell type for quantification, we titered our passage 4 stock on VeroE6 and VeroCCL81 cells. After infection with a dilution series, SARS-CoV-2 replicated in both Vero cell types; however, the viral titers were slightly higher in VeroE6 cells than in Vero CCL81 cells (Figure 2, panel A). In addition, plaques were more distinct and visible on Vero E6 cells (Figure 2, panel B). As early as 2 days postinoculation, VeroE6 cells produced distinct plaques visible by staining with neutral red. In contrast, Vero CCL81 cells produced less clear plaques and was most easily quantitated by staining with neutral red 3 days postinoculation. On the individual plaque monolayers, SARS-CoV-2 infection of Vero E6 cells produced CPE with areas of cell clearance (Figure 2, panel C). In contrast, Vero CCL81 cells had areas of dead cells that had fused to form plaques, but the cells did not clear. Together, these results suggest that VeroE6 cells might be the best choice for amplification and quantification, but both Vero cell types support amplification and replication of SARS-CoV-2.

Because research has been initiated to study and respond to SARS-CoV-2, information about cell lines and types susceptible to infection is needed. Therefore, we examined the capacity of SARS-CoV-2 to infect and replicate in several common primate and human cell lines, including human adenocarcinoma

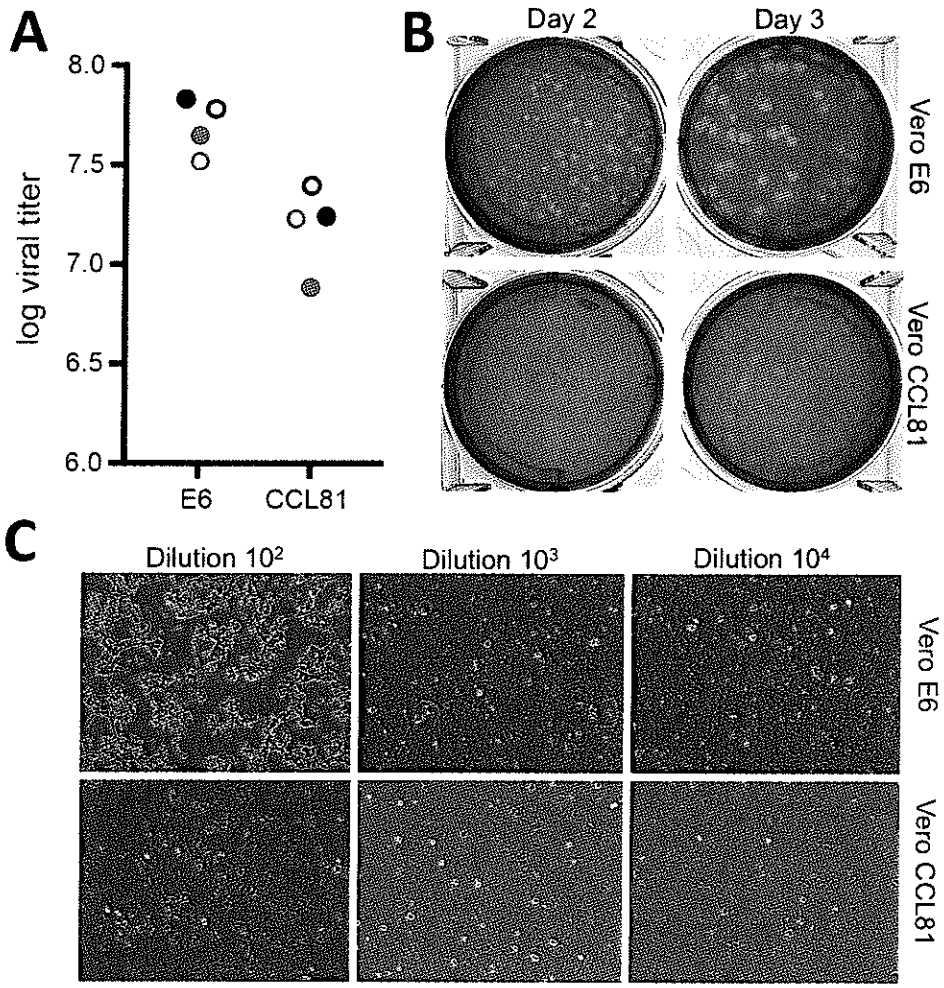

Figure 2. Viral propagation and quantitation of severe acute respiratory syndrome coronavirus 2 from patient with coronavirus disease, United States, 2020. A) Two virus passage 4 stocks (black and gray circles) were quantified by using plaque assay at day 2 (solid circles) and day 3 (open circles) postinfection of Vero E6 and Vero CCL81 cells. B) Plaque morphology for virus on Vero E6 and Vero CCL81 at day 2 and day 3 postinoculation. C) Cell monolayers 2 days postinfection of Vero E6 (top) and Vero CCL81 (bottom) at 3 dilutions. Original magnifications ×40.

cells (A549), human liver cells (HUH7.0), and human embryonic kidney cells (HEK-293T), in addition to Vero E6 and Vero CCL81 cells. We also examined an available big brown bat kidney cell line (EFK3B) for SARS-CoV-2 replication capacity. Each cell line was inoculated at high multiplicity of infection and examined 24 h postinfection (Figure 3, panel A). No CPE was observed in any of the cell lines except in Vero cells, which grew to >10^7 PFU at 24 h postinfection. In contrast, HUH7.0 and 293T cells showed only modest viral replication, and A549 cells were incompatible with SARS-CoV-2 infection. These results are consistent with previous susceptibility findings for SARS-CoV and suggest other common culture systems, including MDCK, HeLa, HEP-2, MRC-5 cells, and embryonated eggs, are unlikely to support SARS-CoV-2 replication (*20*–*22*). In addition, SARS-CoV-2 did not replicate in bat EFK3B cells, which are susceptible to MERS-CoV. Together, the results indicate that SARS-CoV-2 maintains a similar profile to SARS-CoV in terms of susceptible cell lines.

Having established robust infection with SARS-CoV-2 in several cell types, we next evaluated the cross-reactivity of SARS-CoV antibodies against the SARS-CoV-2. Cell lysates from infected cell lines were probed for protein analysis; we found that polyclonal serum against the SARS-CoV spike protein and nucleocapsid proteins recognize SARS-CoV-2 (Figure 3, panels B, C). The nucleocapsid protein, which is highly conserved across the group 2B family, retains >90% amino acid identity between SARS-CoV and SARS-CoV-2. Consistent with the replication results (Figure 3, panel A), SARS-CoV-2 showed robust nucleocapsid protein in both Vero cell types, less protein in HUH7.0 and 293T cells, and minimal protein in A549 and EFK3B cells (Figure 3, panel B). The SARS-CoV spike protein antibody also recognized SARS-CoV-2 spike protein, indicating cross-reactivity (Figure 3, panel C). Consistent with SARS CoV, several cleaved and uncleaved forms of the SARS-CoV-2 spike protein were observed. The cleavage pattern of the SARS spike positive control from Calu3 cells, a respiratory

cell line, varies slightly and could indicate differences between proteolytic cleavage of the spike proteins between the 2 viruses because of a predicted insertion of a furin cleavage site in SARS-CoV-2 (*16*). However, differences in cell type and conditions complicate this interpretation and indicate the need for further study in equivalent systems. Overall, the protein expression data from SARS-CoV nucleocapsid and spike protein antibodies recapitulate replication findings and indicate that SARS-CoV reagents can be used to characterize SARS-CoV-2 infection.

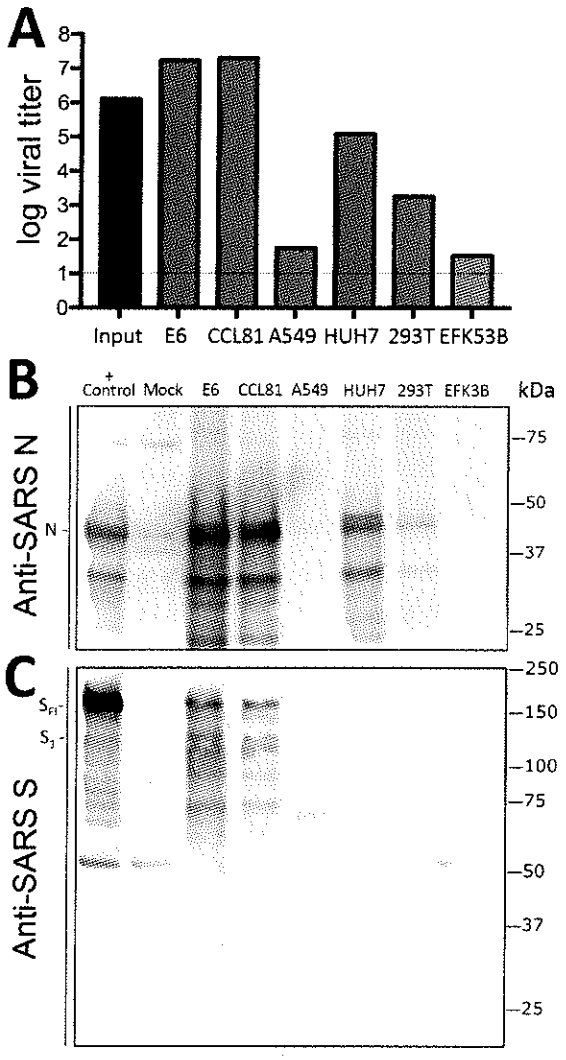

Figure 3. Cell lines from patient with coronavirus disease, United States, 2020, susceptible to SARS coronavirus 2 (SARS-CoV-2). Cell lines were infected with a high multiplicity of infection (>5), washed after adsorption, and subsequently harvested 24 h postinfection for viral titer and protein lysates. A) Viral titer for SARS-CoV-2 quantitated by plaque assay on Vero E6 cells 2 days postinoculation. Infected cell protein lysates were probed by using Western blotting with B) rabbit polyclonal anti-SARS N antibody or C) anti–SARS-CoV S protein antibody. Full-length spike protein (S_{FL}) and spike protein S1 (S_1) are indicated. N, nucleocapsid; S, spike protein; SARS, severe acute respiratory syndrome.

Finally, we evaluated the replication kinetics of SARS-CoV-2 in a multistep growth curve. In brief, we infected Vero CCL-81 and HUH7.0 cells with SARS-CoV-2 at a low multiplicity of infection (0.1) and evaluated viral replication every 6 h for 72 h postinoculation, with separate harvests in the cell-associated and supernatant compartments (Figure 4). Similar to SARS-CoV, SARS-CoV-2 replicated rapidly in Vero cells after an initial eclipse phase, achieving 10^5 $TCID_{50}$/mL by 24 h postinfection and peaking at >10^6 $TCID_{50}$/mL. We observed similar titers in cell-associated and supernatant compartments, which indicated efficient egress. Despite peak viral titers by 48 h postinoculation, major CPE was not observed until 60 h postinoculation and peaked at 72 h postinoculation, indicating that infected monolayers should be harvested before peak CPE is observed. Replication in HUH7.0 cells also increased quickly after an initial eclipse phase but plateaued by 24 h postinoculation in the intracellular compartment at 2 × 10^5 $TCID_{50}$/mL and decreased after 66 h postinoculation. Virus was not detected in the supernatant of infected HUH7 cells until 36 h postinoculation and exhibited lower titers at all timepoints (Figure 4). Major CPE was never observed in HUH7.0 cells. These results are consistent with previous reports for SARS-CoV and MERS-CoV, which suggested similar replication dynamics between the zoonotic CoV strains (*23*,*24*).

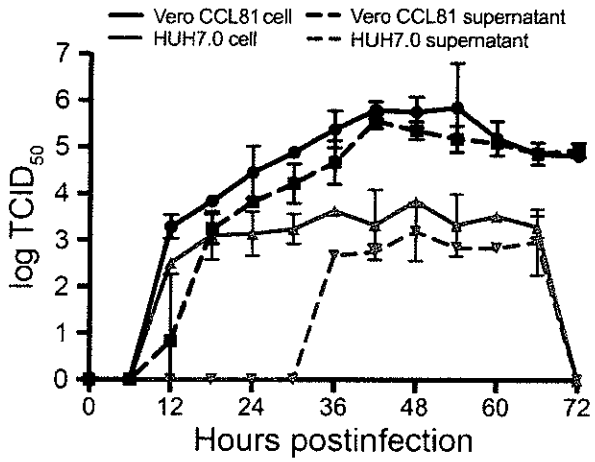

Figure 4. Multistep growth curve for severe acute respiratory syndrome coronavirus 2 from patient with coronavirus disease, United States, 2020. Vero CCL81 (black) and HUH7.0 cells (green) were infected at a multiplicity of infection of 0.1, and cells (solid line) and supernatants (dashed line) were harvested and assayed for viral replication by using $TCID_{50}$. Circles, Vero CCL81 cells; squares, Vero CCL81 supernatants; triangles, HUH7.0 cells; inverted triangles, HUH7.0 supernatants. Error bars indicate SEM. $TCID_{50}$, 50% tissue culture infectious dose.

Discussion

We have deposited information on the SARS-CoV-2 USA-WA1/2020 viral strain described here into the Biodefense and Emerging Infections Research Resources Repository (https://www.beiresources.org) reagent resources (American Type Culture Collection, https://www.atcc.org) and the World Reference Center for Emerging Viruses and Arboviruses, University of Texas Medical Branch (https://www.utmb.edu/wrceva), to serve as the SARS-CoV-2 reference strain for the United States. The SARS-CoV-2 fourth passage virus has been sequenced and maintains a nucleotide sequence identical to that of the original clinical strain from the United States. These deposits make this virus strain available to the domestic and international public health, academic, and pharmaceutical sectors for basic research, diagnostic development, antiviral testing, and vaccine development. We hope broad access will expedite countermeasure development and testing and enable a better understanding of the transmissibility and pathogenesis of this novel emerging virus.

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The reagent described is available through the Biodefense and Emerging Infections Research Resources Repository, National Institutes of Allergy and Infectious Diseases, National Institutes of Health: SARS-related coronavirus 2, isolate USA-WA1/2020, NR-52281.

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REVIEW

The genetic sequence, origin, and diagnosis of SARS-CoV-2

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Abstract
Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is a new infectious disease that first emerged in Hubei province, China, in December 2019, which was found to be associated with a large seafood and animal market in Wuhan. Airway epithelial cells from infected patients were used to isolate a novel coronavirus, named the SARS-CoV-2, on January 12, 2020, which is the seventh member of the coronavirus family to infect humans. Phylogenetic analysis of full-length genome sequences obtained from infected patients showed that SARS-CoV-2 is similar to severe acute respiratory syndrome coronavirus (SARS-CoV) and uses the same cell entry receptor, angiotensin-converting enzyme 2 (ACE2), as SARS-CoV. The possible person-to-person disease rapidly spread to many provinces in China as well as other countries. Without a therapeutic vaccine or specific antiviral drugs, early detection and isolation become essential against novel Coronavirus. In this review, we introduced current diagnostic methods and criteria for the SARS-CoV-2 in China and discuss the advantages and limitations of the current diagnostic methods, including chest imaging and laboratory detection.

Keywords SARS-CoV-2 · COVID-19 · Origin · Diagnosis

Introduction

Coronaviruses are unsegmented single-stranded RNA viruses ranging from 26 to 32 kilobases in length, belonging to the subfamily *Coronavirinae* of the family *Coronaviridae* of the order *Nidovirales* [1]. According to the serotype and genomic characteristics, the *Coronavirinae* subfamily is divided into four major genera: *Alphacoronavirus*, *Betacoronavirus*, *Gammacoronavirus*, and *Deltacoronavirus* [2]. The former two genera primarily infect mammals, whereas the latter two predominantly infect birds [3]. Coronaviruses mainly cause respiratory and gastrointestinal tract infections; six kinds of human CoVs have been previously identified, including the HCoV-NL63 and the HCoV-229E, which belong to the *Alphacoronavirus* genus, and the HCoV-OC43, the HCoVHKU1, the severe acute respiratory syndrome coronavirus (SARS-CoV), and the Middle East respiratory syndrome coronavirus (MERS-CoV), which belong to the *Betacoronavirus* genus [4]. Given the high prevalence and wide distribution of coronaviruses in animals, the large genetic diversity and frequent recombination of their genomes, and increasing human-animal interface activities and frequent cross-species infections, novel coronaviruses are likely to emerge periodically in humans [5].

In December 2019, a group of pneumonia cases was reported at a wholesale seafood market in Wuhan, Hubei province, which was found to be caused by previously unknown Coronaviruses [6]. On December 29, 2019, the local hospitals using a surveillance mechanism for "pneumonia of an unknown etiology," which was established in the wake of the 2003 severe acute respiratory syndrome (SARS) outbreak, identified the first 4 cases which were all associated with the Huanan (Southern China) Seafood Wholesale Market. On December 31, 2019, the Chinese Center for Disease Control and Prevention (China CDC) dispatched a rapid response team to accompany Hubei provincial and Wuhan city health authorities and to conduct an epidemiologic and etiologic investigation. Similar cases were subsequently reported in Wuhan, and many of these patients did not have contacts with the Huanan Seafood Wholesale Markets or animals. Epidemiological investigation showed that about only 1% of

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the patients had direct contact with the live-animal market trade, while more than three quarters were local residents of Wuhan or had made contact with people from Wuhan, suggesting a person-to-person transmission of this novel coronavirus was possible [7]. Airway epithelial cells from infected patients were used to isolate a novel coronavirus, temporarily named 2019-nCoV [8], but later, the Coronavirus Research Group (CSG) of the International Committee for the classification of viruses found that the new coronavirus is related to the SARS virus (SARS-CoV) that swept China in 2003. Both belong to a "species" category called severe acute respiratory syndrome-related coronavirus. Therefore, on February 11, 2020, the International Committee for the classification of viruses designated the name of this coronavirus as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [9]. In addition, the World Health Organization has named the disease caused by the SARS-CoV-2 as coronavirus disease 2019 (COVID-19). The possible person-to-person transmission rapidly spreads to many provinces in China as well as other countries. By February 27, 2020, 78.824 cases were laboratory-confirmed, and 2788 died in China [10]. The current public health emergency is partially similar to the SARS outbreak in southern China in 2002. The two cases share similarities. Both occurred during the winter with initial cases related to an exposure to live animals sold at animal markets, and the amino acid sequence identity between the SARS-CoV-2 and the SARS-CoV S-proteins is 76.47% [11]. The current knowledge of the physical and chemical properties of Coronaviruses is mainly derived from the study of the SARS-CoV and the MERS-CoV. The Coronaviruses are sensitive to exposure to heat (56 °C for 30 min), as well as solvents including ether, 75% ethanol, chlorine-containing disinfectant, peroxyacetic acid, and chloroform. Other lipid solvents can also effectively inactivate the virus except for chlorhexidine [12]. According to Zhong's latest pilot experiment, 4 out of the 62 stool specimens tested positive to the SARS-CoV-2, suggesting oral-fecal route might have played a role in the rapid transmission of SARS-CoV-2 [7]. However, no cases of transmission via the fecal-oral route have yet been reported for SARS-CoV-2. Contamination of fomite is more likely to be caused by airway/hands. At present, respiratory transmission and direct contact transmission are the main routes for SARS-CoV-2.

Genetic sequence and origin of the SARS-CoV-2

The genome of Coronaviruses, ranging from 26 to 32 kilobases in length, includes a variable number of open reading frames (ORFs) [13]. The SARS-CoV-2 genome was reported to possess 14 ORFs encoding 27 proteins [14]. The spike surface glycoprotein plays an essential role in binding to receptors on the host cell and is crucial for determining host tropism and transmission capacity, mediating receptor binding and membrane fusion [15]. Generally, the spike protein of Coronaviruses is functionally divided into the S1 domain, responsible for receptor binding, and the S2 domain, responsible for cell membrane fusion [16]. The eight accessory proteins (3a, 3b, p6, 7a, 7b, 8b, 9b, and orf14) and four major structural proteins, including the spike surface glycoprotein (S), small envelope protein (E), matrix protein (M), and nucleocapsid protein (N), are located in the 3′-terminus of the SARS-CoV-2 genome [14]. When researchers compare the SARS-CoV-2 with the SARS-CoV at the amino acid level, they found the SARS-CoV-2 was quite similar to the SARS-CoV, but there were some notable differences in the 8a, 8b, and 3b protein [14]. When researchers compared the SARS-CoV-2 with the MERS-CoV, they found that the SARS-CoV-2 was distant from and less related to the MERS-CoVs. From the phylogenetic tree based on whole genomes, the SARS-CoV-2 is parallel to the SARS-like bat CoVs, while the SARS-CoV has descended from the SARS-like bat CoV lineage, indicating that SARS-CoV-2 is closer to the SARS-like bat CoVs than the SARS-CoVs based on of the whole-genome sequence [14]. Analysis of the genome from nine patients' samples also confirmed that the SARS-CoV-2 was more similar to two SARS-like bat CoVs from Zhoushan in eastern China, bat-SL-CoVZC45 and bat-SL-CoVZXC21, than to the SARS-CoV and the MERS-CoV [17]. At the whole-genome level, the SARS-CoV-2 shares an 87.99% sequence identity with the bat-SL-CoVZC45 and 87.23% sequence identity with the bat-SL-CoVZXC2, less genetically similar to the SARS-CoV (about 79%) and MERS-CoV (about 50%) [17]. At the protein level, the lengths of most of the proteins encoded by the SARS-CoV-2, the bat-SL-CoVZC45, and the bat-SL-CoVZXC21 were similar, with only a few minor insertions or deletions [17]. Although the SARS-CoV-2 was closer to the bat-SL-CoVZC45 and the bat-SL-CoVZXC21 at the whole-genome level, the receptor-binding domain of the SARS-CoV-2 located in lineage B was closer to that of the SARS-CoV [17]. Given the close relationship between the SARS-CoV-2 and the SARS-CoVs or the SARS-like bat CoVs, further studies of the amino acid substitutions in different proteins could explain how the SARS-CoV-2 differs structurally and functionally from the SARS-CoVs and how these differences affect the functionality and pathogenesis of the SARS-CoV-2.

It was reported that 27 of the first 41 infected patients had been exposed to the Huanan Seafood Market [18]. Thus, it was believed that the new coronavirus originated from the Huanan Seafood Market in Wuhan and spread from animal hosts to humans in the process of wildlife trade, transportation, slaughter, and trade. Bats have the most variety of coronaviruses in their bodies and are the hosts of many kinds of coronaviruses, such as the SARS-CoV and the MERS-CoV

[19]. The SARS-CoV and the MERS-CoV are considered highly pathogenic, and it is very likely that the SARS-CoV was transmitted from bats to palm civets and the MERS-CoV was transmitted from bats to dromedary camels and finally to humans [20, 21]. Given the high sequence similarity between the SARS-CoV-2 and the SARS-like bat CoVs from *Hipposideros* bats in China, the natural host of the SARS-CoV-2 may be the *Hipposideros* bat. The discovery that pangolin coronavirus genomes have 85.5% to 92.4% sequence similarity to SARS-CoV-2 suggests pangolins should be considered as possible hosts in the emergence of SARS-CoV-2 [22].

Diagnosis

According to the seventh edition of Pneumonia Diagnosis and Treatment program for novel coronavirus infection reported by the National Health Commission of the People's Republic of China, suspected cases were defined as patients having fever or respiratory symptoms, a typical ground-glass opacity chest imaging as well as a history of exposure to wildlife in the Wuhan seafood market, and a travel history or contact with people from Wuhan within 2 weeks of diagnosis [12]. Confirmed cases with the SARS-CoV-2 were identified as a positive result of a high-throughput sequencing or an RT-PCR assay for respiratory specimens including nasal and pharyngeal swab specimens, bronchoalveolar lavage fluid, sputum, or bronchial aspirates or a positive result of anti-SARS-CoV-2 IgM/IgG or the titer of anti-SARS-CoV-2 IgG antibody in the recovery period was four times or more higher than in the acute period [12]. At present, the diagnosis of the COVID-19 is mainly based on clinical characteristics, epidemiological history, chest imaging, and laboratory detection.

Clinical characteristics and epidemiological history

The most common symptoms of confirmed patients were fever, cough, and myalgia or fatigue, whereas sputum production, headache, diarrhea, and vomiting were rare [23–26]. Mild cases only have a low fever and mild fatigue, without pneumonia. Severe and moderate cases had clinical manifestations of dyspnea, lymphopenia, and hypoalbuminemia, which mainly occurred in elderly patients [23]. It is worth noting that patients with severe or critical illness may have a moderate or low fever, or even no significant fever [12]. The elderly and those with chronic diseases, including diabetes, hypertension, and cardiovascular disease, have poor prognoses [12]. Most severe patient died of severe pneumonia, severe respiratory failure, and multiple organ failure [26]. Epidemiological investigations indicate that most patients were local residents of Wuhan or had direct exposure to the Huanan Seafood Market, a travel history to Wuhan, or contact with confirmed cases [7]. In addition, outbreaks within family clusters have been reported from several provinces in China [27]. An increasing number of cluster cases including family cluster cases are occurring [24, 25].

Chest imaging

The most common patterns seen on chest CT were bilateral, peripheral, and ground-glass opacity [28, 29]. Less common CT findings were nodules, cystic changes, bronchiolectasis, pleural effusion, and lymphadenopathy [28, 29]. Chest CT images of an early-stage COVID-19 patients showed multiple small plaques and interstitial changes. The findings of a progressive stage chest CT images included a bilateral multiple ground-glass opacity and an infiltrating opacity with consolidation, interstitial thickening or fibrous stripes [29–31]. The diffuse lesions in bilateral lungs could be seen in the most seriously affected patients, whose CT showed as "white lungs" [31].

Laboratory detection

Specific laboratory detection

Isolation of the causal agent and determination of its partial genome sequence provided the basis for next-generation sequencing or real-time reverse transcriptase-polymerase chain reaction (RT-PCR) methods for the SARS-CoV-2 [14, 17]. After the SARS-CoV-2 was isolated from a lower respiratory tract specimen, a diagnostic RT-PCR test was developed. RT-PCR tests were based on the RNA-dependent RNA polymerase (RdRp) gene of the ORF1ab sequence, E gene, N gene, and S gene of the SARS-CoV-2 genome [32–35]. Among these assays, RT-PCR assays targeting the RdRp assay had the highest analytical sensitivity [32]. The SARS-CoV-2 nucleic acid can be detected in nasal and pharyngeal swab specimens, bronchoalveolar lavage fluid, sputum, bronchial aspirates, blood, anal swab, and other samples by an RT-PCR [36, 37]. In a case with severe peptic ulcers after the onset of symptoms, the SARS-CoV-2 was directly detected in the esophageal erosion and at the bleeding site [7]. Some patients infected with the SARS-CoV-2 also displayed gastrointestinal symptoms such as diarrhea [23, 38] because some viruses may enter the digestive tract through the throat, infecting the intestinal epithelial cells and activating the intestinal immune response. Thus, the SARS-CoV-2 nucleic acid can also be detected in the stool samples of some patients [7, 36, 37]. High-throughput sequencing or an RT-PCR assay has become a standard and formative assessment for the diagnosis of the COVID-19 [12]. However, nucleic acid amplification kits sometimes produced false-negative results among patients whose clinical features, chest imaging, and laboratory detection accorded with the COVID-19 [30, 39]. There are several

possible reasons for the false-negative results from the nucleic acid kit. Firstly, although older age was correlated with higher viral load [40], it is not clear whether the viral load in body fluids has a positive linear correlation with the severity of symptoms after infection. If the virus in the suspected patients remains to be rapidly replicated and released in the lungs, the nasal and pharyngeal swabs sampling may not collect enough virus for diagnosis. Secondly, the current common sampling method is to collect nasal and pharyngeal swabs, sputum, or the alveolar lavage fluid [36, 40, 41]. Few patients with the SARS-CoV-2 infection had prominent signs and symptoms of the respiratory tract, indicating that the target cells may be located in the lower airway [18]. The viral nucleic acid is most easily detected in the alveolar lavage fluid, followed by sputum, nasal, and pharyngeal swabs [41–43]. A study of 4880 cases showed that the alveolar lavage fluid exhibited the most highest positive rate of 100% for SARS-CoV-2 ORF1ab gene; the sputum exhibited a 49.12% positive rate, and the nasal and pharyngeal swabs samples showed a poor positive rate of 38.25% [41]. Alveolar lavage fluid collection is generally suitable for patients with a severe or critical illness, not mild cases. Sputum specimens are also more difficult to obtain because few patients with the SARS-CoV-2 infection had sputum production [7, 18]. Due to the limitations associated with operations and patient acceptance, the most common sampling method in clinical practice is nasal and pharyngeal swab collection. However, respiratory samples collected from 80 individuals at different stages of infection showed a median of $7{\cdot}99 \times 10^4$ in nasal and pharyngeal swab samples and $7{\cdot}52 \times 10^5$ in sputum samples [36]. Sputum samples generally showed higher viral loads than throat swab samples [36, 43]. The low viral load in nasal and pharyngeal swab makes the diagnosis of the SARS-CoV-2 more difficult. On the other hand, RT-PCR test results of pharyngeal swab specimens were variable and potentially unstable [44]. It was reported that patients with initial non-positive results were eventually confirmed with COVID-19 by 3~5 repeated swab PCR tests [44]. The phenomenon of SARS-CoV-2 positive in the stool samples but negative nucleic acid in throat swab specimens indicated that selecting fecal samples for a nucleic acid test may be an alternative strategy [45]. Considering that the SARS-CoV-2 nucleic acid can be detected in nasal and pharyngeal swab specimens, bronchoalveolar lavage fluid, sputum, bronchial aspirates, blood, and anal swab [36, 37], it is suggested to collect samples from multiple site of the same patient at different stages and combine them for detection to improve the positive rate. Thirdly, the SARS-CoV-2 is an RNA virus with low stability, which is easily degraded by RNA enzymes released after exogenous or cellular destruction, affecting the final detection efficiency. Improper sampling location, insufficient sampling strength, and irregular sample delivery process account for the false-negative results of the nucleic acid kit test [39]. Besides, in order to improve the sensitivity of detection, most manufacturers choose two or more regions of viral nucleic acid sequence for detection, including the ORF1ab sequence, E gene, N gene, and S gene of the SARS-CoV-2 genome [32–35]. In actual tests, there is a certain proportion of positive results of a single target gene locus indicating that the sensitivity of the reagent to different gene regions is indeed different [41], which may also be caused by the competition between the loci of two or three target genes. Furthermore, reagent reaction conditions, reaction system, and nucleic acid addition amount may affect the sensitivity of detection and analysis [46]. It is an effective measure for the clinical laboratory to carry out quality control for each batch of reagents by using the confirmed negative and positive samples before routine work.

Based on the above reasons, detection of the viral RNA using RT-PCR can only achieve a sensitivity of 30~60% [41, 47, 48], depending on the course and condition of the patient, the type and number of clinical specimens collected, and the protocol used. The older had higher positive rate than the young [41] which may be explained by the finding that the older was correlated with higher viral load [40]. Supplement serum IgM/IgG antibody detection against the SARS-CoV-2 internal nucleoprotein (NP) and surface spike protein receptor-binding domain (RBD) can make up for the shortcomings of RT-PCR in some cases [40, 49]. The antibody is the product of a humoral immune response after infection with the virus. Generally, IgM antibodies rise within a few days after a viral infection and can be detected as soon as a week of incubation, and IgG antibodies appear in the middle and late stages of the infection. There is a process of a continuous increase in the antibody titer, and it remains in the blood circulation for a long time. At the moment, the most widely used methods for serodiagnosis of the SARS-CoV-2 infection in clinical microbiology laboratories are antibody detection in acute- and convalescent-phase sera by colloidal gold immunochromatography and enzyme-linked immunosorbent assay (ELISA) [40]. In short, a test for IgM/IgG antibodies can also determine whether a patient has been infected with the SARS-CoV-2 recently or previously and act as a supplementary detection to identify patients with high clinical suspicion of the SARS-CoV-2 infection but negative RT-PCR findings [40, 49]. The new serological diagnostic kits for IgM and IgG antibodies for SARS-CoV-2 have the advantages of high sensitivity and early diagnosis. In addition, the operational requirements of antibody detection in clinical microbiology laboratories are relatively low, fast, capable of large quantities, and can be completed in basic laboratories compared with the nucleic acid test. Anti-SARS-CoV-2 IgM antibody was positive at 3~5 days after onset, and the titer of anti-SARS-CoV-2 IgG antibody in the recovery period was four times or more higher than in the acute period [12]. Although the supplementary antibody test can make up for the missed diagnosis of RT-PCR, it still cannot diagnose all infected patients. The

detection of IgM and IgG antibodies can only achieve a sensitivity of 70% at 4~6 days after admission for COVID-19 patients (unpublished data from our group). The detection of IgM and IgG antibodies may be futile for the elderly, because of hypoimmunity and a weak antibody production capacity.

Nonspecific laboratory detection

The laboratory examination of patients at an early stage showed leucopenia, lymphopenia, high level of aspartate aminotransferase, C-reactive protein (CRP), and erythrocyte sedimentation rate [18]. Most patients had normal serum levels of procalcitonin. Compared with moderate cases, severe cases more frequently had lymphopenia, with higher levels of alanine aminotransferase, lactate dehydrogenase, C-reactive protein, ferritin, and D-dimer as well as markedly higher levels of IL-2R, IL-6, IL-10, and TNF-α [23]. Typical abnormal laboratory findings in pediatric patients were elevated creatine kinase MB, decreased lymphocytes, leucopenia, and elevated procalcitonin [24]. Recent studies have also shown another potential diagnostic biomarker for the SARS-CoV-2 diagnosis. Renin cleaves liver-derived angiotensinogen (AGT) into angiotensin I, which is then further processed by the angiotensin-converting enzyme (ACE) into the octapeptide angiotensin II. The abnormal increase of angiotensin II has been reported to be associated with hypertension, heart failure, and lung and kidney dysfunction as well as several pathophysiological features, including inflammation, metabolic dysfunction, and aging [50, 51]. Xu et al. performed structural modeling of the S-protein of the SARS-CoV-2 to evaluate its ability to interact with human angiotensin-converting enzyme 2 (ACE2) molecules. Because of the loss of hydrogen bond interactions due to replacing Arg426 with Asn426 in the SARS-CoV-2 S-protein, the binding free energy for the SARS-CoV-2 S-protein increased by 28 kcal mol^{-1} when compared with the SARS-CoV S-protein binding. The results revealed that the SARS-CoV-2 S-protein has a strong binding affinity to human ACE2 [11]. A study discovered the markedly increased level of angiotensin II in the plasma samples from SARS-CoV-2-infected patients was linearly correlated with viral load and lung injury [52]. It is suggested that the imbalance of the renin-angiotensin-aldosterone system is caused by the SARS-CoV-2, and angiotensin receptor blocker (ARB) drugs may be used as a potential repurposing treatment of the SARS-CoV-2 infection. Similar studies have demonstrated that the SARS-CoV could bind to its receptor ACE2, downregulating its expressions, resulting in increased angiotensin II levels in mouse blood samples, signaling through angiotensin II receptor 1, leading to an acute lung injury [53]. Besides, markedly, elevation of angiotensin II level in the H7N9-infected patients was associated with the disease severity and outcomes [54].

Discussion

Chest CT imaging showed that 76.4% of infected patients manifested as pneumonia on admission, which was mainly ground-glass opacity (50%) and bilateral patchy shadowing (46.4%). The majority of severe patients could be diagnosed by chest X-ray and chest CT imaging. Despite these predominant manifestations, it was reported that 221 out of the 926 (23.87%) in severe cases compared with 9 out of the 173 non-severe cases (5.20%) who had no abnormal radiological findings were diagnosed by symptoms plus RT-PCR positive findings, suggesting that not all patients had abnormal chest radiological findings of pneumonia. Chest CT images of the early-stage COVID-19 patients showed unilateral or bilateral ground-glass opacity, which was similar to some non-COVID-19 images of patients with the respiratory syncytial viral (RSV), mycoplasma, and parainfluenza virus, suggesting that chest CT scans cannot the identify COVID-19 patients and the non-COVID-19 patients in some cases. Co-infection with other viruses such as influenza A/B, rhino/enterovirus, respiratory syncytial virus, other atypical pathogens, fungi, and bacteria has been reported in the COVID-19 patients [49, 55]. Mixed infection among COVID-19 patients makes the diagnosis of chest CT images more difficult. Besides, positive respiratory pathogen results cannot serve as evidence for the exclusion of SARS-COV-2 infection. Methods of pathogen-specific detection are mainly divided into four types, including virus culture, nucleic acid detection, antigen detection, and antibody detection. In terms of virus culture, the cultivation of the SARS-CoV-2 requires biosafety level 3 laboratory facilities, which are not available in most clinical microbiology laboratories. Thus, the cultivation of the SARS-CoV-2 is mainly used for scientific research. Commercial antigen detection kits require the preparation of monoclonal antibodies and polyclonal antibodies, whereas it costs a long time from production to extraction during antibody preparation, and the preparation process is complicated. Detection of the viral nucleic acid using an RT-PCR assay has become a standard and formative assessment for the diagnosis of COVID-19. However, detection of viral RNA using RT-PCR can only achieve a sensitivity of 30~60%, depending on the course and condition of the patient, the type and number of clinical specimens collected, and the protocol used. In order to improve the positive rate of detection, it is suggested to collect multiple site samples of the same patient at different stages repeatedly and combine them for detection. The phenomenon of SARS-CoV-2 positive in the stool samples but negative nucleic acid in throat swab specimens should be taken seriously. Patients with early or mild illness may have a low viral load in nasal and pharyngeal swabs, resulting in false-negative nucleic acid tests. Thus, selecting fecal samples for a nucleic acid test may be an alternative strategy, regardless of the presence or absence of gastrointestinal symptoms such as

diarrhea. In addition, a fecal-oral transmission might exist in the transmission of 2019-nCoV; thus, the transmission via gastrointestinal secretions should be fully considered to control the rapid spread worldwide. Whole genome sequencing (WGS) method can overcome the mutation problems which cause false-negative results in RT-PCR [55, 56], whereas it is not applicable to clinical practice considering the economic status of patients. For individuals with high clinical suspicion of the SARS-CoV-2 infection but negative RT-PCR findings, the detection of IgM/IgG antibodies should be considered. We recommend IgM antibody testing 1 week after infection and IgG antibody testing 4 weeks after infection. Although the supplementary antibody test can make up for the missed diagnosis of RT-PCR, it cannot diagnose all the infected patients. Collectively, for chest CT scans, RT-PCR assays, and the detection of IgM/IgG antibodies, multiple and repetitive tests should be considered during different stages of the COVID-19. Further research of SARS-CoV-2 and the development of more sensitive detection methods will facilitate the diagnosis of COVID-19. In addition, the development of broad-spectrum antiviral drugs and vaccines will enhance the ability to manage future outbreaks caused by this cluster of viruses.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethics approval Not applicable.

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Review

SARS-CoV-2: an Emerging Coronavirus that Causes a Global Threat

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Abstract

An ongoing outbreak of pneumonia caused by a novel coronavirus, currently designated as the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), was reported recently. However, as SARS-CoV-2 is an emerging virus, we know little about it. In this review, we summarize the key events occurred during the early stage of SARS-CoV-2 outbreak, the basic characteristics of the pathogen, the signs and symptoms of the infected patients as well as the possible transmission pathways of the virus. Furthermore, we also review the current knowledge on the origin and evolution of the SARS-CoV-2. We highlight bats as the potential natural reservoir and pangolins as the possible intermediate host of the virus, but their roles are waiting for further investigation. Finally, the advances in the development of chemotherapeutic options are also briefly summarized.

Key words: Coronavirus, Novel coronavirus, pneumonia, SARS-CoV-2, COVID-19

Introduction

On 23 Feb 2020, the lock-down of Wuhan, a central city in China, has alarmed people all over the world of an emerging novel coronavirus that is posing a major public health and governance challenges. The novel virus, previously called the 2019-novel coronavirus (2019-nCoV), is currently designated as the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). As of 27 Feb, this emerging infection has been reported in 47 countries, causing over 82,294 infections with 2,804 deaths (Fig. 1) [1]. This novel virus is also becoming a mounting threat to Chinese and global economies.

Coronaviruses (CoVs) are members of the family Coronaviridae, the enveloped viruses that possess extraordinarily large single-stranded RNA genomes ranging from 26 to 32 kilobases in length [2]. CoVs have been identified in both avian hosts and various mammals, including bat, camels, dogs and masked palm civets, and are previously regarded as pathogens that only cause mild diseases in the immunocompetent people until the emergence of the coronavirus causing severe acute respiratory syndrome (SARS-CoV) in late of 2002 [3-6]. Currently, at least seven coronavirus species are known to cause diseases in humans. The viruses of 229E, OC43, NL63 and HKU1 only cause common cold symptoms, which are mild. Severe illness can be caused by the remaining three viruses, namely SARS-CoV, which resulted in the outbreak of SARS in 2002 and 2003 [3,4]; the coronaviruses that are responsible the Middle East respiratory syndrome (MERS-CoV), which emerged in 2012 and remains in the circulation in camels [7]; and SARS-CoV-2, the viruses emerged in December 2019 in Wuhan of China and a great effort is being undertaken to contain its spreading [8]. In this review, we will briefly introduce the outbreak history of SARS-CoV-2, the signs and symptoms of the infected patients, its transmission dynamics, the advances in the understanding on its evolutional origin and the chemotherapeutic options being developed for the treatment of its infection.

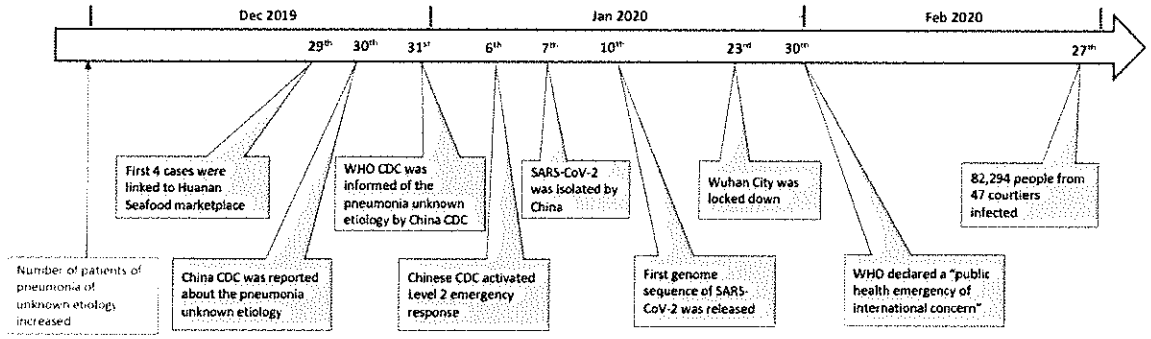

Figure 1. Key events in the early stage of SARS-CoV-2 outbreak.

The key events of SARS-CoV-2 outbreak and the pathogen characteristics

Since December 2019, an increasing number of patients with pneumonia of unknown etiology in Wuhan, a city with 11 million people, have alarmed the local hospital. On 29 December 4 cases were linked to Huanan Seafood wholesale market [9], where non-aquatic live animals, including several kinds of wild animals, were also on the sales. The local Center for Disease Control (CDC) then found additional patients linked to the same market after investigation, and reported to China CDC on 30 Dec 2019 [9]. The second day, World Health Organization (WHO) was informed of the cases of pneumonia of unknown etiology by China CDC [10]. On 6 Jan 2020, a level 2 emergency response was launched by China CDC [11].

The causal agent was not identified until 7 Jan 2020; a new type of coronavirus was isolated by Chinese authority [10]. The genome sequence of SARS-CoV-2 (WH-Human_1) was first released and shared by China on 10 Jan [12]. The isolation and identification of SARS-CoV-2 apparently facilitated the development of molecular diagnostic methods and the confirmation of the infected patients. As of 21 Jan, there are 270 cases were confirmed from Wuhan [13]. On 23 Jan, Wuhan city was locked down by local government. On 30 Jan, WHO declared a "public health emergency of international concern" (Fig. 1).

Subsequently, the viruses were successfully isolated from several laboratories [8,14,15]. The virion of SARS-CoV-2 looks like a solar corona by transmission electron microscopy imaging: the virus particle is in a spherical shape with some pleomorphism; the diameter of the virus particles range from 60 to 140 nm with distinctive spikes about 8 to 12 nm in length [8]. The observed morphology of SARS-CoV-2 is consistent with the typical characteristics of the Coronaviridae family. The genome sequence of SARS-CoV-2 from clinical samples has been obtained by several laboratories with deep sequencing [8,14-18]. The viral genome of SARS-CoV-2 is around 29.8 kilobase, with a G+C content of 38%, in total consisting of six major open reading frames (ORFs) common to coronaviruses and a number of other accessory genes [14,16]. The sequences analysis showed that the genome sequences of viruses from different patients are very conserved [14,15,19], implying that the human virus evolves recently.

Signs and symptoms of patients infected by SARS-CoV-2

A typical characteristic of the SARS-CoV-2 infected patient is pneumonia, now termed as Coronavirus Disease 2019 (COVID-19), demonstrated by computer tomographic (CT) scan or chest X -ray [3,8,18]. In the early stages, the patients showed the acute respiratory infection symptoms, with some that quickly developed acute respiratory failure and other serious complications [20]. The first three patients reported by the China Novel Coronavirus Investigating and Research Team all developed severe pneumonia and two of these three patients with available clinical profiles showed a common feature of fever and cough [8]. A subsequent investigation of a family of six patients in the University of Hong Kong-Shenzhen Hospital demonstrated that all of them had pulmonary infiltrates, with a variety of other symptoms [18]. The chest X-ray and CT imaging in a study showed that 75% of 99 patients demonstrated bilateral pneumonia and the remaining 25% unilateral pneumonia [21]. Overall, 14% of the patients showed multiple mottling and ground-glass opacity [21]. The first cases of coronavirus infection in the United States also showed basilar streaky opacities in both lungs by chest radiography. However, the pneumonia for this patient was only detected on the day 10 of his illness [22]. It is also of note that one of patients among the family of six patients did not present any other symptoms and signs, but had ground-glass lung opacities identified by CT scan [18].

Table 1. Common signs and symptoms of SARS-CoV-2 infected patients from four reports

Signs or Symptoms	Number of patients with signs or symptoms from each report				Number of patients with signs or symptoms	Total number of patients	Percentage
	Report 1 [21]	Report 2 [23]	Report 3 [24]	Report 4 [25]			
Fever	82 (n=99)	40 (n=41)	136 (n=138)	975 (n=1099)	1233	1377	90%
Cough	81 (n=99)	31 (n=41)	82 (n=138)	745 (n=1099)	939	1377	68%
Sputum production/ Expectoration	NR	11 (n=39)	37 (n=138)	370 (n=1099)	418	1276	33%
Shortness of breath/ Dyspnoea	31 (n=99)	22 (n=40)	43 (n=138)	205 (n=1099)	301	1376	22%
Headache	8 (n=99)	3 (n=38)	9 (n=138)	150 (n=1099)	170	1374	12%
Sore throat/Pharyngalgia	5 (n=99)	NR	24 (n=138)	153 (n=1099)	182	1336	14%
Diarrhoea	2 (n=99)	1 (n=38)	14 (n=138)	42 (n=1099)	59	1374	4%

NR: Not Recorded.

At least four comprehensive studies on the epidemiological and clinical characteristics of SARS-CoV-2 infected patients have been performed [21, 23-25]. The most common signs and symptoms of patients are fever and cough [21,23-25]. Fatigue was complained by 96% of patients (n=138) in one study [24], but was less outstanding (18%, n=44) in another report [23]. A combinational analysis of the common recorded signs or symptoms of the reported cases found that fever was observed in around 90% of the SARS-CoV-2 infected patients; the number of patients with cough is relatively less (68%) compared to fever (Table 1). In addition, shortness of breath or dyspnea, muscle ache, headache, chest pain, diarrhea, haemoptysis, sputum production, rhinorrhoea, nausea and vomiting, sore throat, confusion, and anorexia were also observed in a proportion of the patients [21,23-25] (Table 1).

A common feature of patients of SARS, MERS or COVID-19 is the presence of severe acute respiratory syndrome; however, the estimated fatality rate of COVID-19 (2.3%) is much lower than SARS (~10%) and MERS (~36%) [26,27]. Furthermore, the viruses responsible for above three diseases are evolutionary distinct (See below for details) [19].

Transmission of the virus

It is clear now that SARS-CoV-2 can be transmitted by human-to-human despite the majority of the early cases had contact history with the Huanan Seafood market [11,18,28]. Analysis of 425 patients with confirmed COVID-19 showed that the incubation period is 3 to 7 days. The mean was 5.2 days (95% CI: 4.1 to 7.0), and the 95th percentile of the distribution is 12.5 days (95% CI: 9.2 to 18) [11]. Notably, it was reported that the incubation period could be as long as 24 days in a rare case [25]. The basic reproductive number (R_0) up to the period of 4 Jan 2020 was estimated based on the study of 425 patients to be 2.2 (meaning that one patient has been spreading infection to 2.2 other people) [11], slightly smaller than the value of 2.68 by a modelling in another [29]. The R_0 of SARS-CoV-2 from both of these two studies is smaller than that of SRAS, which are 3 before public health measures were implemented [30]. However, subsequent investigation based on the analysis of high-resolution real-time human travel and infection data estimated that the R_0 is much larger, ranging from 4.7 to 6.6 before the control measures [31], implying that SARS-CoV-2 is highly contagious and more infectious than initially estimated. This conclusion is consistent with the wide spread of SARS-CoV-2 within a short period time and was also echoed by the finding that SARS-CoV-2 Spike (S) protein had 10- to 20-fold higher affinity to human angiotensin-converting enzyme 2 (ACE2) receptor than that of SARS-CoV based on the Cryo-EM structure analysis of S proteins [32]. Similar to SARS-CoV, the entry of SARS-CoV-2 into host cells depends on the recognition and binding of S protein to ACE2 receptor of the host cells [14,33]. The high affinity of S protein to ACE2 receptor likely contributes to the quick spreading of virus. The finding of ACE2 as the receptor of SARS-CoV-2 also indicates that human organs with high ACE2 expression level, such as lung alveolar epithelial cells and enterocytes of the small intestine, are potentially the target of SARS-CoV-2 [34].

As a new coronavirus, it is not known yet about how SARS-CoV-2 spreads. Current knowledge for SARS-CoV-2 transmission is largely based on what is known from the similar coronaviruses, particularly SARS-CoV and MERS-CoV, in which human-to-human transmission occurs through droplets, contact and fomites. SARS-CoV is predominantly transmitted through indirect or direct contact with mucous membranes in the mouth, eyes, or nose [35]. It has been shown that unprotected eyes and exposed mucous membranes are vulnerable to SARS-CoV transmission [36]. A member of the national expert panel on pneumonia was infected by SARS-CoV-2 after the inspection in Wuhan [37]. As he wore a N95 mask but not any eye protector, and experienced eye redness before the onset of pneumonia, it was thus suspected that unprotected exposure of the eyes to

SARS-CoV-2 might be another transmission pathway [37]. However, SARS-CoV-2 was not detected from the conjunctival swab sample in a confirmed COVID-19 patent with conjunctivitis [38], suggesting that more evidences are needed before concluding the conjunctival route as the transmission pathway of SARS-CoV-2. The mode of transmission by MERS-CoV is not well understood but is believed to spread largely via the respiratory close contact route [39,40].

Based on the transmission mode of SARS-CoV and MERS-CoV, a serial of preventive measures have been recommended, including avoiding close contact with people suffering from acute respiratory infections and frequent hand-washing [41]. The viruses of SARS-CoV-2 were also detected in the stool samples in some patients but not all [18,22], suggesting that a possible fecal-oral transmission occurs [42]. A systematic study showed that viruses could be detected in oral swabs, anal swabs and blood samples of the patients, and the anal swabs and blood could test positive when oral swab tested negative [43]. Furthermore, a trend of shift from more oral positive in the collected samples during the early period of patient infection to more anal positive during later period of infection was also found [43]. Therefore, a multiple shedding routes of SARS-CoV-2 might exist.

One of the challenges for preventive control of SARS-CoV-2 spreading is that the viruses are likely transmitted by asymptomatic contact. A German businessman was found infected by SARS-CoV-2 after attending a conference together with a colleague, who had no signs or symptoms of infection but had become ill due to the SARS-CoV-2 infection later [44]. This observation suggests that infected patients likely start to shed viruses before the onset of any symptom, which undoubtedly will bring great challenge to the current practice of preventive control by measuring body temperature. Despite the claim of the transmission by asymptomatic contact has been challenged [45], other asymptomatic carriers were also observed to transmit the viruses of SARS-CoV-2 [46,47]. Consistently, a study found that an asymptomatic patient had a similar vial loads in the samples of nasal and throat swabs to that of the symptomatic patients [48].

The origin and evolution of SARS-CoV-2

It is critical to identify the origin, native host(s) and evolution pathway of the virus that causes an outbreak of a pandemic. This information can help understand the molecular mechanism of its cross-species spread and implement a proper control measure to prevent it from further spreading. The association of initially confirmed SARS-CoV-2 cases with Huanan Seafood market suggested that the marketplace has played a role in the early spreading [11,23], however, whether it is the origin of the outbreak and what is the native host(s) of SARS-CoV-2 remain uncertain. In fact, the firstly documented patient was not linked to Huanan Seafood market [23].

The analysis of SARS-CoV-2 origin was firstly performed based on the genome sequence of virus isolates from six patients [19]. When compared with SARS-CoV and MERS-CoV, the nucleotide sequences of SARS-CoV-2 showed a higher homology with that of SARS-CoV while was relatively poor with that of MERS-CoV [19]. Despite some of the six major OFRs of SARS-CoV-2 genes share less than 80% identity in nucleotide acids to SARS-CoV, the seven conserved replicase domains in ORF1ab has 94.6% sequence identity in amino acids between SARS-CoV-2 and SARS-CoV [14], suggesting that these two viruses might belong to the same species. The origin of SARS-CoV has been extensively investigated. Masked palm civets were initially considered to transmit SARS-CoV to humans as a close variant of SARS-CoV was detected from palm civets [49]. This conclusion was supported by the fact that three of the four patients had the record of contact with palm civets during the two small-scale of SARS outbreaks occurred in late 2003 and early 2004 [50, 51]. However, a deep investigation based on the genome sequence of isolated viruses showed that SARS-CoV-like virus in civet had not been circulating for long [52]. Subsequently, coronaviruses with high similarity to the human SARS-CoV or civet SARS-CoV-like virus were isolated from horseshoe bats, concluding the bats as the potential natural reservoir of SARS-CoV whereas masked palm civets are the intermediate host [53-56].

It is thus reasonable to suspect that bat is the natural host of SARS-CoV-2 considering its similarity with SARS-CoV. The phylogenetic analysis of SARS-CoV-2 against a collection of coronavirus sequences from various sources found that SARS-CoV-2 belonged to the *Betacoronavirus* genera and was closer to SARS-like coronavirus in bat [19]. By analyzing genome sequence of SARS-CoV-2, it was found that SARS-CoV-2 felled within the subgenus *Sarbecovirus* of the genus Betacoronavirus and was closely related to two bat-derived SARS-like coronaviruses, bat-SL-CoVZC45 and bat-SL-CoVZXC21, but were relatively distant from SARS-CoV [15, 18, 57-59]. Meanwhile, Zhou and colleagues showed that SARS-CoV-2 had 96.2% overall genome sequence identity throughout the genome to BatCoV RaTG13, a bat coronavirus detected in *Rhinolophus affinis* from Yunnan province [14]. Furthermore, the phylogenetic

analysis of full-length genome, the receptor binding protein spike (S) gene, and RNA-dependent RNA polymerase (RdRp) gene respectively all demonstrated that RaTG13 was the closest relative of the SARS-CoV-2 [14]. However, despite SARS-CoV-2 showed high similarity to coronavirus from bat, SARS-CoV-2 changed topological position within the subgenus *Sarbecovirus* when different gene was used for phylogenetic analysis: SARS-CoV-2 was closer to bat-SL-CoVZC45 in the S gene phylogeny but felled in a basal position within the subgenus *Sarbecovirus* in the ORF1b tree [57]. This finding implies a possible recombination event in this group of viruses. Of note, the receptor-binding domain of SARS-CoV-2 demonstrates a similar structure to that of SARS-CoV by homology modelling but a few variations in the key residues exist at amino acid level [15, 19].

Despite current evidences are pointing to the evolutional origin of SARS-CoV-2 from bat virus [15, 57], an intermediate host between bats and human might exist. Lu et. al. raised four reasons for such speculation [15]: First, most bat species in Wuhan are hibernating in late December; Second, no bats in Huanan Seafood market were sold or found; Third, the sequence identity between SARS-CoV-2 and bat-SL-CoVZC45 or bat-SL-CoVZXC21, the closest relatives in their analyses, is lower than 90%; Fourth, there is an intermediate host for other human-infecting coronaviruses that origin from bat. For example, masked palm civet and dromedary camels are the intermediate hosts for SARS-CoV [49] and MERS-CoV respectively [60]. A study of the relative synonymous codon usage (RSCU) found that SARS-CoV-2, bat-SL-CoVZC45, and snakes had similar synonymous codon usage bias, and speculated that snake might be the intermediate host [61]. However, no SARS-CoV-2 has been isolated from snake yet.

Pangolin was later found to be a potential intermediate host for SARS-CoV-2. The analysis of samples from Malytan pangolins obtained during anti-smuggling operations from Guangdong and Guangxi Customs of China respectively found novel coronaviruses representing two sub-lineages related to SARS-CoV-2 [62]. The similarity of SARS-CoV-2 to these identified coronaviruses from pangolins is approximately 85.5% to 92.4% in genomes, lower than that to the bat coronavirus RaTG13 (96.2%) [14,62]. However, the receptor-binding domain of S protein from one sub-lineage of the pangolin coronaviruses shows 97.4% similarity in amino acid sequences to that of SARS-CoV-2, even higher than that to RaTG13 (89.2%) [62]. Interestingly, the pangolin coronavirus and SARS-CoV-2 share identical amino acids at the five critical residues of RBD of S protein, while RaTG13 only possesses one [62]. The discovery of coronavirus close to SARS-CoV-2 from pangolin suggests that pangolin is a potential intermediate host. However, the roles of bat and pangolin as respective natural reservoir and intermediate host still need further investigation.

Chemotherapeutic options for SARS-CoV-2 infection

As an emerging virus, there is no effective drug or vaccine approved for the treatment of SARS-CoV-2 infection yet. Currently, supportive care is provided to the patients, including oxygen therapy, antibiotic treatment, and antifungal treatment, extra-corporeal membrane oxygenation (ECMO) etc. [21,22]. To search for an antiviral drug effective in treating SARS-CoV-2 infection, Wang and colleagues evaluated seven drugs, namely, ribavirin, penciclovir, nitazoxanide, nafamostat, chloroquine, remdesivir (GS-5734) and favipiravir (T-750) against the infection of SARS-CoV-2 on Vero E6 cells *in vitro* [63]. Among these seven drugs, chloroquine and remdesivir demonstrated the most powerful antiviral activities with low cytotoxicity. The effective concentration (EC_{50}) for chloroquine and remdesivir were 0.77μM and 1.13μM respectively. Chloroquine functions at both viral entry and post-entry stages of the SARS-CoV-2 infection in Vero E6 cells whereas remdesivir does at post-entry stage only. Chloroquine is a drug used for an autoimmune disease and malarial infection with potential broad-spectrum antiviral activities [64,65]. An EC_{90} (6.90 μM) against the SARS-CoV-2 in Vero E6 cells is clinically achievable *in vivo* according to a previous clinical trial [66]. Remdesivir is a drug currently under the development for Ebola virus infection and is effective to a broad range of viruses including SARS-CoV and MERS-CoV [67,68]. Functioning as an adenosine analogue targeting RdRp, Remdesivir can result in premature termination during the virus transcription [69,70]. The EC_{90} of remdesivir against SARS-CoV-2 in Vero E6 cells is 1.76 μM, which is achievable *in vivo* based on a trial in nonhuman primate experiment [63, 69]. Encouragingly, in the first case of SARS-CoV-2 infection in the United States, treatment with remdesivir was provided intravenously to the patient on the day 7 without any adverse events observed. The patient's clinical condition was improved on day 8 and the previous bilateral lower-lobe rales disappeared, implying the remdesivir might be effective to the treatment of SARS-CoV-2 infection [22]. This result, however, should be interpreted with caution as this is only single case study and a proper trial control was lacking. In addition, baricitinib, a Janus kinase inhibitor, was also predicted to reduce

the ability of virus to infect lung cell by an analysis of BenevolentAI [71].

Currently, chloroquine and remdesivir are under phase 3 clinical trial and open-label trial for treatment of SARS-CoV-2 infection respectively (Table 2) [72]. Preliminary results showed that chloroquine phosphate had apparent efficacy in treatment of COVID-19 [73]. However, caution must be taken during clinical use of chloroquine as its overdose is highly fatal without known antidote [74]. Despite the lack of documented *in vitro* data supporting the antiviral efficacy on SARS-CoV-2, several antiviral chemotherapeutic agents have been registered for the clinical trials for the treatment of COVID-19 (Table 2) [72].

Conclusion remarks

SARS-CoV-2 is an emerging pathogen, without any effective drug available for treatment at the moment. It spreads quickly and can result in death of the infected patients. Despite the current mortality rate is 2.3% [26], the emergence of large number of infected patients within short period of time could result in the collapse of health care system, and thus the mortality rate might be elevated. Effective preventive measures must be implemented to control it from global spreading. In addition, great effort should be made on the development of vaccine and antiviral drugs. Meanwhile, the intermediate host and the molecular mechanism of its cross-species spread should be further investigated. Legislation should be employed to prohibit the trade of wild animals, the potential intermediate host(s) of various viruses, to prevent the outbreak of this and other novel viruses in future.

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Table 2. Summary of chemotherapeutic drugs under clinical trial for COVID-19

Name of Drug	Target and Mode of Action in other Viruses	*In Vitro* Antiviral Activity to SARS-CoV-2	Clinical Trial Status for COVID-19	Clinical Trial Registration Number
Remdesivir (GS-5734)	Inhibits RdRp [70]	Tested [63]	Phase 3	NCT04252664; NCT04257656
Favipiravir	Inhibits RdRp [75]	Tested [63]	Randomized trial	ChiCTR2000029544; ChiCTR2000029600
Ribavirin	Inhibits viral RNA synthesis and mRNA capping [76]	Tested [63]	Randomized trial, in combination a pegylated interferon	ChiCTR2000029387
Lopinavir	Inhibits 3C like protease (3Clpro) [77]	Not tested	Phase 3	NCT04252274; NCT04251871; NCT04255017; ChiCTR2000029539
Ritonavir	Inhibits 3Clpro [77]	Not tested	Phase 3	NCT04251871; NCT04255017; NCT04261270
Darunavir and Cobicistat	Inhibits HIV protease [78]	Not tested	Phase 3	NCT04252274
ASC09F (HIV protease inhibitor)	Inhibits HIV protease [79]	Not tested	Phase 3, in combination with oseltamivir	NCT04261270
Chloroquine	A lysosomatropic base that appears to disrupt intracellular trafficking and viral fusion events [80]	Tested [63]	Open-label trial	ChiCTR2000030054; ChiCTR2000029939; ChiCTR2000029935; ChiCTR2000029899; ChiCTR2000029898; ChiCTR2000029837; ChiCTR2000029803; ChiCTR2000029761; ChiCTR2000029740; ChiCTR2000029559; ChiCTR2000029542; ChiCTR2000029868; ChiCTR2000029826; ChiCTR2000029762; ChiCTR2000029760; ChiCTR2000029609
Arbidol (Umifenovir)	Block viral fusion [81]	Not tested	Phase 4	NCT04260594; NCT04254874; NCT04255017
Oseltamivir	Inhibit neuaminidase [82]	Not tested	Phase 3 and Phase 4	NCT04255017; NCT04261270

Competing Interests

The authors have declared that no competing interest exists.

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Isolation and rapid sharing of the 2019 novel coronavirus (SARS-CoV-2) from the first patient diagnosed with COVID-19 in Australia

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The known: By 12 March 2020, 140 cases of COVID-19 (the illness caused by SARS-CoV-2) had been confirmed in Australia; three patients had died. At the end of January, the sequence of the virus had been shared but no laboratory outside China had grown the virus or had access to live virus.

The new: We describe the clinical course and laboratory features of the first reported case of COVID-19 in Australia, as well as the isolation, sequencing, imaging, and rapid global sharing of virus isolated from the patient.

The implications: Rapid identification, propagation and international sharing of SARS-CoV-2 is an important step in collaborative scientific efforts and diagnostic test validation in response to this public health emergency.

Abstract

Objectives: To describe the first isolation and sequencing of SARS-CoV-2 in Australia and rapid sharing of the isolate.

Setting: SARS-CoV-2 was isolated from a 58-year-old man from Wuhan, China who arrived in Melbourne on 19 January 2020 and was admitted to the Monash Medical Centre, Melbourne from the emergency department on 24 January 2020 with fever, cough, and progressive dyspnoea.

Major outcomes: Clinical course and laboratory features of the first reported case of COVID-19 (the illness caused by SARS-CoV-2) in Australia; isolation, whole genome sequencing, imaging, and rapid sharing of virus from the patient.

Results: A nasopharyngeal swab and sputum collected when the patient presented to hospital were each positive for SARS-CoV-2 (reverse transcription polymerase chain reaction). Inoculation of Vero/hSLAM cells with material from the nasopharyngeal swab led to the isolation of SARS-CoV-2 virus in culture. Electron microscopy of the supernatant confirmed the presence of virus particles with morphology characteristic of viruses of the family *Coronaviridae*. Whole genome sequencing of the viral isolate and phylogenetic analysis indicated the isolate exhibited greater than 99.99% sequence identity with other publicly available SARS-CoV-2 genomes. Within 24 hours of isolation, the first Australian SARS-CoV-2 isolate was shared with local and overseas reference laboratories and major North American and European culture collections.

Conclusions: The ability to rapidly identify, propagate, and internationally share our SARS-CoV-2 isolate is an important step in collaborative scientific efforts to deal effectively with this international public health emergency by developing better diagnostic procedures, vaccine candidates, and antiviral agents.

The recognition in 2019 of the first outbreak in Wuhan, China, of a respiratory disease (COVID-19) associated with a novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) triggered an international response unparalleled in its scale and tempo.[1-3] In particular, the rapid sharing and integration of clinical and epidemiological data has facilitated understanding of the spectrum of clinical disease caused by SARS-CoV-2 and the extent of its global spread, although there are still many unanswered questions. Further, rapid genomic analyses have corroborated epidemiological investigations, suggesting a global point source outbreak of a novel betacoronavirus originating in Wuhan.[4,5]

The fundamental pillars of the control of any infectious disease are effective prevention, diagnostic, and treatment strategies. For viral pathogens, the propagation of live virus and the timely dissemination of the viral isolate to domestic and international scientific and public health agencies are critical. Rapid sharing of material has allowed laboratories to validate their diagnostic assays and to confirm their ability to detect SARS-CoV-2. In this report we describe the clinical course and laboratory features of the first reported case of COVID-19 in Australia, together with the isolation, sequencing, and imaging of the virus.

Case report and clinical course

A 58-year-old man from Wuhan, China, felt unwell on the day of his arrival in Melbourne (19 January 2020). In China, he had had no contact with live food markets, people known to have COVID-19, or hospitals. His medical history included type 2 diabetes mellitus, and he had ceased smoking four years previously. He developed fever on 20 January and a cough with sputum production on 23 January; on 24 January, he was admitted to the Monash Medical Centre, Melbourne, from its emergency department with progressive dyspnoea. His temperature was 38.1°C, his heart rate 95 beats/min, and O_2 saturation 94% on room air. A chest x-ray showed subtle ill-defined opacities in the middle zones bilaterally and in the left lower zone. A thoracic computed tomography scan on admission day four identified extensive ground glass opacities with a peribronchovascular and peripheral distribution in the middle to upper zones of the lungs (Box 1). Full blood examination results included a lymphocyte count of 0.80×10^9/L (reference range, $1.0–4.0 \times 10^9$/L). C-reactive protein concentration peaked on admission day 6 at 182 mg/L (reference range, 0–5 mg/L). Liver function test abnormalities peaked on admission day 12 — alkaline phosphatase, 210 U/L (reference range, 30–110 U/L); γ-glutamyltransferase, 416 U/L (reference range, 30–110 U/L); alanine aminotransferase, 183 U/L (reference range, 5–40 U/L) — and hepatic steatosis was evident on liver ultrasound. Intravenous ceftriaxone (2 g/day)

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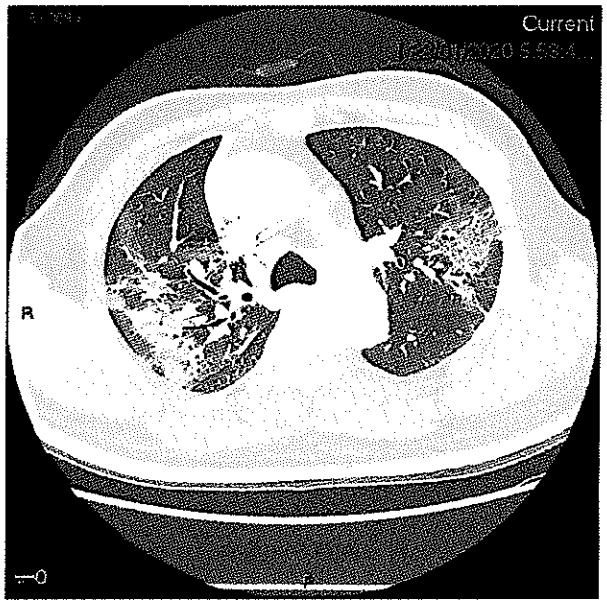
1 Thoracic computed tomography (CT) image of patient on admission day 4



and azithromycin (500 mg/day) were commenced on admission day 4 to treat potential secondary bacterial pneumonia, although no bacterial pathogen was identified. Low-flow oxygen (maximum 3 L/min via nasal prongs) was administered until admission day 10. The patient gradually improved; fever, productive cough and dyspnoea resolved by admission day 12, and he was discharged from hospital on 7 February (admission day 15).

Methods

Diagnostic testing for SARS-CoV-2

Real time reverse transcription (RT) polymerase chain reaction (PCR) testing for SARS-CoV-2 was performed on material from an initial nasopharyngeal swab in 200 µL viral transport medium, and separately for sputum, urine, faeces, and serum samples. Briefly, an in-house real time RT-PCR assay was developed, and all positive tests confirmed by nested RT-PCR, using previously described methods.[7] PCR products underwent in-house Sanger sequencing, which confirmed the presence of SARS-CoV-2 (online Supporting Information, 1.1–1.3).

Virus culture and electron microscopy

Material from the initial nasopharyngeal swab was used to inoculate a Vero/hSLAM cell line (European Collection of Authenticated Cell Cultures [ECACC] #04091501). Flasks were monitored for the development of viral cytopathic effect and 140 µL aliquots removed every 48 hours to assess virus burden by real time RT-PCR.

For electron microscopy, a 4 mL aliquot of supernatant from cell cultures grown in the presence of 4 µg/mL trypsin was inactivated with 0.5% glutaraldehyde for 12 h and clarified by centrifugation at 1000 g for 3 min. Supernatant was negatively stained with 3% phosphotungstic acid (pH 7.0) and examined with an FEI Tecnai T12 electron microscope at 80kV. The remaining pellet was stained *en bloc* and embedded in resin; 70 nm sections were examined with an FEI Tecnai F30 electron microscope at 200kV (Supporting Information, 2.1–2.2).

Whole genome sequencing of SARS-CoV-2 and bioinformatic analysis

We extracted RNA for whole genome sequencing of the viral isolate. Briefly, RNA was extracted from clarified cell culture supernatant and randomly amplified cDNA prepared by sequence-independent single-primer amplification (SISPA).[8] Sequencing was performed with a combination of Oxford Nanopore Technologies and Illumina short-read sequencing. Genomic assembly of the BetaCoV/Australia/VIC/01/2020 genome was confirmed by parallel *de novo* and reference-guided methods (Supporting Information, 3.1–3.4).

Results

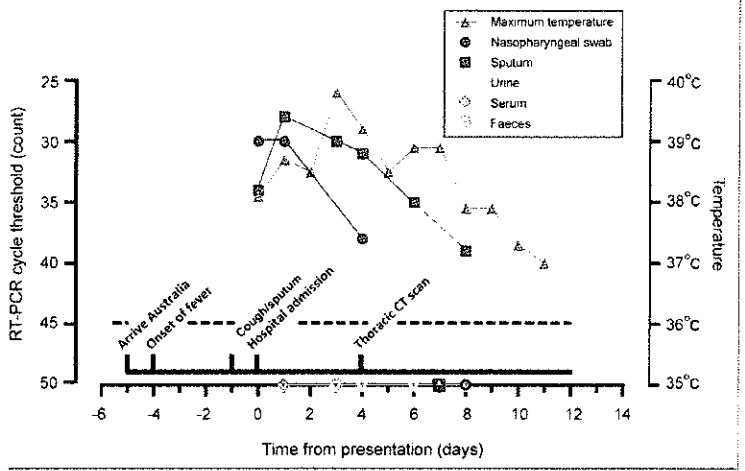
Detection of SARS-CoV-2 in clinical samples

A nasopharyngeal swab and sputum collected on presentation were positive for SARS-CoV-2 on real time RT-PCR assay. Serial daily RT-PCR testing of nasopharyngeal swabs and sputum from the patient indicated a gradual decline in viral load in sputum between admission days 1 and 8, and a decline in viral load and disappearance from nasopharyngeal swabs by admission day 7. No virus was detected in urine samples, nor in single faecal (admission day 3) or plasma samples (admission day 1) (Box 2).

Growth, visualisation, and global sharing of SARS-CoV-2 virus

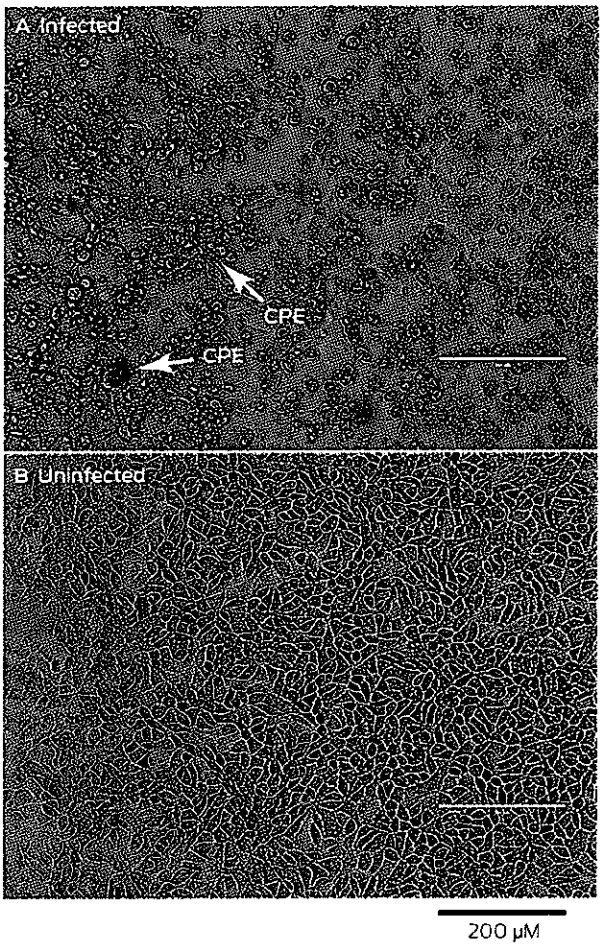
Two days after inoculation of the VERO/hSLAM cell line, a subtle viral cytopathic effect was observed, and was distinct at day 6 compared with an uninfected control cell line (Box 3). RT-PCR testing of the cell line supernatant confirmed a high viral load, suggesting productive viral infection (Box 4). Electron micrographs of the negatively stained supernatant showed spherical

2 Clinical course of first Australian case of COVID-19, including laboratory investigations

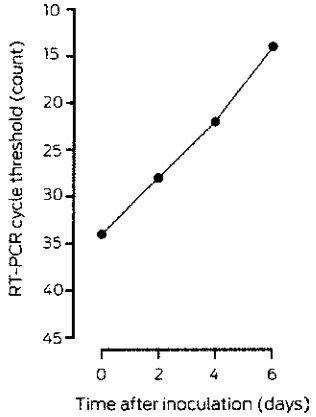


SARS-CoV-2 was quantified by real time RT-PCR. The cycle threshold count is shown for each specimen type; an increase in count value is consistent with reduced viral load. The assay limit of detection (dashed line) threshold is a count of 45; open symbols beneath the threshold indicate null detection of virus. ◆

3 Light microscopy of Vero/hSLAM cells. A. Cells infected with material from patient, with viral cytopathic effect (CPE) evident six days after inoculation. B. Uninfected (control) cells



4 SARS-CoV-2 viral load, quantified by real time polymerase chain reaction (RT-PCR) of supernatant from virus-infected Vero/hSLAM cell culture*



* Lower threshold cycle count values indicate higher viral loads ◆

and pleomorphic virus-like particles of 90–110 nm diameter; the particles displayed prominent spikes (9–12 nm), characteristic of viruses from the family *Coronaviridae* (Box 5, A). Electron micrographs of sectioned VERO/hSLAM cells showed cytoplasmic membrane-bound vesicles containing coronavirus particles (Box 5, B) Following several failures to recover virions with the characteristic fringe of surface spike proteins, it was found that adding trypsin to the cell culture medium immediately improved virion morphology.

In consultation with the World Health Organization, the viral isolate was shared with domestic and international reference laboratories within 24 hours, and lodgement with major North American and European culture collections for further distribution is underway.

Phylogenetic analysis

Phylogenetic analysis indicated that the genome sequence of our isolate (BetaCoV/Australia/VIC01/2020) exhibited greater than 99.99% sequence identity with other publicly available SARS-CoV-2 genomes (online Supporting Information, 3.4), consistent with the epidemiological features of this case originating in Wuhan.[10] Compared with the National Center for Biotechnology Information (NCBI) SARS-CoV-2 reference sequence (NC_045512.3), there were three previously described single nucleotide polymorphisms and a 10 base pair deletion in the 3′ untranslated region (3′UTR) (Supporting Information, 3.4). Our sequences are available at GenBank (accession number, MT007544.1), and the genome was rapidly uploaded to the Global Initiative of Sharing All Influenza (GISAID) (accession number, EPI_ISL_406844).

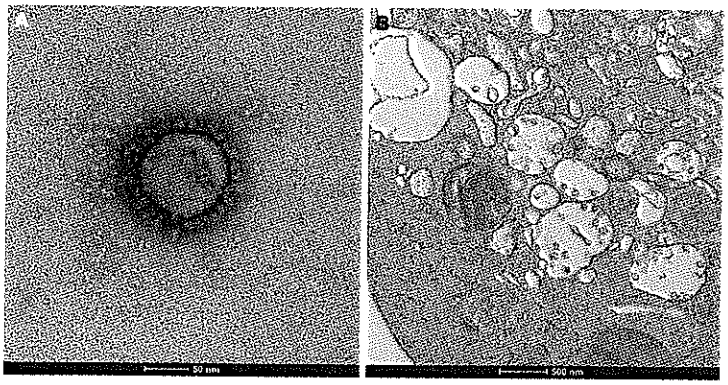
Discussion

We have described the first reported case of COVID-19 in Australia, with rapid diagnosis, and isolation, imaging, and sharing of the causative agent, SARS-CoV-2. By 12 March 2020, there had been 140 confirmed cases in Australia; three patients had died.[1] Although 65% of confirmed cases around the world have been reported from China, an increasing number are being reported in South Korea, Italy, and Iran, and limited human-to-human transmission has been described.[9,11,12] Although the number of cases in Australia is relatively small, the political and societal effects (as in other countries) have already been considerable, including travel restrictions to and from mainland China, the Republic of Korea, Italy, and Iran.[13] The sustainability of these measures and their effects on local and global control remain to be established, but the consequences of the outbreak will probably be felt for many months, if not longer.

The clinical features in our case were consistent with other recent reports, including the initial presentation of fever, cough, and progressive dyspnoea.[14] It is notable that the viral burden was greatest in sputum specimens, which remained positive for SARS-CoV-2 for eight days after initial presentation, compared with four days for nasopharyngeal swabs (Box 2). The decline in viral load was correlated with the resolution of fever and, ultimately, clinical improvement. One unresolved question is whether patients who are clinically stable and deemed fit to be discharged from hospital but have PCR-detectable virus are infectious, or whether this indicates only the persistence of non-infectious, residual viral RNA.

We applied standard techniques to isolate the virus, but we were the first group to isolate it outside China during the early stages of the epidemic. Potential reasons for our success could be the

5 Electron micrographs of cell culture supernatant. A. 100 nm spherical virion displaying the characteristic crown-like fringe of spike proteins. B. Infected VERO/hSLAM sections with membrane-bound vesicles containing virus



viral burden of the collected specimens and the extensive clinical experience in our reference laboratory.

An important aspect of the scientific response to the COVID-19 outbreak has been the rapid sharing of information about diagnostic assays and genomic data, enabling rapid elucidation of the emergence and spread of the novel virus. In addition, a major principle of our laboratory response in Australia was to immediately share the viral isolate with the WHO and other laboratories to facilitate rapid validation of diagnostic testing. We continue to share live virus with other agencies, both locally and overseas, involved in the development and testing of therapeutic agents and vaccines. This is an essential function of public health reference and research laboratories, and we strongly encourage others to apply a similarly collaborative approach to streamlining efforts to diagnose, prevent, and treat COVID-19 during this public health emergency.

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Supporting Information

Additional Supporting Information is included with the online version of this article.

IN THE HIGH COURT OF SOUTH AFRICA
(WESTERN CAPE DIVISION)

CASE NO:5852/2021

In the Matter between:

RICARDO MAARMAN	APPLICANT
AND	
THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	FIRST RESPONDENT
AND	
THE MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS	SECOND RESPONDENT
AND	
PROFESSOR SALIM ABDOOL KARIM on behalf of the GOVERNMENTAL COVID 19 ADVISORY COMMITTEE	THRID RESPONDENT

NOTICE IN TERMS OF RULE 16A
SUBMISSIONS BY AMICUS CURIAE

TAKE NOTICE THAT;

The applicant herein is raising Constitutional issues in an application on ***20 April 2021.***

THE CONSTITUTIONAL PRINCIPLES INVOLVED

1. The Constitution provides that the Republic of South Africa is a sovereign, democratic state founded, inter alia, on the following values: Life, Human dignity, the achievement of equality and the advancement of human rights and freedoms and the Rule of Law.

2. The Constitution provides that "All spheres of government and all organs of state within each sphere must be loyal to the Constitution, the Republic and its people; respect the constitutional status and not assume any power or function except those conferred on them in terms of the Constitution.

3. The Bill of Rights applies to all law, and binds the legislature, the executive, the judiciary and all organs of state.

4. Everyone has inherent dignity and the right to have their dignity respected and protected.

5. Everyone has the right to life, bodily and psychological integrity; To make decisions concerning the security and control over their body; Freedom to practice their trade, Freedom of movement, occupation and profession; Not to be treated in a cruel, inhuman or degrading way; Their right to have access to health care services; Just administrative action.

6. Every citizen has the right to administrative action that is lawful, reasonable, and procedurally fair.

7. These abovementioned rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality, and freedom, taking into account all relevant factors, including the nature of the right; the importance of the purpose of the limitation;

the nature and extent of the limitation; the relation between the limitation and its purpose; and less restrictive means to achieve the purpose.

8. No law including the DMA, may limit any right entrenched in the Bill of Rights.

9. It is therefore submitted that, in so far as the Regulations or any Direction Purportedly issued pursuant thereto, that will violate the above-mentioned fundamental rights will be inconsistent with the Constitution, and therefore illegal and void if the SARS-CoV-2-virus is not proven to exist.

10. Furthermore, the rights in the Bill of Rights cannot be infringed upon or limited in any way save in terms of the provisions of section 36 or 37.

11. The national state of disaster, announced in terms of the DMA, has been called on the mere allegation of the existence of the SARS-CoV-2-virus, and the applicant stands on his Fundamental right to test whether the violation of his and the entire nation's Constitutional rights have been based on the existence of the SARS-CoV-2-virus.

THE STATE MAY NOT INTERFERE WITH THOSE FREEDOMS, EXCEPT UNDER SECTION 36 OF THE CONSTITUTION.

1. My respectful submission is that until the Respondent has produced the SARS-CoV-2-virus to be tested by independent experts in the

appropriate circumstances that the Limitation of the rights of the Applicant and the Nation's rights to freedom of movement is not justified in terms of Section 36. (1) of the Constitution.

2. According to Section 36. (1) The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors.

3. We are not asking this honourable Court to do the Section 36 test in this matter, or to decide on the existence of the SARS-CoV-2-virus we are simply asking that the respondent produces the isolated and purified physical SARS-CoV-2-virus (not a culture isolate or any mixture within in which the supposed virus is, nor a photograph or the RNA-sequence only), to the applicant at the place of his choice and under the security measures as preferred by the respondent, within 7 days, in order for us to test whether these extremely harsh disaster enforced on the nation is in fact based on the existence of the SARS-CoV-2-virus.

4. The nature of the rights here being limited are fundamental rights in terms of chapter two; the right to bodily and psychological integrity; The right to make decisions concerning the security and control over their own bodies; Freedom to practice their trade, freedom of movement, occupation, and profession; Not to be treated in a cruel, inhuman or

degrading way; Their right to have access to health care services; the right to just administrative action.

5. These are fundamental rights that cannot be limited if there are no evidence of the existence of the SARS-CoV-2-virus.

SECTION 39 OF THE CONSTITUTION AND ITS RELEVANCE TO THE FACTS PRESENTED

1. With regards to the nature of the matter, Section 39 (1)(a) and (b) respectively, have to be cited, as it is part and parcel of the fabric of our society, that this section be included here, which states that:

2. When interpreting the Bill of Rights, a court, tribunal or forum-
   (a) must promote the values that underlie an open and democratic society Based on human dignity , equality and freedom;
   (b), must consider international law; and
   (c), must consider a foreign law.

3. Its relevance, that the court should in accordance with the above be open the facts presented below, which in turn sheds light on the Portuguese Judgment, The Court here concludes that:

"Any diagnostic test must be interpreted in the context of the actual possibility of the disease, which existed before its realization. For Covid-19, this decision to perform the test depends on the previous assessment of the existence of

symptoms, previous medical history of Covid 19 or presence of antibodies, any potential exposure to this disease and no likelihood of another possible diagnosis." "One of the potential reasons for presenting positive results may lie in the prolonged shedding of viral RNA, which is known to extend for weeks after recovery, in those who were previously exposed to SARS-CoV-2. However, and more relevantly, there is no scientific data to suggest that low levels of viral RNA by RT-PCR equate to infection, unless the presence of infectious viral particles have been confirmed by a laboratory. In summary, Covid-19 tests that show false positives are increasingly likely, in the current epidemiological climate panorama in the United Kingdom, with substantial personal, health and social system consequences."

4. To prove the existence of something especially when it is mixed or incorporated with other things is to first separate or isolate it, then to measure it, to determine its parameters and to determine its qualities. An RNA or DNA sequence is not proof of existence, e.g., having the DNA sequence of a person does not mean that the person exist, to prove the person exists the DNA sequence must be matched to a DNA sequence obtained verifiably directly from the physical person.

5. Here follows explanations regarding the supposed isolation of SARS-CoV-2: as described in an article entitled The Genetic Sequence, Origin, Diagnosis of SARS-CoV-2, written by Huihui Wang et al.RM9

Ans 105-
7

- "Confirmed cases with SARS-CoV-2 were identified as a positive result of a high-throughput sequencing or an RT-PCR assay for respiratory specimens including nasal and pharyngeal swab"

- "Airway epithelial cells from infected patients were used to isolate a novel coronavirus, temporarily named 2019-nCoV, but later, the Coronavirus Research Group of the International Committee for the Classification of viruses found that the new coronavirus is related to the SARS-virus" The International Committee for the Classification of viruses is affiliated to the International Council of Sciences, which in turn has a formal relationship with UNESCO since 1947, which in turn is a specialised agency of the UN.

- "In addition, the World Health Organisation has named the disease caused by SARS-CoV-2 as coronavirus disease 2019 (Covid-19)".

- "After the SARS-CoV-2 was isolated from the lower respiratory tract specimen, a diagnostic RT-PCR test was developed. RT-PCR tests based on the RNA-dependent RNA polymerase (RdRp) gene of the ORF1ab sequence, E gene, N gene and S gene of the SARS-CoV-2 genome"

- "The genome of coronaviruses, ranging from 26 to 32 kilobases in length, includes a variable number"

- "The SARS-CoV-2 genome was reported to possess 14 ORF's encoding 27 proteins"

WHEREIN IT WILL ASK FOR AN ORDER AS FOLLOWS.

1. That this Application is heard as a matter of urgency and that the Applicant's failure to comply with the time limits imposed by the Rules of this Honourable Court be condoned in terms of Rule 6 (12).

2. That the respondents produce the isolated and purified physical SARS-CoV-2-virus (not a culture isolate or any mixture within in which the supposed virus is, nor a photograph or the RNA-sequence only), to the applicant at the place and in terms of their security measures of choice, within 7 days.

3. Further or alternative relief.

4. Cost of the application if opposed.

REGISTRAR

Kindly stamp this notice and then place it on the notice board designated for that purpose for a period of 20 days.

ANY INTERESTED PARTY;

In these proceedings may be admitted therein as amicus curiae upon such terms and conditions as may be agreed upon in writing by the parties in terms of the Rules of Court.

TAKE NOTICE FURTHER; that the Applicant has appointed ***VICTOR AND ASSOCIATES, 24*** Viola Road, Bloubergstrand, Cape Town, ***C/O ROB GREEN*** Attorneys, Room 305 Benzal House, 3 Barrack Street, Cape Town as its attorney of record and his service address as the address at which the Applicant will accept service of all process in these proceedings.

KINDLY PLACE THE MATTER ON THE NOTICE BOARD ACCORDINGLY.

DATED AT CAPE TOWN ON THIS THE 28th DAY OF MARCH 2021.

_____

T VICTOR AND ASSOCIATES

24 Viola Road

Bloubergstrand

Cape Town

TEL 074 707 8168

FAX 086 294 5204

EMAIL victorlegalinfo@gmail.com

C/O

ROB GREEN Attorneys,

Room 305 Benzal House, 3 Barrack Street, Cape Town)

TO: **THE REGISTRAR CAPE TOWN HIGH COURT**

AND TO; **THE RESPONDENTS**

ALL RESPONDENTS SERVED AT THE OFFICE OF THE STATE ADVOCATE CAPE TOWN

Rg6 109

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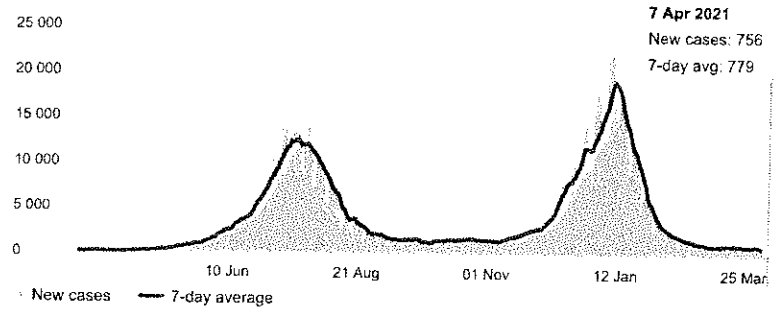


Each day shows new cases reported since the previous day · Last updated: 2 days ago · Source: JHU CSSE COVID-19 Data · About this data

Cases

Total South Africa

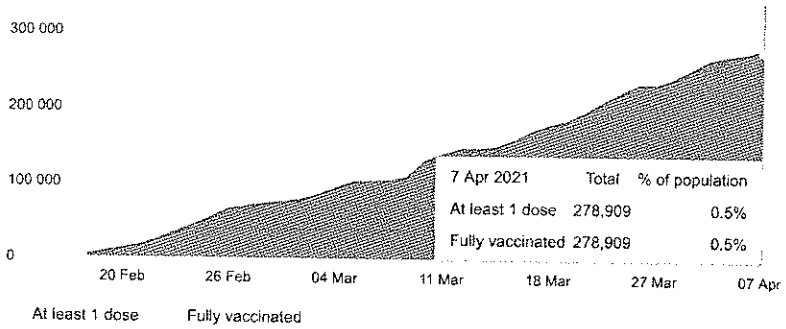
Cases	Recovered	Deaths
1,55M	1,48M	53 111
+756	+1 001	+79

'+' shows new cases reported yesterday · Last updated: 2 days ago · Source: JHU CSSE COVID-19 Data · About this data

Vaccinations

From Our World in Data · Last updated: 2 days ago

Total South Africa All time



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https://www.worldometers.info › coronavirus

Coronavirus Update (Live): 133,856,896 Cases and ...

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COVID-19 vacc
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Map of cases (last 14 da

Angola Za
South Afr
Total cases 1
(25 March – 7 A
South Afr

Sources: Wikipedia and others

Cases overview

South Africa

Total cases	Recove
1,55M	1,48M
+756	+1 001

Worldwide

Total cases	Recove
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→ More location

'+' shows new cases reported y hours ago · Sources: Wikipedi Data. · About this data

Coronavirus disease (COV disease caused by a newly

Most people who fall sick w experience mild to modera without special treatment.

HOW IT SPREADS

The virus that causes COV through droplets generatec coughs, sneezes, or exhale heavy to hang in the air, ar surfaces.

You can be infected by bre are within close proximity c

RM6 110

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Coronavirus Update (Live)

Live statistics and coronavirus news tracking the number of ...

The United Kingdom

United Kingdom Coronavirus update with statistics and ...

More results from worldometers.info »

https://sacoronavirus.co.za

COVID-19 South African Coronavirus News And Information.

South Africa's official **Coronavirus** (**Covid**-19)online news and information portal. In association with The Department of Health and the NHI.

⚠ Common questions

Can the COVID-19 survive in drinking water?

How dangerous is the coronavirus disease?

Can I get the coronavirus disease from swimming in a swimming pool?

Can the coronavirus spread via feces?

For informational purposes only. Consult your local medical authority for health advice.

Top stories

https://coronavirus.westerncape.gov.za › covid-19-dash...

Covid-19 Dashboard | Covid-19 Response

View area-specific cases by downloading the suburb and town cases document. Download suburb and town cases Disclaimer: This is the best available data at ...

https://www.capetown.gov.za › general › coronavirus-u...

The City of Cape Town - Coronavirus Updates

... 20and%20lists/**COVID**-19_Lockdown_Operations_Service_Notifications.pdf" target="_blank">See ... **statistics**

Weekly **Covid**-19 dashboard.

http://www.sabcnews.com › tracking-the-coronavirus

CORONAVIRUS: Your daily update - SABC News - Breaking ...

1 day ago — The country also recorded 37 new **COVID**-19-related fatalities on Tuesday, bringing the total number of deaths to 53 032. Latest SA **stats**:.

https://www.statista.com › ... › State of Health

• South Africa: coronavirus cases per province | Statista

Gauteng's **COVID**-19 cases were 5 times less than figures found in the Western Cape ...

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RM 7 111

DEPARTMENT OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS

NO. 313

15 MARCH 2020

DISASTER MANAGEMENT ACT, 2002

DECLARATION OF A NATIONAL STATE OF DISASTER

Considering the magnitude and severity of the COVID-19 outbreak which has been declared a global pandemic by the World Health Organisation (WHO) and classified as a national disaster by the Head of the National Disaster Management Centre, and taking into account the need to augment the existing measures undertaken by organs of state to deal with the pandemic, I, Dr Nkosazana Dlamini Zuma, the Minister of Cooperative Governance and Traditional Affairs, as designated under Section 3 of the Disaster Management Act, 2002 (Act No. 57 of 2002) ("the Act"), in terms of -

1) Section 27(1) of the Act, hereby declare a national state of disaster having recognised that special circumstances exist to warrant the declaration of a national state of disaster; and

2) Section 27(2) of the Act may, when required, make regulations or issue directions or authorise the issue of directions concerning the matters listed therein, only to the extent that it is necessary for the purpose of —

   (a) assisting and protecting the public;

   (b) providing relief to the public;

   (c) protecting property;

   (d) preventing or combatting disruption; or

   (e) dealing with the destructive and other effects of the disaster.

NC Zuma

DR NKOSAZANA DLAMINI ZUMA, MP

MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS

DATE: 15. 03. 2020.

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CONCLUSION - 11-11-2020

(*Electronic Judgment prepared by Law Clerk Maria do Carmo Martins Loureiro*)

Case No. 1783 / 20. 7T8PDL.L1

Judicial Court of the District of Azores - Criminal Court of Ponta Delgada

Held at the 3rd Criminal Section of the Lisbon Court of Appeal

*

I - REPORT

1. On 08/26-2020, the request for *habeas corpus* was granted, as the confinement/detention was illegal, determining thereafter the immediate release of Respondents in the main action A., B ..., C...and D ....hereinafter referred to as the "Respondents".

2. Then appeared the **REGIONAL HEALTH AUTHORITY**, represented by the Regional Health Directorate of the Autonomous Region of the Azores, to appeal this decision, requesting for an order to validate the mandatory confinement of the Respondents, as they are carriers of the SARS-CoV-2 virus (C....) and for being under active surveillance, due to high risk exposure, as declared by the health authorities (A., B ... and D.).

4. The application for leave to appeal was granted.

5. The Mº Pº (Public Ministry), in their reply, contended that the present appeal must be dismissed as it has no legal basis.

6. Appeared before this Court the General Public Prosecutor.

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II - PREVIOUS POINT.

As the argument filed by the Appellant must be rejected, the Court will limit itself under the terms of paragraphs 1, a), and 2 of article 420 of the Penal Code, to briefly specify the basis of its decision.

III - GROUNDS.

1. The decision rendered by the Court "*a quo*" reads as follows:

Proven facts:

1. *On 08/01/2020, the Respondents arrived on the island of São Miguel, by plane from the Federal Republic of Germany, where, 72 (seventy-two) hours prior to their arrival, they had carried out a COVID-19 test, with a negative result, and which results were presented and delivered to the Regional Health Authority, upon arrival at the airport, in Ponta Delgada.*

2. *On 07/08/2020 and already during their stay on the island of São Miguel, Respondents C... and D.... did a second COVID-19 test.*

3. *On 10/08/2020 and still during their stay on the island of São Miguel, Respondents A... and B.... did a second COVID-19 test.*

4. *On 08/08/2020, Respondent C... was informed via a telephone call that her COVID-19 test which was conducted the previous day showed a positive result of the COVID-19 virus.*

5. *From 08/08/2020, Respondent C.... stopped residing with the remaining three Respondents, and proceeded to always maintain a distance of no less than 2 (two) meters from the other Respondents.*

6. *On 10/08/2020, Respondents A..., B... and D... were informed via a telephone call that their tests had a "negative" result.*

7. *On 10/08/2020, a separate document was sent to each Respondents respectively via email, signed by the Delegate of the Health Department of the Municipality of Lagoa, F..., reference is made to paragraphs 25 and 26 which states as follows:*

...Notification of Prophylactic Isolation - Coronavirus SARS-CoV-2 / Disease COVID - 19, and two attachments (only one sent in English) stating the

following (the content of the notification was the same for each Respondent, save for each Respondent's details):

"Isolation (...)

Notification of Prophylactic Isolation

Coronavirus SARS- CoV-2 / COVID disease - 19

Mário Viveiros Silva Lagoa Health Authority

Under the terms of the Normative Circulars nr DRSCINF / 2020/22 of 2020/03/25 and DRS CNORM2020 / 39B of 2020/08/04 of the REGIONAL HEALTH AUTHORITY (in annex) and Norm no. 015/2020, of 24 / 07/2020 of the General Health Directorate (attached) I determine the

PROPHYLACTIC ISOLATION

OF

(...)

Holder of the Citizen Card / PASSPORT No. (...), valid ... until ... with the social security identification number for the period from 08/08/2020 to 22/08/2020 due to contagion hazard and as a preventative measure for COVID 19 (SARS-Cov-2)

Date 2020/08/10 (...)

8. *The Respondents requested that the test results be forwarded to them. The test reports conducted by Respondents C... and D... were forwarded to them via e-mail on 13/08/2020 and Respondents A... and B... received on the day before yesterday, 08/24/2020, via e-mail. Said reports were provided to the Respondents in Portuguese.*

9. *Between the 1st and the 14th of August the Respondents were staying in the accommodation Marina Mar II, in Vila Franca do Campo.*

10. *From August 14th onwards, the Respondents have been staying at "THE LINCE AZORES GREAT HOTEL, CONFERENCE & SPA", in Ponta Delgada (where they are currently staying), by order of the Health Delegate as described in 7 as follows:*

- In room 502 are Respondents A... and B....

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- In room 501 is Respondent C....

- In room 506 is Respondent D....

11. *The Respondents tried at least 3 times to contact the COVID19 helpline (296 249 220) in their own language or, at least, in English, to no avail, since the agents only answer and respond in Portuguese, a language that the Respondents cannot understand.*

12. *At the hotel, meals are delivered to the room, by room services, at predetermined times and according to a choice made by a third party, except during the first 3 days at Hotel Lynce where breakfast was served, and the remaining meals through room service.*

13. *On August 15, while fulfilling the prophylactic isolation established by the Health Delegate, Respondent C... started suffering from an inflammation in the mouth, apparently caused by the dental device she uses.*

14. *Respondent C attempted to contact the COVID-19 helpline in order to shared this situation with the Regional Health Authority, to whom she requested the necessary medical support.*

15. *This request was ignored by the aforementioned helpline, that did not provide Respondent C... the necessary support and assistance.*

16. *Not having had any support, two days later, on August 17th, properly protected by a mask and gloves, Respondent B... left her room, travelled to the closest pharmacy to the hotel, where she acquired an ointment to temporarily quell the inflammation, having returned immediately to the hotel and to her room.*

17. *On 19/08/2020 an email was sent by the Health Delegate, G...., To the Respondents, stating the following:*

> *"(...) C will only be considered cured after having a negative test result and a 2nd negative test, whereafter, the Health Delegation will contact you (...) (sic).*

18. *On 21/08/2020 it was transmitted to the four Respondents, by the Health Delegate G...., via e-mail, the following message: "When the quarantine is over, you have to do a test and if the test is negative you may leave the house" (sic).*

19. *On that same day, Respondent A.... wrote an e-mail to the aforementioned doctor and Health Delegate, Dr. João Martins Sousa (translated into Portuguese in free regime):*

> *"Dear Dr. G....,*
>
> *We have already done two COVID-19 / person tests, all of which were negative (A..., B.... And D....))...and after that we spent 2 weeks in isolation, and none of us have any symptoms !!*
>
> *Do you have Dr. G's documents...., please confirm.*
>
> *Nobody told us anything about the new tests after the isolation time?! We have already rescheduled our flights and plan to leave the island.*
>
> *Explain the reason for your statement.*
>
> *Why was the COVID test of C... not done yesterday."*

20. *The Respondents did not receive any response to the aforementioned email, with the exception of Respondent C.... who was notified of the scheduling of the new screening test for 29/08/2020.*

21. *On 20/08/2020, Respondent C.... carried out a third COVID-19 test, and the following day (21/08/2020), only via a telephone call, she was informed that the result was positive.*

22. *Respondent C.... requested that documentary evidence indicating the positive result be sent to her, which was then indeed forwarded to her via e-mail yesterday, 08/24/2020.*

23. *The Respondents questioned the reception staff at the hotel where they are staying and were told that none of the four Respondents, without exception, will be able to leave their rooms.*

24. *The Respondents do not have, nor have they ever presented, any symptom of the virus (fever, cough, muscle pain, sneezing, lack of smell or palate).*

25. *The Respondents were not advised of the content of the two documents sent to them as reflected in paragraph 7 above.*

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26. *The Respondents are habitually resident in the Federal Republic of Germany, as reflected in these pleadings.*

Rationale:

The question that arises herein is based on the fact that the Respondents are deprived of their freedom (from the 10th of August until the present date, as shown by the proven facts) and, consequently, being able to use the present *habeas corpus* institution. - as we will now explain -, the question is whether or not there is a legal basis for this deprivation of their freedom.

Indeed, without even questioning the organic constitutionality of the Resolution of the Council of the Regional Government No. 207/2020, of July 31, 2020, currently in force within the scope of the procedures approved by the Government of Azores in containing the spread of the SARS-COV- 2 in this Autonomous Region, in the present situation, the detention / confinement of the Respondents since 10 August is materialized by a communication made via e-mail, in Portuguese, in the terms given as proven under point 7.

Now, as is clear from point 7 of the proven facts, the regional health authority, through the respective Health Delegate of the territorial area where the Respondents were staying, determined their prophylactic isolation under the Normative Circulars No. **DRSCINF / 2020 / 22 of 2020/03/2025 and DRS CNORM2020 / 39B of 2020/08/04 of the REGIONAL HEALTH AUTHORITY** and Norm no. 015/2020, of 24/07/2020 of the General Directorate of Health. It was through a communication with the aforementioned, as is emphasized, in normative circulars and a norm of the General Directorate of Health, that the Regional Health Authority deprived the Respondents of their freedom, because of the proven facts it derives to the satiety that, in the rigor of the concepts, were detained from the 10th to the 14th of August 2020 in a hotel in Vila Franca do Campo and from the 14th of August 2020 until the present date confined, and therefore detained, in a hotel room in this city of Ponta Delgada. We cannot ignore the facts proven herein because as it stands out, the Respondents' power of movement and right of mobility - or of any other individual who is in the same situation - are so limited that the first time they went out of their rooms was to attend this court and make statements (with the exception of the visit of Respondent B to the pharmacy.... in clear despair to help her daughter's pain in the proven facts).

In short, after analysing the factuality of the matter, it is inexorable to conclude that we are facing a true deprivation of the personal and physical freedom of the Respondents, which prevents them not only from moving, but also from being with their families, having been separated for about 16 days (Respondents A... and B... and her daughter, Respondent C...) and, in the case of Respondent D.... completely alone, without any physical contact with

anyone. To say that there is no deprivation of freedom because at any time they may be absent from their respective rooms, in which they find themselves is a fallacy, just look at the communications that were made after the 10th of August, none of them being in German language, and the conditions in which they have lived (keeping in mind that they are foreign citizens with the inherent linguistic barrier) or requesting their return to their country of origin is a fallacy, and for this conclusion, the latest communications transmitted in Portuguese, underlining of which the one given as proven under point 8 stands out, in particular "*Namely, when the quarantine is over, you have to do a COVID19 test and if the result is negative, you can leave your rooms.*"

Therefore, if the Respondents are deprived of their freedom, in the face of proven circumstances, it is necessary to trace the path in which we move, initiating the procedure through the Portuguese legislative system: The Constitution of the Republic of Portugal (CRP).

Thus, at the level of the hierarchy of norms, it is necessary to remember that, according to article 1 of the CRP, "Portugal is a sovereign Republic, based on the dignity of the human person and on the popular will and committed to the construction of a free, fair and supportive society." Hence, it is clear that the meaning of the unity in which our system of fundamental rights is created, is based on human dignity - the principle of the dignity of the human person is the essential reference of the entire system of fundamental rights.

One of them, the most relevant in view of its structuring nature of the democratic state itself, is the principle of equality, provided for in article 13 of the CRP, which states, in its paragraph 1, that "*All citizens have the same social dignity and are equal before the law*", adding paragraph 2, that "*No one can be privileged, benefited, harmed, deprived of any right or exempted from any duty due to ancestry, sex, race, language, territory of origin, religion, political or ideological beliefs, education, economic situation, social status or sexual orientation.*"

And, in light of the facts hereto, under the heading "*right to freedom and security*", article 27, no. 1 of the CRP provides, "*Everyone has the right to freedom and security*", referring José Lobo Moutinho, in an annotation to that article, that freedom is an absolute decisive and essential moment - not to say, the very constitutive way of being - of the human person (Ac. n ° 607/03: "ontic demand"), which lends him that dignity in which the legal order finds its granitic foundation (and, above all, legal-constitutional) Portuguese (Article 1 of the Constitution). In this sense, one can say the cornerstone of the social building" (Ac. N ° 1166/96)" (aut.cit., In op. Cit., P. 637).

Since human freedom is not one-dimensional, and can take on multiple dimensions, as exemplified in articles 37 and 41 of the CRP, the freedom in question in article 27, is physical freedom, understood as freedom of bodily movement, of coming and going, freedom of

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movement, stipulating in paragraph 2 of this last article that "*No one may be totally or partially deprived of freedom, unless as a result of a condemnatory judicial sentence for the practice of an act punishable by law with imprisonment or judicial application of a security measure.*" underline.

The exceptions to this principle are typed in paragraph 3, which provides that: An exception for this principle is deprivation of freedom, for the time and under the conditions determined by law, in the following cases:

a) Arrest in serious offenses;

b) Detention or preventive detention for strong indications of a wilful crime that corresponds to imprisonment exceeding more than three years;

c) Arrest, detention or other coercive measure subject to judicial control, of a person who has entered or remains illegally in national territory or against whom extradition or expulsion proceedings are underway;

d) Disciplinary imprisonment imposed on military personnel, with guaranteed appeal at a competent court;

e) Subjecting a minor to protection, assistance or educational measures in an appropriate establishment, ordered by the competent judicial court;

f) Detention by judicial decision in virtue of disobedience of an order made by a court or to ensure appearance before the competent judicial authority;

g) Detention of suspects, for the purpose of identification, in cases and for the time strictly necessary;

h) Admission of a patient with a psychic anomaly in an appropriate therapeutic establishment, ordered or confirmed by the competent judicial authority."

Finally, it should be reminded that, in case of deprivation of freedom against the provisions of the Constitution and the Law, the State has the duty to indemnify the injured party under the terms established by the law, as follows under paragraph 5 of article 27, emphasizing, in line with article 3 of the CRP:

(...) 2. *The State is subordinate to the Constitution and is based on democratic legality.*

3. *The validity of laws and other acts of the State, autonomous regions, local authorities and any other public entities depend on their compliance with the Constitution.*

Wherefore, having drawn up the legal territory, we must carefully analyse the facts under which the Regional Health Authority proceeded in *casu*.

Respondents A., B ... and D ... performed a screening test for the SARS-CoV-2 virus, the result of which was negative for all, with the same test being positive for Respondent C...., which led to the aforementioned order of prophylactic isolation and consequent permanence in the terms exposed and proven.

Therefore, given the content of the notification made to the Respondents, this court cannot fail to express, *ab initio*, its perplexity at the determination of prophylactic isolation to the four Respondents.

As is clear from the definition given by the General Directorate of Health, *"Quarantine and isolation are measures of social isolation essential in public health. They are especially used in response to an epidemic and are intended to protect the population from transmission of a virus. The difference between quarantine and isolation stems from the state of illness of the person who wishes to isolate. That is:*

Quarantine is used in people who are assumed to be healthy, but may have been in contact with an infected patient;

Isolation is the measure used for people with a disease, so that through social distance they do not infect other citizens."

(em https://www.sns24.gov.pt/tema/doencas-19/isolamento/?fbclid=IwAR34hD77oLCpxUVYJ9Ol4ttgwo4tsTOvPfIa3Uyoh0EJEbCs3jEihkaEPAY#sec-0).

In light of the present matter, the Regional Health Authority decided to make a blank slate of essential concepts, because they delimit differentiated treatment (as distinct pleonasm), the position of infected people and of those who were in contact with infected people, in the face of the order of prophylactic isolation to all the Respondents, although only one of them tested positive to the aforementioned screening test. Furthermore, they decided to ignore the Resolution of the Government Council no. 207/2020 of 31 of July, prohibiting the mandatory submission of the judicial validation of the competent court, confirming that it is mandatory quarantine, when it derives to the satiety of the facts that Respondents A., B ... and D ..., at most, are subject to mandatory quarantine.

It was not done so within the 24 hours as provided for in paragraph 6 of the aforementioned Resolution, not even within a broader period - as in the 48 hours provided for in article 254, paragraph 1, point a), of the Penal Code, or in article 26, no. 2, of the LSM (Law of Mental

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Health) - continuing to effect any communication and, therefore, the evident restriction of the freedom of the Respondents A., B ... and D ... will always be illegal.

Accordingly, the aforementioned Government Council Resolution no. 207/2020, of July 31, 2020, provides in point 4 that in cases where the SARS-CoV-2 virus test result is positive, the local health, within the scope of its competences, will determine the procedures to be followed. Respondent C ... positive in the screening test for the virus in question, was notified, in the same terms as the other Respondents, of the order of prophylactic isolation between 08/10/2020 to 08/22/2020.

At this point, it is necessary to make it clear that the notification made as proven under point 7, is brought from what is contained in the DGS015 / 2020 Standard (Covid-19 Decree), a rule referred to in it in addition to the normative circulars (available in https://www.dgs.pt/directrizes-da-dgs/normas-e-circulares-normativas/norma-n-0152020-de-24072020-pdf.aspx), in the subject matter here:

(...) High Risk Exposure Contacts

15. A person classified as having high risk exposure, in accordance with Annexure I is subject to:

    a. Active surveillance for 14 days, since the date of the last exposure;

    b. Determination of prophylactic isolation, at home or other place defined at the local level, by the Health Authority, until the end of the period of active surveillance, according to the model of Dispatch nº 2836-A / 2020 and / or n 3103-A / 20202 (model accessible in http://www.seg-social.pt/documents/10152/16819997/GIT_70.docx/e6940795-8bd0-4fad-b850-ce9e05d80283)

Following this norm of the General Directorate of Health, one reads, amongst others, in the normative circular No. DRSCNORM / 2020 / 39B, of 2020-08-04 (available on http://www.azores.gov.pt/NR/rdonlyres/25F80DC1-51E6-4447-8A38-19529975760/1125135/CN39B_signed1.pdf),

(...)

a. Having contact with high risk cases

High risk cases are treated as suspect cases until the laboratory result comes out. These people should be screened for SARS-CoV-2. High risk cases are considered to be

i. People residing with a confirmed case of COVID-19; (...)

ii. Surveillance and Control of Nearby Contacts

3. With high risk cases, it is estimated that the incubation period of the disease (time elapsed from exposure to the virus to the appearance of symptoms) is between 1 and 14 days. They must comply with 14 prophylactic isolation days, even if they have negative screening tests during that period, and a test should be performed on the 14th day. If the 14th day test result is negative, they are discharged. If high risk cases cohabit with the positive case, they should only be discharged when determining the cure of the positive case, and, therefore, the respective prophylactic isolation should be extended.

(...)

13. Compliance with prophylactic isolation

All persons identified as suspected cases, until the negative results are known, must comply with prophylactic isolation.

All persons who tested positive for Covid-19 and who are discharged after a cure test (admitted in a hospital or home), do not need to undergo a new isolation period of 14 days or repeat a new test on the 14th day.

All passengers disembarking at airports in the Region from airports located in areas considered to be zones of active community transmission or with transmission chains for the SARS-CoV-2 virus must comply with the procedures in force in the Region at the time.

Wherefore, we shall analyse the legal value of norms / guidelines from the General Health Directorate and normative circular 39B, from 04/08/2020, of the Regional Health Directorate, leaving no doubt that we have entered the sphere of administrative guidelines.

In this regard, with the requirement of reporting to the Tax Authority - which has the same administrative legal position as the National Health Authority in the *ius imperium* of the State-, CASALTA NABAIS (Tax Law, 6th ed., Almedina, p. 197), **"the so-called administrative guidelines, traditionally presented in the most diverse forms such as instructions, circulars, circular-letters, normative orders, regulations, opinions, etc."**, which are very frequent in tax law, constitute internal regulations that they only

have the tax administration as their recipient, they must only comply with this, being, therefore, mandatory only for the bodies hierarchically situated below the agency that originated them.

That is precisely the reason as to why they are not binding on individuals or courts. Whether they are organizational regulations, which defines rules applicable to the internal functioning of the tax administration, creating working methods of action, or whether they are interpretative regulations, which proceed to the interpretation of legal (or regulatory) precepts.

It is true that they densify, make explicit or develop the legal precepts, previously defining the content of the acts to be performed by the administration when they are applied. But that does not make them the standard of validity for the acts they support. In fact, the assessment of legality of the actions of the tax administration must be carried out through direct confrontation with the corresponding legal norm and not with the internal regulation, which interposed between the norm and the act".

The problem of the normative relevance of the Circulars for Administration (Tax) was already raised and considered in the Constitutional Court Judgments nº 583/2009 and 42/14, of 11/18/2009 and 9/09/12, respectively, having been decided, which decision we agree, that the prescriptions contained in the Circulars for Tax Administration, regardless of their persuasive irradiation in the practice of citizens, do not constitute norms for the purposes of the constitutionality of the control system committed to the Constitutional Court.

As underlined in the aforementioned judgment (Judgment 583/2009) "(...) These acts, in which the "circulars" are prominent, emanate from the power of self-organization and the hierarchical power of the Administration. They contain generic service orders and it is for this reason and only within the respective subjective scope (of the hierarchical relationship) that theymust be complied with. They incorporate guidelines for future action, transmitted in writing to all subordinates of the administrative authority that issued them. These are standardized decision-making modes, assumed to rationalize and simplify the operation of services. This is worth saying that, although they can indirectly protect legal certainty and ensure equal treatment through uniform application of the law, they do not regulate the matter which they deal with, in relation to individuals, nor do they constitute a decision rule for the courts. "

Consequently, lacking a heteronomous binding force for individuals, and imposing themselves on the judge only because of the doctrinal value they may have, the rules contained in the "circulars" do not constitute rules for the purposes of the constitutionality of the control system within the jurisdiction of the Constitutional Court.

With that being said, it allows us to conclude that the administrative guidelines conveyed in the form of normative circulars, as in the present case, do not constitute provisions of legislative value that can be the subject to a declaration of formal unconstitutionality - see Judgment of the Supreme Administrative Court, of 06/21/2017, available for consultation at www.dgsi.pt.

It should be clear that the norms invoked by the Regional Health Authority, that supported the deprivation of freedom imposed on the Respondents, through notification of prophylactic isolation, are non-binding administrative guidelines to the Respondents. Reference is made hereto below:

Normative Circular No. DRSCNORM / 2020 / 39B: "For: Health Service Units

Regional Health Council, Municipal Health Delegates (C / c Regional Civil Protection Service and

Azores Firefighters, Azores Health Line) Subject: Screening for SARS-CoV-2 and addressing suspected or confirmed cases of SARS-CoV-2 infection Source: Regional Health Directorate (...)

Norm 015/2020, of 7/24/2020: "SUBJECT: COVID-19: Tracking Contacts KEYWORDS: Coronavirus, SARS-CoV-2, COVID-19, Tracking Contacts (Contact Tracing), Epidemiological Investigation

FOR: Health System (...).

In this sequence, and, in summary form, this court cannot fail to underline that in the present case, deprivation of freedom of persons, absolutely lacks any legal basis, and a defense that the public health is as stake cannot stand, since the court always acts in the same way, that is, in accordance with the law, moreover, hence the need for judicial confirmation enshrined in the Mental Health Law in the case of compulsory confinement, given the factuality found above, results as follows:

- The Respondents have been confined to a room for about 16 days, based on a notification of "prophylactic isolation" until 22/08/2020, a period that has already passed, which in any case it is illegal as a means of detaining people for the reasons already explained (reference is made to the constitutional rules set out above);

- there has never been any information, communication or notification given to the Respondents, as it should, in their mother tongue, nor have they been provided with an interpreter. From the outset, in violation of the European Convention on Human Rights (art. 5º, no. 2 and 6, paragraph 3, paragraph a) and the Penal Code (see article 92 of the Penal Code),

that is, in our legal system, when a foreign person is detained and cannot speak Portuguese, an interpreter is immediately appointed, and, in the case of the Respondents, who limited themselves to travel to this island and enjoy its beauty, they were never granted such an opportunity;

- Since 22/08/2020, the Respondents have been confined to a room based on the following communications:

- On 19/08/2020, the Respondents received an e-mail correspondence from the Health Delegate, Dr. G..., , stating the following:

> *"(...) C... will only be considered cured after having a negative test result and a 2nd negative test result, when this takes place, the health delegation will contact you (...) (sic).*

- On 21/08/2020, the following message was transmitted to the four Respondents, by the Health Delegate Dr. G..., via e-mail: *"When the quarantine is over, you have to do a test and if it is negative you may leave the room"(sic);*

- The Respondents' deprivation of freedom was not subject to any judicial scrutiny.

As stated initially, we could still consider the organic constitutionality of the Resolution of the Government Council No. 1207/2020, of June 31, however, we believe it is an unimportant question for the object of the decision to be made, which is to be swift, because with such a resolution, the decision cannot be different, based on the decision of the Constitutional Court, of 07/31/2020, in the scope of the process no. 424/2020, and, because the position of the Regional Health Authority in the present circumstances leads to the application of normative circulars, with the value explained above.

Finally, and because this court has been recently successively ruling within the scope of this institution of "*habeas corpus*" in the face of the orders issued by the Regional Health Authority, we allow ourselves to subscribe and underline the following excerpt from the first decision of this Criminal Investigative Court:

"The issue of compulsory confinement in the case of contagious diseases, and the terms under which it must occur, is a pressing issue, and which is not supported by article 27, paragraph 3, of the CRP, namely in its paragraph h), where it only foresees the admission of a patient with a psychic anomaly in an appropriate therapeutic establishment, decreed or confirmed by a competent judicial authority. It is urgent to legislate on this matter, establishing, in a clear way, the fundamental principles which it must obey, leaving the detailed aspects to the derived law - and only these".

As stated by Professor Gian Luigi Gatta, which we quote here in a free translation, "*right now, the country's energies are focused on an emergency. But the need to protect fundamental rights, also and above all in an emergency, the Courts are required to do their part. Because, in addition to medicine and science, law - and human rights law in the first place - must be at the forefront: not to prohibit and sanction - as is being emphasized too much today - but to guarantee and protect everyone. Today the emergency is called a coronavirus. We don't know tomorrow. And what we do or don't do today, to maintain compliance with the fundamental principles of the system, can condition our future.*" (in "I diritti fondamentali alla evidence of the coronavirus. Perché a legge sulla quarantena is necessary",) ".

It will not be difficult to admit and accept that the legislative turmoil generated around the prevention of the spread of COVID-19 will continue– being itself the protection of public health, but this turmoil can never harm the right to freedom and security and, ultimately, the absolute right to human dignity.

A decision must be made. (...)

Therefore, in light of the above, the confinement of Respondents A., B ..., C ... and D ... is illegal, I decide to uphold the present request for *habeas corpus* and, consequently, determine the immediate restitution of their freedom.

2. The Respondent made the following statements, based on its arguments:

1. The present appeal is directed against the decision issued by the honourable Court to which understood that "the confinement of Respondents A., B ..., C ... and D ... is illegal" and decided "to uphold the present request for *habeas corpus* and, consequently, to determine their immediate restitution to freedom."
2. Just for the sake of procedural economy, that is, because it is of little relevance for the assessment of the merits of the case, the factuality that has been proven is not appealed, however, it should be noted that it was based solely on the statements of the Respondents themselves.
3. The contested decision on the grounds that the Respondent did not comply with point 6 of the Resolution of the Council of the Regional Government of the Azores No. 207/2020, of July 31, 2020, violated the scope of application of the same Resolution, defined in point I of the same Resolution;

4. The judicial validation of mandatory quarantine, provided for in point 6 of the said resolution, only applies to the mandatory quarantine for passengers who do not accept, alternatively, any of the procedures provided for in point I of the aforementioned Resolution.
5. The Respondents complied with the procedure provided for in point a) of point 1 of Resolution No. 207/2020, of July 31, 2020, so they could never be subject to mandatory quarantine under that Resolution and, consequently, there is no place for judicial validation, provided for in point 6 of Resolution No. 207/2020, of 31 July 2020.
6. Contrary to what is defended in the contested decision, the Portuguese legal system allows the adoption of exceptional measures, including separation of persons, subject mandatory confinement of infected persons and with a high probability of being infected, through the mechanism provided for in article 17 Of Law no. 81/2009, of 21 August.
7. The Council of Ministers legitimately made use of the exceptional regulatory power, provided for in Article 17 of Law No. 81/2009, through the Resolutions of the Council of Ministers No. 55- A / 2020, of July 31, 2020 and No. 63-A / 2020, of August 14.
8. Paragraph 2 of the Resolution of the Council of Ministers no. 55-A / 2020, of July 31, 2020, ordered measures of an exceptional nature, necessary to prevent COVID -19, to be applied throughout the national territory, namely those provided for in the regime attached to the resolution.
9. Article 2 of the regulation attached hereto, reads as follows:

   "Article 2

   Mandatory confinement

   1 – Compulsory confinement in a health establishment, at their home or in another place defined by health authorities is applicable to:

      a) Patients with COVID -19 and those infected with SARS -CoV-2;

      b) Citizens to whom the health authority or other health professionals have determined to be active surveillance.

   2 - (...)"

10. Respondent C ... when infected with the SARS-CoV-2 virus, in compliance with article 2, paragraph 1, point a) of Annex I of the Resolution of the Council of Minister No. 55A / 2020, had to be in mandatory confinement.

11. The Court *a quo*, by ordering the *habeas corpus* of C ... and allowing her freedom of movement violated Article 17 of Law No. 81/2009, of 21 August, by reference to Article 2, paragraph 1, point a) of Annex I of the Resolution of the Council of Minister No. 55-A / 2020;

12. Respondents A., B ... and D ... according to the rules stipulated by the National Health Authority, contained in Norm 015/2020, of 07/24/2020, are parties with High Risk Exposure, and should be subject to:

    a. Active surveillance for 14 days, since the date of the last exposure.

    b. Determination of prophylactic isolation, at home or other place defined at local level, by the Health Authority, until the end of the period of active surveillance, according to the model of Dispatch no. 2836-A / 2020 and / or n. ° 3103-A / 20202"

13. Respondents A., B ... and D ... when subject to active surveillance, in compliance with article 2, paragraph 1, point b) of Annexure 1 of the Resolution of the Council of Minister no. ° 55-A / 2020, had to be in mandatory confinement.

14. The Court *a quo*, by ordering the *habeas corpus* of A., B ... and D ... and allowing their freedom of movement, violated Article 17 of Law No. 81/2009, of 21 August, by reference to Article 2 (1) (b) of Annexure I of Resolution of the Council of Minister No. 55-A / 2020.

15. It is imperative that the contested decision be revoked and replaced by one that validates the Respondents' mandatory confinement, as they are carriers of the SARS -CoV-2 virus (C...) and because they are under active surveillance, for high risk exposure , decreed by the health authorities (A., B ... and D ...).

3. In his reply, the M°P° concluded as follows:

1 - The Constitutional Court ruling of 7/31-2020 (Proc. 403/2020; 1. 'Section; Cons. José António Teles Pereira), after concluding that the mandatory confinement, either through quarantine or through prophylactic isolation , constitutes a true deprivation of freedom, not provided for in art. 27 (2) of the CRP, and that all deprivations of freedom require prior authorization from the Assembly of the Republic, which was not the case with the Resolutions of the Regional Government of the Azores, which imposed a mandatory quarantine, considered verified the organic unconstitutionality of the referred standards.

2 - These rules, declared unconstitutional by the Constitutional Court, are identical to those contained in the Resolutions of the Council of Ministers no. 55A / 2020, of 31-07, 63-A / 2020, of 14-08, and 70-A / 2020, 11-09, and no. 88-A / 2020, 14-10, insofar as they provide for deprivation of freedom not provided for in an appropriate legal document emanating from the competent entity, as well as not found in the exceptions provided for in art. 27, paragraph 3, of the C.R.P., for which reason they must also be disapplied for violation of art. 27. No. 1 of the C.R.P ..

3 - Provided for art. 5, paragraph 1, al. e), the European Convention on Human Rights (Convention for the Protection of Human Rights and Fundamental Freedoms - Rome, 0411-1950), concerning the Right to Freedom and Security, that "*Everyone has the right to freedom and security* "and that" *No one can be deprived of their freedom, except in the following cases and in accordance with legal procedure: (...) "If it concerns the legal confinement of a person liable to spread a contagious disease, of a mentally unstable person, an alcoholic, a drug addict or a criminal*", we can conclude that the deprivation of freedom of a person liable to spread a contagious disease is a form of confinement and that, according to the Convention, it is possible for States to provide in their national legislation the detention of these people.

4 - Bearing in mind the constitutional principle of the normality of the measures of deprivation of freedom, and not provided for art. 27, of the C.R.P., in none of the clauses of its paragraph 3, the deprivation of freedom of a person "liable to spread a contagious disease".

5 - And having the subparagraph h) - which foresees the admission of a patient with a psychic anomaly to an appropriate therapeutic establishment - added by art. 11.0, no. 6, of Constitutional Law no. 1/97, of 20 September (4. 'constitutional revision), at a time when the European Convention on Human Rights already expressly provided for the arrest of a person liable to spread contagious disease,

6 - And that the constitutional legislator, neither in said constitutional revision nor in a subsequent one, added another clause to paragraph 3 of art. 27 to foresee this possibility, as it did with the confinement of a patient with a psychic anomaly, we can conclude that we are facing a conscious decision by the constitutional legislator not to allow the deprivation of the freedom of a person liable to spread a contagious disease, just for that fact.

7 – From the analysis of the constitutional regime of the right to freedom and security provided for in art. 27, no. 1, of the CRP, we can conclude, therefore, that it is not possible for the legislator, even through the Assembly of the Republic or the Government authorized by it, to create deprivations of freedom that are not provided

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for in no. 3 of the aforementioned constitutional norm, namely with regards to persons with infectious and contagious diseases, whether these deprivations of freedom are confinements, quarantines or prophylactic isolations, without incurring any rules created for that purpose in a material unconstitutionality for violation of said constitutional norm.

8 - With reference again to the legal regime for the confinement of people with contagious diseases, Law No. 2036 of 09-08-1949 provided for the possibility of promoting the isolation or confinement of people with infectious diseases, but only, in situations where there was a serious danger of contagion (spreading), with recourse to an authority of the isolation or confinement decision.

9 - Art. 17 of Law no. 81/2009, of 21-08 in turn, which revoked Law no. 2036 of 9/8/1949, allows the member of the Government responsible for health to have a special regulatory power, according to the stipulated by base XX of Law no. 48/90, of 24-08 (Basic Law of Health), namely, "to take necessary measures of exception in case of emergency in public health, including the restriction, suspension or the closure of activities or the separation of people who are not sick, means of transport or goods, who have been exposed, in order to avoid the possible spread of infection or contamination ».

10 – In light of the above, it is clear that the possibility of promoting the isolation or confinement of people with infectious and contagious diseases is not provided for in this law, as provided for in Law No. 2036 of 09/08/1949. On the other hand, since the measures taken by the health authorities respect the Constitution does not provide for the deprivation of freedom of persons with infectious and contagious diseases.

«Separation of people who are not sick, means of transport or goods, who have been exposed», must be in accordance with the Constitution of the Republic of Portugal and cannot reach the core of the right to freedom, that is, they must not constitute total deprivation of freedom.

11 - On the other hand, the current Basic Law on Health - Law No. 95/2019, of 04-09 - provides in Base 34, regarding the defence of public health, that the public health authority can «b) Allow , according to the Constitution and the law, confinement or compulsory health care for people who would otherwise be a danger to public health ».

12 - Law no. 82/2009, of 02-04, which regulates the legal regime for the designation, competence and functioning of the entities that exercise the power of health authorities, provides in its art. 5 ° the powers of the health authority, namely, "c) To trigger, in

accordance with the Constitution and the law, the confinement or compulsory provision of health care to individuals who may be a threat to public health".

13 - It follows that, the measures taken by the health authorities must be in line with the Constitution and Legislation and should not provide for the deprivation of freedom of persons with infectious and contagious diseases. If the interpretation to be given to the expression "confinement or compulsory provision of health care to individuals in a situation of harm to public health" is in the sense that health authorities may order confinement, or other restrictive measure of freedom of movement, or compulsory provision of people with infectious and contagious diseases. Such an interpretation of the law is materially unconstitutional as it violates of art. 27. No. 1 of the C.R.P ..

14 - Defining Law No. 27/2006, of 03-07 (Basic Law for Civil Protection) "Serious accident" as an unusual event with relatively limited effects in time and space, capable of affecting people and other beings living, goods or the environment, but establishing in art. 5, paragraph 1, al. a) as the principle of priority of public interest, relative to civil protection, over the interests of national defence, internal security and public health, we can conclude that serious public health situations, such as the current pandemic, are not included in the public interest regarding civil protection, therefore, are not included in the concepts of "major accident" and "catastrophe" referred to in art. 3 of the Civil Protection Law.

15 - It can also be concluded that the Resolutions of the Council of Ministers - and the Resolutions of the Council of the Regional Government - which were based on the Basic Law of Civil Protection to declare "the alert situation, within the scope of the COVID-19 pandemic", namely Resolutions of the Council of Ministers no. 55-A / 2020, of 31-07, 63-A / 2020, of 14-08, 68-A / 2020, of 28-08, and 70-A / 2020, of 11-09 - revoked by Resolution of the Council of Ministers no. 88-A / 2020, of 14-10, currently in force-, which foresee in point 2 the "mandatory confinement, in establishment of health, in their home or in another place defined by the health authorities: (...) "*a) Patients with COVID19 and those infected with SARS-CoV-2; (...) "b) Citizens whom the health authority or other health professionals have determined that must be under active surveillance*" have no legal basis, as the Civil Protection Law does not apply to situations of danger to health public.

16 - We can thus conclude that the Resolutions of the Council of Ministers no. 55A / 2020, of 31-07, 63-A / 2020, of 14-08, 68-A / 2020, of 28-08, 81 / 2020, 29-09 - the latter was revoked by Resolution of the Council of Ministers no. 88 -A / 2020, 14-10, currently in force -, and its Annexure, which were issued by the Government, created a regime that restricts the freedom of citizens with infectious and contagious diseases (quarantines,

prophylactic isolation, etc.). In order to reinforce the application of a deprivation of freedom that not allowed by the Constitution or provided for in an enabling law, in cases of people with infectious disease or a danger to public health, they established the combination of a crime of disobedience for such violations and the penalty provided for such a crime, directly violates art. 27 (1) of the C.R.P., therefore, due to it being unconstitutional, they should not be applicable in this specific case, as its contrary to the Respondent's request,

17 - Leave the decision *sub judice*.

4. The Appellant is the REGIONAL HEALTH AUTHORITY, represented by the Regional Health Directorate of the Autonomous Region of the Azores.

Decree-Law no. 11/93, of 1993-01-15, in its current version (Statute of the National Health Service) determines that (emphasis added):

Article 1

The National Health Service, hereinafter referred to as NHS, is a hierarchical and set group of institutions and official services that provide health care, operating under the management or supervision of the Minister of Health.

Article 3

1 - The NHS is organized in health regions.

2 – The health regions are divided into health sub-regions, integrated by health areas.

Article 6

1 - In each health region there is a regional health administration, hereinafter referred to as ARS.

2 - The ARS has legal personality, administrative and financial autonomy and their own assets.

3- The ARS has the functions of planning, allocating resources, guiding and coordinating activities, managing human resources, technical and administrative support, and also assessing the functioning of institutions and services providing healthcare.

4 - (...).

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Decree-Law No. 22/2012 stipulates as follows:

Article 1

1 - The Regional Health Administrations, I. P., for short referred to as ARS, I.P., are public institutions integrated in the indirect administration of the State, endowed with administrative, financial and own assets.

2 - The ARS, I. P., proceeds with their duties, under the supervision of the members of the Government responsible for the health department.

3 - The ARS, I.P., is governed by the rules contained in the present decree-law, by the provisions of the framework law of public institutions and the Statute of the National Health Service and by the other rules applicable thereto.

Article 3

1 - The ARS, I. P., has the mission of guaranteeing the population of the respective geographical area of intervention, access to the provisions of health care, adapting the available resources to the needs of the people and complying with and enforcing health policies and programs in their area of intervention.

2 - It is the responsibility of each ARS, I. P., within the scope of the territorial circumscription to proceed with the following:

a) Execute the national health policy, in accordance with the global policies and sectors, aiming at their rational organization and the optimization of resources;

b) Participate in the definition of intersectoral planning coordination measures, with the objective of improving healthcare provision;

c) Collaborate in the preparation of the National Health Plan and monitor the respective execution at regional level;

d) Develop and encourage activities in the field of public health, in order to guarantee the protection and promotion of the health of the population;

e) Ensure the execution of local intervention programs with a view to reducing the consumption of psychoactive substances, preventing addictive behaviours and reducing dependencies;

f) Develop, consolidate and participate in the management of the National Integrated Continuing Care Network according to the defined guidelines;

g) Ensure the regional planning of human, financial and material resources, including the execution of the necessary investment projects, of the institutions and services providing health care, supervising their allocation;

h) To prepare, in accordance with the guidelines defined at national level, the list of facilities and equipment;

i) To allocate, in accordance with the guidelines defined by the Central Administration of the Health System, I. P., financial resources to institutions and services providing health care integrated or financed by the National Health Service and private entities with or without profit making, providing health care or acting within the scope of the areas referred to in paragraphs e) and f);

j) To enter into, monitor and review contracts within the scope of public-private partnerships, in accordance with the guidelines defined by the Central Administration of the Health System, I. P., and allocate the respective financial resources;

l) Negotiate, conclude and monitor, in accordance with the guidelines defined at national level, contracts, protocols and conventions of a regional scope, as well as carry out the respective assessment and review, in the scope of healthcare provision as well as in the areas referred to in points e) and f);

m) Guide, provide technical support and evaluate the performance of health care institutions and services, in accordance with the defined policies and guidelines and regulations issued by the competent central services and bodies in the different areas of intervention;

n) To ensure the adequate articulation between the health care services in order to guarantee compliance with the referral network;

o) To allocate financial resources, through the signing, monitoring and review of contracts within the scope of integrated continuous care;

p) Elaborate functional programs of health establishments;

q) Licensing private units providing health care and units in the area of addictions and addictive behaviours in the social and private sector;

r) Issue opinions on master plans for health units, as well as on the creation, modification and fusion of services;

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s) Issue opinions on the acquisition and expropriation of land and buildings for the installation of health services, as well as on projects of the facilities of health care providers.

3 - In order to carry out their duties, the ARS, I. P., may collaborate with each other and with other entities in the public or private sector, with or without profit, under the terms of the legislation in force.

5. The required *habeas corpus* is part of the provisions of article 220 of the Penal Code, which reads as follows:

Habeas corpus due to illegal confinement

1 - Those detained under the order of any authority, may request from the judge of the area where such order was granted, for leave to appeal, on any of the following grounds:

a) The period upon which leave to appeal should be applied has lapsed;

b) Confinement is not on places legally permitted;

c) The confinement was carried out or ordered by an incompetent entity;

d) The confinement is motivated by a factor not allowed by law.

2 - The request can be signed by the detainee or by any citizen in the exercise of their political rights.

3 - Any authority that raises an unlawful obstacle to the submission of the application referred to in the preceding paragraphs or to its referral to the competent judge is punishable with the penalty provided for in article 382 of the Penal Code.

6. Evaluation

Article 401 of the Penal Code stipulates the following:

1 - Entitled to appeal:

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a) The Public Ministry, regarding any decisions, even if in the exclusive interest of the Respondent

b) The Respondent, in light of judgment granted against them;

c) Parties to a civil matter, in light of judgment granted against each one of them;

d) Those who have been ordered to pay any amounts, in accordance with terms of this Code, or have to defend a right affected by the decision.

2 - Anyone who has no interest in the action cannot appeal.

7. The first question that arises here is that of the Respondent's legitimacy, in the context of an appeal in criminal proceedings.

i. We are within the scope of a criminal jurisdiction, the purpose of which is to ensure the effective exercise of the *jus puniendi* of the State, that is, which is dedicated to investigating and deciding on behaviour that constitutes a crime or administrative offense. It is in this context and with such purpose in mind that the Law determines who has the legitimacy to be able to discuss the legality of a judgment granted by a criminal court.

ii. In this case, we note that the Appellant is not a Respondent and has not made any request of a civil nature that, given the principle of accession, would determine her position as Plaintiff or Defendant.

iii. Thus, before the Law and taking into account the list of interveners that the legislator understood may have the legitimacy to intervene in a process in this type of jurisdiction, on appeal, we must immediately conclude that the Appellant lacks legitimacy to be able to come and discuss the content of a judicial decision in this context.

iv. In fact, the practice of any crime, or any offense of an administrative nature, is not discussed here, being certain that the question of possible consequences at criminal level, of the recognition of the existence of an illegal detention/confinement, is a matter that will have to be discussed in its own - that is, in an investigation that may be opened for this purpose, being completely unrelated to the decision of the present case.

v. We conclude, therefore, that the Appellant lacks *locus standi* to bring an appeal against the decision rendered by the court "*a quo*".

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8. Regardless of the question of *locus standi*, it appears that, likewise, the Appellant lacks interest in taking action.

i. As is clear from peaceful jurisprudence and doctrine in this regard, the interest in taking action means the need for someone to have to use the appeal mechanism as a way of reacting against a decision that disadvantages the interests that he/she defends or that has frustrated his/her legitimate expectation or benefit.

ii. Now, in the present case, the question is - did the decision give rise to any disadvantage for an interests that the ARS defends? Or a legitimate expectation or benefit?

The answer is manifestly negative.

iii. ARS continues its duties, under the supervision of the Government responsible for the health area.

Thus, and immediately, either in view of the functions that are committed to it, or in view of their manifest hierarchy, in the face of guardianship, it will have to be concluded that no ARS pursues its own and autonomous interest, which it must defend. Whoever will continue, eventually, will be the respective Minister or the Government, since the "interests" of the ARS will not be theirs, but will be included in the health policy of the ministry that oversees such an entity.

Note, moreover, that in the definition of its duties, they are not assigned any specific defence function, autonomously and in their own name, in judicial terms, of any interests that fall within its functions, which, with regard to criminal or administrative offenses, are none ...

iv. For its part, the interest that the Appellant itself intends to defend and that appears in the request, at the end of this appeal - the validation of the mandatory confinement of the Respondents, for being carriers of the SARS -CoV-2 virus (Angelique Hörner) and for being in active surveillance, for high-risk exposure, decreed by health authorities (A., B ... and D ...) - is in itself contradictory and goes beyond the purpose and scope of a criminal court. Contradictory because the Appellant does not admit that the confinement corresponds to deprivation of freedom. If that is the case, there is no glimpse of where the Appellant's jurisdiction is based in the jurisdiction of a criminal court to validate "confinements". Outside the scope of a criminal court, because it is not

up to the court to make declarative decisions to validate infections or diseases ...

v. Finally, it is not seen that a legitimate expectation or benefit has an entity that falls under a Government body, seen frustrated by the decision now being appealled.

vi. It follows that the Appellant does not have an interest in taking action, which is why, under the provisions of paragraph 2 of article 401 of the Criminal Penal Code, it cannot appeal the decision.

9. The decision granted by the court "*a quo*" to receive the present appeal does not bind this court (article 414 of the C.P.Penal), so there is nothing to prevent its rejection.

10. Nevertheless, to further clarify the aspects mentioned hereto, we state the following:

Even if this were not understood, the appeal presented would prove to be manifestly unfounded, for the following succinct reasons:

i. First of all, due to the exhaustive and correct reasoning set out in the decision by the "*a quo*" court, the content of which is fully subscribed.

In fact, under the Constitution and the Law, health authorities do not have the power or legitimacy to deprive anyone of their freedom - even under the label of "confinement", which effectively corresponds to detention - since such a decision can only be determined or validated by judicial authority, that is, the exclusive competence, in face of the Law that still governs us, to order or validate such deprivation of freedom, is exclusively affected by an autonomous power, the Judiciary.

Hence it follows that any person or entity that issues an order, the content of which leads to the deprivation of physical, ambulatory, freedom of others (whatever the order may be: confinement, isolation, quarantine, prophylactic protection, etc.), that does not fit the legal provisions, namely in the provisions of article 27 of the CRP and without such decision-making power having been conferred, by virtue of Law - from the RA, within the strict scope of the declaration of state of emergency or site, respecting the principle of proportionality - to specify the terms and conditions of such deprivation, will be proceeding to an illegal detention/confinement, because ordered by an incompetent entity and because motivated by a fact for which the law does not allow (this matter has been dealt with previously, with regards to other phenomenon of public health, namely with regard to HIV and tuberculosis infection, for example. And, as far as anyone knows, no one has ever been deprived of their freedom, due

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to suspicion or certainty of suffering from such diseases, precisely because the Law does not allow).

It is in this scope that, without any shadow of doubt, the situation under consideration in this case, being certain that the adequate means of defence, against illegal confinement, is subsumed to the appeal at the request of *habeas corpus*, provided for in art. c) and d) of the Penal Code.

And rightly, the court "*a quo*" ordered the immediate release of four people who were illegally deprived of their freedom.

ii. Secondly, because the request made in the appeal, proves to be impossible.

Alternatively:

11. In fact, it is requested to validate "the mandatory confinement of the Respondents, as they are carriers of the SARS-CoV-2 virus (C...) and because they are under active surveillance, due to high risk exposure, decreed by health authorities (A., B ... and D ...). "

12. It is with great astonishment that this court is faced with such a request, especially if we take into account that the Appellant is active in the health sector.

Since when is it up to a court to make clinical diagnoses, on its own initiative and based on possible test results? Or the ARS? Since when is the diagnosis of a disease made by decree or by law?

13. As the Appellant has more than an obligation to know, a diagnosis is a medical act, the sole responsibility of a doctor.

This is what results unequivocally and peremptorily from Regulation No. 698/2019, of 5.9 (regulation that defines the doctors' own acts), published in DR.

There it is determined, in an imperative way (which requires its compliance by all, including the Appellant) that (emphasis added):

Article 1

Purpose

This regulation defines the professional acts specific to doctors, their responsibility, autonomy and limits, within the scope of their performance.

Article 3

Object

1 - The doctor is the professional, legally qualified to practice medicine, capable of diagnosing, treating, preventing or recovering from diseases and other health problems, and able to provide care and intervene on individuals, groups of individuals or population groups, whether sick or healthy, with a view to protecting, improving or maintaining your state and health level.

2 - Doctors who have a current registration with the Portuguese Medical Association are the only professionals who can practice as doctors, under the terms of the Portuguese Medical Association's Statute, approved by Decree-Law No. 282/77, of 5 July, with the changes introduced by Law 117/2015, of 31 August and these regulations.

Article 6

General medical act

1 - The medical act consists of diagnostic, prognostic, surveillance, investigation, medical-legal expertise, clinical coding, clinical audit, prescription and execution of pharmacological and non-pharmacological therapeutic measures, medical, surgical and rehabilitation, health promotion and disease prevention in all its dimensions, namely physical, mental and social of people, population groups or communities, respecting the ethical values of the medical profession.

Article 7

The act of diagnostic

The identification of a disorder, disease or the state of a disease by studying its symptoms and signs and analysing the tests performed is a basic health procedure that must be performed by a doctor and, in each specific area, by a specialist doctor and aims to institution of the best preventive, surgical, pharmacological, non-pharmacological or rehabilitation therapy.

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14. Even under the Mental Health Law, Law no. 36/98, of 24 July, the diagnosis of the pathology that can lead to compulsory internment is mandatorily performed by specialist doctors and their technical and scientific judgment - inherent clinical-psychiatric evaluation - it is subtracted from the judge's free assessment (see articles 13, 3, 16 and 17 of the said Law).

15. Thus, any diagnosis or any act of health surveillance (as is the case of determining the existence of viral infection and high risk of exposure, which are shown to be covered by these concepts) made without prior medical observation to Respondents, without the intervention of a doctor enrolled in the OM (that proceeded to the evaluation of its signs and symptoms, as well as the examinations that it deemed appropriate to its condition), violates such Regulation, as well as the provisions of article 97 of the Statute of the Portuguese Medical Association, and configure crime p. and p. by article 358 al.b) (Usurpation of functions) of C. Penal (Penal Code), if dictated by someone who does not have this quality, that is, who is not a doctor enrolled in the Professional Health Body Council.

It also violates Article 6 (1) of the Universal Declaration on Bioethics and Human Rights, which Portugal subscribed to and is internally and externally obliged to respect.

It is thus clear that the prescription of auxiliary diagnostic methods (as is the case with tests for the detection of viral infection), as well as the diagnosis of the existence of a disease, in relation to each and every person, is a matter that cannot be carried out by Law, Resolution, Decree, Regulation or any other normative way, as these are acts that our legal system reserves to the exclusive competence of a doctor, being sure that, in advising his patient, he should always try to obtain the your informed consent.

16. In *casu*, there is no indication or proof, that such diagnosis was actually carried out by a professional qualified under the Law and who had acted in accordance with good medical practices.

In fact, what follows from the facts taken for granted, is that none of the Respondents were seen by a doctor, which is frankly inexplicable, given the alleged seriousness of the infection.

17. In fact, the only element that appears in the proven facts in this regard is the performance of RT-PCR tests, one of which presented a positive result in relation to one of the Respondents.

i. However, in view of the current scientific evidence, this test is, in itself, incapable of determining, beyond reasonable doubt, that such positivity corresponds, in fact, to the infection of a person by the SARS-CoV-2 virus, by various reasons, of which we highlighted (to which is added the issue of gold standard which, due to its specificity, we will not even address):

This reliability depends on the number of cycles that make up the test;

This reliability depends on the amount of viral load present.

ii. Indeed, the RT-PCR (polymerase chain reaction) tests, molecular biology tests that detect the RNA of the virus, commonly used in Portugal to test and list the number of infected persons (after nasopharyngeal collection), are performed by amplifying samples, through repetitive cycles.

The number of cycles of such amplification results in the greater or lesser reliability of such tests.

iii. The problem is that this reliability is shown, in terms of scientific evidence (and in this field, the judge will have to rely on the knowledge of experts in the field), more than debatable.

This is the result, amongst others, of the very recent and comprehensive Correlation study between 3790 qPCR positives samples and positive cell cultures including 1941 SARS-CoV-2 isolates, by Rita Jaafar, Sarah Aherfi, Nathalie Wurtz, Clio Grimaldier, Van Thuan Hoang, Philippe Colson, Didier Raoult, Bernard La Scola, Clinical Infectious Diseases, ciaa1491, https: //doi.org/10.1093/cid/ciaa149 https://academic.oup.com/cid/advance- article / doi / 10.1093/cid/ciaa1491/5912603, published at the end of September this year, by Oxford Academic, carried out by a group that brings together some of the greatest European and world experts in the field.

This study concludes, in *free translation*:

"*At a cycle threshold (ct) of 25, about 70% of the samples remained positive in the cell culture (i.e. they were infected): in a ct of 30, 20% of the samples remained positive; in a ct of 35, 3%*

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of the samples remained positive; and at a ct above 35, no sample remained positive (infectious) in cell culture (see diagram).

This means that if a person has a positive PCR test at a cycle threshold of 35 or higher (as in most laboratories in the USA and Europe), the chances of a person being infected are less than 3%. The probability of a person receiving a false positive is 97% or higher".

iv. What follows from these studies is simple - the possible reliability of the PCR tests carried out depends, from the outset, on the threshold of amplification cycles that they carry, in such a way that, up to the limit of 25 cycles, the test reliability will be about 70%; if 30 cycles are carried out, the degree of reliability drops to 20%; if 35 cycles are reached, the degree of reliability will be 3%.

v. However, in the present case, the number of amplification cycles with which PCR tests are carried out in Portugal, including the Azores and Madeira, is unknown, since we were unable to find any recommendation or limit in this regard.

vi. In a very recent study by Elena Surkova, Vladyslav Nikolayevskyy and Francis Drobniewski, accessible at https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30453-7/fulltext, published in the equally prestigious *The Lancet, Respiratory Medicine*, it is mentioned (in addition to the multiple questions that the accuracy of the test itself raises, regarding the specific detection of the sars-cov virus 2, due to strong doubts about the fulfilment of the so-called gold standard) that (*free translation*):

"*Any diagnostic test must be interpreted in the context of the actual possibility of the disease, which existed before its realization. For Covid-19, this decision to perform the test depends on the previous assessment of the existence of symptoms, previous medical history of Covid 19 or presence of antibodies, any potential exposure to this disease and no likelihood of another possible diagnosis.*"

"*One of the potential reasons for presenting positive results may lie in the prolonged shedding of viral RNA, which is known to extend for weeks after recovery, in those who were previously exposed to SARS-CoV-2. However, and more relevantly, there is no scientific data to suggest*

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that low levels of viral RNA by RT-PCR equate to infection, unless the presence of infectious viral particles have been confirmed by a laboratory.

In summary, Covid-19 tests that show false positives are increasingly likely, in the current epidemiological climate panorama in the United Kingdom, with substantial personal, health and social system consequences."

18. Thus, with so many scientific doubts, expressed by experts in the field, which are the ones that matter here, as to the reliability of such tests, ignoring the parameters of their performance and there being no diagnosis made by a doctor, in the sense of existence of infection and risk, it would never be possible for this court to determine that C ... was a carrier of SARS-CoV-2 virus, even if A., B ... and D ... had high-risk exposure.

19. In summary, it will be said that, since the appeal is inadmissible, due to lack of *locus standi* and lack of interest in acting by the Appellant, as well as manifestly unfounded, it will have to be rejected, under of the provisions of articles 401 nº1 par. a), 417 nº6 par. b) and artº420 nº1 par. a) and b), all of the Penal Code.

IV – DECISION

In view of the above, and under the provisions of articles 417, paragraph 6, al. b) and 420 nº1 als. a) and b), both of the Penal Code, the appeal filed by REGIONAL HEALTH AUTHORITY, represented by the Regional Health Directorate of the Autonomous Region of the Azores, is rejected.

Under the terms of paragraph 3 of article 420 of the Penal Code, the Judgment is granted against the Appellant in the procedural sanction of 4 UCs, as well as in the T.J of 4 UCs with costs.

Immediately inform the court "*a quo*" of this judgment.

Lisbon, November 11, 2020

Digital Signatures: Margarida Ramos de Almeida (rapporteur) Ana Paramés

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REVIEW

The genetic sequence, origin, and diagnosis of SARS-CoV-2

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Abstract
Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is a new infectious disease that first emerged in Hubei province, China, in December 2019, which was found to be associated with a large seafood and animal market in Wuhan. Airway epithelial cells from infected patients were used to isolate a novel coronavirus, named the SARS-CoV-2, on January 12, 2020, which is the seventh member of the coronavirus family to infect humans. Phylogenetic analysis of full-length genome sequences obtained from infected patients showed that SARS-CoV-2 is similar to severe acute respiratory syndrome coronavirus (SARS-CoV) and uses the same cell entry receptor, angiotensin-converting enzyme 2 (ACE2), as SARS-CoV. The possible person-to-person disease rapidly spread to many provinces in China as well as other countries. Without a therapeutic vaccine or specific antiviral drugs, early detection and isolation become essential against novel Coronavirus. In this review, we introduced current diagnostic methods and criteria for the SARS-CoV-2 in China and discuss the advantages and limitations of the current diagnostic methods, including chest imaging and laboratory detection.

Keywords SARS-CoV-2 · COVID-19 · Origin · Diagnosis

Introduction

Coronaviruses are unsegmented single-stranded RNA viruses ranging from 26 to 32 kilobases in length, belonging to the subfamily *Coronavirinae* of the family *Coronaviridae* of the order *Nidovirales* [1]. According to the serotype and genomic characteristics, the *Coronavirinae* subfamily is divided into four major genera: *Alphacoronavirus*, *Betacoronavirus*, *Gammacoronavirus*, and *Deltacoronavirus* [2]. The former two genera primarily infect mammals, whereas the latter two predominantly infect birds [3]. Coronaviruses mainly cause respiratory and gastrointestinal tract infections; six kinds of human CoVs have been previously identified, including the HCoV-NL63 and the HCoV-229E, which belong to the *Alphacoronavirus* genus, and the HCoV-OC43, the HCoVHKU1, the severe acute respiratory syndrome coronavirus (SARS-CoV), and the Middle East respiratory syndrome coronavirus (MERS-CoV), which belong to the *Betacoronavirus* genus [4]. Given the high prevalence and wide distribution of coronaviruses in animals, the large genetic diversity and frequent recombination of their genomes, and increasing human-animal interface activities and frequent cross-species infections, novel coronaviruses are likely to emerge periodically in humans [5].

In December 2019, a group of pneumonia cases was reported at a wholesale seafood market in Wuhan, Hubei province, which was found to be caused by previously unknown Coronaviruses [6]. On December 29, 2019, the local hospitals using a surveillance mechanism for "pneumonia of an unknown etiology," which was established in the wake of the 2003 severe acute respiratory syndrome (SARS) outbreak, identified the first 4 cases which were all associated with the Huanan (Southern China) Seafood Wholesale Market. On December 31, 2019, the Chinese Center for Disease Control and Prevention (China CDC) dispatched a rapid response team to accompany Hubei provincial and Wuhan city health authorities and to conduct an epidemiologic and etiologic investigation. Similar cases were subsequently reported in Wuhan, and many of these patients did not have contacts with the Huanan Seafood Wholesale Markets or animals. Epidemiological investigation showed that about only 1% of

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the patients had direct contact with the live-animal market trade, while more than three quarters were local residents of Wuhan or had made contact with people from Wuhan, suggesting a person-to-person transmission of this novel coronavirus was possible [7]. Airway epithelial cells from infected patients were used to isolate a novel coronavirus, temporarily named 2019-nCoV [8], but later, the Coronavirus Research Group (CSG) of the International Committee for the classification of viruses found that the new coronavirus is related to the SARS virus (SARS-CoV) that swept China in 2003. Both belong to a "species" category called severe acute respiratory syndrome-related coronavirus. Therefore, on February 11, 2020, the International Committee for the classification of viruses designated the name of this coronavirus as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [9]. In addition, the World Health Organization has named the disease caused by the SARS-CoV-2 as coronavirus disease 2019 (COVID-19). The possible person-to-person transmission rapidly spreads to many provinces in China as well as other countries. By February 27, 2020, 78,824 cases were laboratory-confirmed, and 2788 died in China [10]. The current public health emergency is partially similar to the SARS outbreak in southern China in 2002. The two cases share similarities. Both occurred during the winter with initial cases related to an exposure to live animals sold at animal markets, and the amino acid sequence identity between the SARS-CoV-2 and the SARS-CoV S-proteins is 76.47% [11]. The current knowledge of the physical and chemical properties of Coronaviruses is mainly derived from the study of the SARS-CoV and the MERS-CoV. The Coronaviruses are sensitive to exposure to heat (56 °C for 30 min), as well as solvents including ether, 75% ethanol, chlorine-containing disinfectant, peroxyacetic acid, and chloroform. Other lipid solvents can also effectively inactivate the virus except for chlorhexidine [12]. According to Zhong's latest pilot experiment, 4 out of the 62 stool specimens tested positive to the SARS-CoV-2, suggesting oral-fecal route might have played a role in the rapid transmission of SARS-CoV-2 [7]. However, no cases of transmission via the fecal-oral route have yet been reported for SARS-CoV-2. Contamination of fomite is more likely to be caused by airway/hands. At present, respiratory transmission and direct contact transmission are the main routes for SARS-CoV-2.

Genetic sequence and origin of the SARS-CoV-2

The genome of Coronaviruses, ranging from 26 to 32 kilobases in length, includes a variable number of open reading frames (ORFs) [13]. The SARS-CoV-2 genome was reported to possess 14 ORFs encoding 27 proteins [14]. The spike surface glycoprotein plays an essential role in binding to receptors on the host cell and is crucial for determining host tropism and transmission capacity, mediating receptor binding and membrane fusion [15]. Generally, the spike protein of Coronaviruses is functionally divided into the S1 domain, responsible for receptor binding, and the S2 domain, responsible for cell membrane fusion [16]. The eight accessory proteins (3a, 3b, p6, 7a, 7b, 8b, 9b, and orf14) and four major structural proteins, including the spike surface glycoprotein (S), small envelope protein (E), matrix protein (M), and nucleocapsid protein (N), are located in the 3′-terminus of the SARS-CoV-2 genome [14]. When researchers compare the SARS-CoV-2 with the SARS-CoV at the amino acid level, they found the SARS-CoV-2 was quite similar to the SARS-CoV, but there were some notable differences in the 8a, 8b, and 3b protein [14]. When researchers compared the SARS-CoV-2 with the MERS-CoV, they found that the SARS-CoV-2 was distant from and less related to the MERS-CoVs. From the phylogenetic tree based on whole genomes, the SARS-CoV-2 is parallel to the SARS-like bat CoVs, while the SARS-CoV has descended from the SARS-like bat CoV lineage, indicating that SARS-CoV-2 is closer to the SARS-like bat CoVs than the SARS-CoVs based on of the whole-genome sequence [14]. Analysis of the genome from nine patients' samples also confirmed that the SARS-CoV-2 was more similar to two SARS-like bat CoVs from Zhoushan in eastern China, bat-SL-CoVZC45 and bat-SL-CoVZXC21, than to the SARS-CoV and the MERS-CoV [17]. At the whole-genome level, the SARS-CoV-2 shares an 87.99% sequence identity with the bat-SL-CoVZC45 and 87.23% sequence identity with the bat-SL-CoVZXC2, less genetically similar to the SARS-CoV (about 79%) and MERS-CoV (about 50%) [17]. At the protein level, the lengths of most of the proteins encoded by the SARS-CoV-2, the bat-SL-CoVZC45, and the bat-SL-CoVZXC21 were similar, with only a few minor insertions or deletions [17]. Although the SARS-CoV-2 was closer to the bat-SL-CoVZC45 and the bat-SL-CoVZXC21 at the whole-genome level, the receptor-binding domain of the SARS-CoV-2 located in lineage B was closer to that of the SARS-CoV [17]. Given the close relationship between the SARS-CoV-2 and the SARS-CoVs or the SARS-like bat CoVs, further studies of the amino acid substitutions in different proteins could explain how the SARS-CoV-2 differs structurally and functionally from the SARS-CoVs and how these differences affect the functionality and pathogenesis of the SARS-CoV-2.

It was reported that 27 of the first 41 infected patients had been exposed to the Huanan Seafood Market [18]. Thus, it was believed that the new coronavirus originated from the Huanan Seafood Market in Wuhan and spread from animal hosts to humans in the process of wildlife trade, transportation, slaughter, and trade. Bats have the most variety of coronaviruses in their bodies and are the hosts of many kinds of coronaviruses, such as the SARS-CoV and the MERS-CoV

[19]. The SARS-CoV and the MERS-CoV are considered highly pathogenic, and it is very likely that the SARS-CoV was transmitted from bats to palm civets and the MERS-CoV was transmitted from bats to dromedary camels and finally to humans [20, 21]. Given the high sequence similarity between the SARS-CoV-2 and the SARS-like bat CoVs from *Hipposideros* bats in China, the natural host of the SARS-CoV-2 may be the *Hipposideros* bat. The discovery that pangolin coronavirus genomes have 85.5% to 92.4% sequence similarity to SARS-CoV-2 suggests pangolins should be considered as possible hosts in the emergence of SARS-CoV-2 [22].

Diagnosis

According to the seventh edition of Pneumonia Diagnosis and Treatment program for novel coronavirus infection reported by the National Health Commission of the People's Republic of China, suspected cases were defined as patients having fever or respiratory symptoms, a typical ground-glass opacity chest imaging as well as a history of exposure to wildlife in the Wuhan seafood market, and a travel history or contact with people from Wuhan within 2 weeks of diagnosis [12]. Confirmed cases with the SARS-CoV-2 were identified as a positive result of a high-throughput sequencing or an RT-PCR assay for respiratory specimens including nasal and pharyngeal swab specimens, bronchoalveolar lavage fluid, sputum, or bronchial aspirates or a positive result of anti-SARS-CoV-2 IgM/IgG or the titer of anti-SARS-CoV-2 IgG antibody in the recovery period was four times or more higher than in the acute period [12]. At present, the diagnosis of the COVID-19 is mainly based on clinical characteristics, epidemiological history, chest imaging, and laboratory detection.

Clinical characteristics and epidemiological history

The most common symptoms of confirmed patients were fever, cough, and myalgia or fatigue, whereas sputum production, headache, diarrhea, and vomiting were rare [23–26]. Mild cases only have a low fever and mild fatigue, without pneumonia. Severe and moderate cases had clinical manifestations of dyspnea, lymphopenia, and hypoalbuminemia, which mainly occurred in elderly patients [23]. It is worth noting that patients with severe or critical illness may have a moderate or low fever, or even no significant fever [12]. The elderly and those with chronic diseases, including diabetes, hypertension, and cardiovascular disease, have poor prognoses [12]. Most severe patient died of severe pneumonia, severe respiratory failure, and multiple organ failure [26]. Epidemiological investigations indicate that most patients were local residents of Wuhan or had direct exposure to the Huanan Seafood Market, a travel history to Wuhan, or contact with confirmed cases [7]. In addition, outbreaks within family clusters have been reported from several provinces in China [27]. An increasing number of cluster cases including family cluster cases are occurring [24, 25].

Chest imaging

The most common patterns seen on chest CT were bilateral, peripheral, and ground-glass opacity [28, 29]. Less common CT findings were nodules, cystic changes, bronchiolectasis, pleural effusion, and lymphadenopathy [28, 29]. Chest CT images of an early-stage COVID-19 patients showed multiple small plaques and interstitial changes. The findings of a progressive stage chest CT images included a bilateral multiple ground-glass opacity and an infiltrating opacity with consolidation, interstitial thickening or fibrous stripes [29–31]. The diffuse lesions in bilateral lungs could be seen in the most seriously affected patients, whose CT showed as "white lungs" [31].

Laboratory detection

Specific laboratory detection

Isolation of the causal agent and determination of its partial genome sequence provided the basis for next-generation sequencing or real-time reverse transcriptase-polymerase chain reaction (RT-PCR) methods for the SARS-CoV-2 [14, 17]. After the SARS-CoV-2 was isolated from a lower respiratory tract specimen, a diagnostic RT-PCR test was developed. RT-PCR tests were based on the RNA-dependent RNA polymerase (RdRp) gene of the ORF1ab sequence, E gene, N gene, and S gene of the SARS-CoV-2 genome [32–35]. Among these assays, RT-PCR assays targeting the RdRp assay had the highest analytical sensitivity [32]. The SARS-CoV-2 nucleic acid can be detected in nasal and pharyngeal swab specimens, bronchoalveolar lavage fluid, sputum, bronchial aspirates, blood, anal swab, and other samples by an RT-PCR [36, 37]. In a case with severe peptic ulcers after the onset of symptoms, the SARS-CoV-2 was directly detected in the esophageal erosion and at the bleeding site [7]. Some patients infected with the SARS-CoV-2 also displayed gastrointestinal symptoms such as diarrhea [23, 38] because some viruses may enter the digestive tract through the throat, infecting the intestinal epithelial cells and activating the intestinal immune response. Thus, the SARS-CoV-2 nucleic acid can also be detected in the stool samples of some patients [7, 36, 37]. High-throughput sequencing or an RT-PCR assay has become a standard and formative assessment for the diagnosis of the COVID-19 [12]. However, nucleic acid amplification kits sometimes produced false-negative results among patients whose clinical features, chest imaging, and laboratory detection accorded with the COVID-19 [30, 39]. There are several

possible reasons for the false-negative results from the nucleic acid kit. Firstly, although older age was correlated with higher viral load [40], it is not clear whether the viral load in body fluids has a positive linear correlation with the severity of symptoms after infection. If the virus in the suspected patients remains to be rapidly replicated and released in the lungs, the nasal and pharyngeal swabs sampling may not collect enough virus for diagnosis. Secondly, the current common sampling method is to collect nasal and pharyngeal swabs, sputum, or the alveolar lavage fluid [36, 40, 41]. Few patients with the SARS-CoV-2 infection had prominent signs and symptoms of the respiratory tract, indicating that the target cells may be located in the lower airway [18]. The viral nucleic acid is most easily detected in the alveolar lavage fluid, followed by sputum, nasal, and pharyngeal swabs [41–43]. A study of 4880 cases showed that the alveolar lavage fluid exhibited the most highest positive rate of 100% for SARS-CoV-2 ORF1ab gene; the sputum exhibited a 49.12% positive rate, and the nasal and pharyngeal swabs samples showed a poor positive rate of 38.25% [41]. Alveolar lavage fluid collection is generally suitable for patients with a severe or critical illness, not mild cases. Sputum specimens are also more difficult to obtain because few patients with the SARS-CoV-2 infection had sputum production [7, 18]. Due to the limitations associated with operations and patient acceptance, the most common sampling method in clinical practice is nasal and pharyngeal swab collection. However, respiratory samples collected from 80 individuals at different stages of infection showed a median of $7{\cdot}99 \times 10^4$ in nasal and pharyngeal swab samples and $7{\cdot}52 \times 10^5$ in sputum samples [36]. Sputum samples generally showed higher viral loads than throat swab samples [36, 43]. The low viral load in nasal and pharyngeal swab makes the diagnosis of the SARS-CoV-2 more difficult. On the other hand, RT-PCR test results of pharyngeal swab specimens were variable and potentially unstable [44]. It was reported that patients with initial non-positive results were eventually confirmed with COVID-19 by 3~5 repeated swab PCR tests [44]. The phenomenon of SARS-CoV-2 positive in the stool samples but negative nucleic acid in throat swab specimens indicated that selecting fecal samples for a nucleic acid test may be an alternative strategy [45]. Considering that the SARS-CoV-2 nucleic acid can be detected in nasal and pharyngeal swab specimens, bronchoalveolar lavage fluid, sputum, bronchial aspirates, blood, and anal swab [36, 37], it is suggested to collect samples from multiple site of the same patient at different stages and combine them for detection to improve the positive rate. Thirdly, the SARS-CoV-2 is an RNA virus with low stability, which is easily degraded by RNA enzymes released after exogenous or cellular destruction, affecting the final detection efficiency. Improper sampling location, insufficient sampling strength, and irregular sample delivery process account for the false-negative results of the nucleic acid kit test [39]. Besides, in order to improve the sensitivity of detection, most manufacturers choose two or more regions of viral nucleic acid sequence for detection, including the ORF1ab sequence, E gene, N gene, and S gene of the SARS-CoV-2 genome [32–35]. In actual tests, there is a certain proportion of positive results of a single target gene locus indicating that the sensitivity of the reagent to different gene regions is indeed different [41], which may also be caused by the competition between the loci of two or three target genes. Furthermore, reagent reaction conditions, reaction system, and nucleic acid addition amount may affect the sensitivity of detection and analysis [46]. It is an effective measure for the clinical laboratory to carry out quality control for each batch of reagents by using the confirmed negative and positive samples before routine work.

Based on the above reasons, detection of the viral RNA using RT-PCR can only achieve a sensitivity of 30~60% [41, 47, 48], depending on the course and condition of the patient, the type and number of clinical specimens collected, and the protocol used. The older had higher positive rate than the young [41] which may be explained by the finding that the older was correlated with higher viral load [40]. Supplement serum IgM/IgG antibody detection against the SARS-CoV-2 internal nucleoprotein (NP) and surface spike protein receptor-binding domain (RBD) can make up for the shortcomings of RT-PCR in some cases [40, 49]. The antibody is the product of a humoral immune response after infection with the virus. Generally, IgM antibodies rise within a few days after a viral infection and can be detected as soon as a week of incubation, and IgG antibodies appear in the middle and late stages of the infection. There is a process of a continuous increase in the antibody titer, and it remains in the blood circulation for a long time. At the moment, the most widely used methods for serodiagnosis of the SARS-CoV-2 infection in clinical microbiology laboratories are antibody detection in acute- and convalescent-phase sera by colloidal gold immunochromatography and enzyme-linked immunosorbent assay (ELISA) [40]. In short, a test for IgM/IgG antibodies can also determine whether a patient has been infected with the SARS-CoV-2 recently or previously and act as a supplementary detection to identify patients with high clinical suspicion of the SARS-CoV-2 infection but negative RT-PCR findings [40, 49]. The new serological diagnostic kits for IgM and IgG antibodies for SARS-CoV-2 have the advantages of high sensitivity and early diagnosis. In addition, the operational requirements of antibody detection in clinical microbiology laboratories are relatively low, fast, capable of large quantities, and can be completed in basic laboratories compared with the nucleic acid test. Anti-SARS-CoV-2 IgM antibody was positive at 3~5 days after onset, and the titer of anti-SARS-CoV-2 IgG antibody in the recovery period was four times or more higher than in the acute period [12]. Although the supplementary antibody test can make up for the missed diagnosis of RT-PCR, it still cannot diagnose all infected patients. The

detection of IgM and IgG antibodies can only achieve a sensitivity of 70% at 4~6 days after admission for COVID-19 patients (unpublished data from our group). The detection of IgM and IgG antibodies may be futile for the elderly, because of hypoimmunity and a weak antibody production capacity.

Nonspecific laboratory detection

The laboratory examination of patients at an early stage showed leucopenia, lymphopenia, high level of aspartate aminotransferase, C-reactive protein (CRP), and erythrocyte sedimentation rate [18]. Most patients had normal serum levels of procalcitonin. Compared with moderate cases, severe cases more frequently had lymphopenia, with higher levels of alanine aminotransferase, lactate dehydrogenase, C-reactive protein, ferritin, and D-dimer as well as markedly higher levels of IL-2R, IL-6, IL-10, and TNF-α [23]. Typical abnormal laboratory findings in pediatric patients were elevated creatine kinase MB, decreased lymphocytes, leucopenia, and elevated procalcitonin [24]. Recent studies have also shown another potential diagnostic biomarker for the SARS-CoV-2 diagnosis. Renin cleaves liver-derived angiotensinogen (AGT) into angiotensin I, which is then further processed by the angiotensin-converting enzyme (ACE) into the octapeptide angiotensin II. The abnormal increase of angiotensin II has been reported to be associated with hypertension, heart failure, and lung and kidney dysfunction as well as several pathophysiological features, including inflammation, metabolic dysfunction, and aging [50, 51]. Xu et al. performed structural modeling of the S-protein of the SARS-CoV-2 to evaluate its ability to interact with human angiotensin-converting enzyme 2 (ACE2) molecules. Because of the loss of hydrogen bond interactions due to replacing Arg426 with Asn426 in the SARS-CoV-2 S-protein, the binding free energy for the SARS-CoV-2 S-protein increased by 28 kcal mol^{-1} when compared with the SARS-CoV S-protein binding. The results revealed that the SARS-CoV-2 S-protein has a strong binding affinity to human ACE2 [11]. A study discovered the markedly increased level of angiotensin II in the plasma samples from SARS-CoV-2-infected patients was linearly correlated with viral load and lung injury [52]. It is suggested that the imbalance of the renin-angiotensin-aldosterone system is caused by the SARS-CoV-2, and angiotensin receptor blocker (ARB) drugs may be used as a potential repurposing treatment of the SARS-CoV-2 infection. Similar studies have demonstrated that the SARS-CoV could bind to its receptor ACE2, downregulating its expressions, resulting in increased angiotensin II levels in mouse blood samples, signaling through angiotensin II receptor 1, leading to an acute lung injury [53]. Besides, markedly, elevation of angiotensin II level in the H7N9-infected patients was associated with the disease severity and outcomes [54].

Discussion

Chest CT imaging showed that 76.4% of infected patients manifested as pneumonia on admission, which was mainly ground-glass opacity (50%) and bilateral patchy shadowing (46.4%). The majority of severe patients could be diagnosed by chest X-ray and chest CT imaging. Despite these predominant manifestations, it was reported that 221 out of the 926 (23.87%) in severe cases compared with 9 out of the 173 non-severe cases (5.20%) who had no abnormal radiological findings were diagnosed by symptoms plus RT-PCR positive findings, suggesting that not all patients had abnormal chest radiological findings of pneumonia. Chest CT images of the early-stage COVID-19 patients showed unilateral or bilateral ground-glass opacity, which was similar to some non-COVID-19 images of patients with the respiratory syncytial viral (RSV), mycoplasma, and parainfluenza virus, suggesting that chest CT scans cannot the identify COVID-19 patients and the non-COVID-19 patients in some cases. Co-infection with other viruses such as influenza A/B, rhino/enterovirus, respiratory syncytial virus, other atypical pathogens, fungi, and bacteria has been reported in the COVID-19 patients [49, 55]. Mixed infection among COVID-19 patients makes the diagnosis of chest CT images more difficult. Besides, positive respiratory pathogen results cannot serve as evidence for the exclusion of SARS-COV-2 infection. Methods of pathogen-specific detection are mainly divided into four types, including virus culture, nucleic acid detection, antigen detection, and antibody detection. In terms of virus culture, the cultivation of the SARS-CoV-2 requires biosafety level 3 laboratory facilities, which are not available in most clinical microbiology laboratories. Thus, the cultivation of the SARS-CoV-2 is mainly used for scientific research. Commercial antigen detection kits require the preparation of monoclonal antibodies and polyclonal antibodies, whereas it costs a long time from production to extraction during antibody preparation, and the preparation process is complicated. Detection of the viral nucleic acid using an RT-PCR assay has become a standard and formative assessment for the diagnosis of COVID-19. However, detection of viral RNA using RT-PCR can only achieve a sensitivity of 30~60%, depending on the course and condition of the patient, the type and number of clinical specimens collected, and the protocol used. In order to improve the positive rate of detection, it is suggested to collect multiple site samples of the same patient at different stages repeatedly and combine them for detection. The phenomenon of SARS-CoV-2 positive in the stool samples but negative nucleic acid in throat swab specimens should be taken seriously. Patients with early or mild illness may have a low viral load in nasal and pharyngeal swabs, resulting in false-negative nucleic acid tests. Thus, selecting fecal samples for a nucleic acid test may be an alternative strategy, regardless of the presence or absence of gastrointestinal symptoms such as

diarrhea. In addition, a fecal-oral transmission might exist in the transmission of 2019-nCoV; thus, the transmission via gastrointestinal secretions should be fully considered to control the rapid spread worldwide. Whole genome sequencing (WGS) method can overcome the mutation problems which cause false-negative results in RT-PCR [55, 56], whereas it is not applicable to clinical practice considering the economic status of patients. For individuals with high clinical suspicion of the SARS-CoV-2 infection but negative RT-PCR findings, the detection of IgM/IgG antibodies should be considered. We recommend IgM antibody testing 1 week after infection and IgG antibody testing 4 weeks after infection. Although the supplementary antibody test can make up for the missed diagnosis of RT-PCR, it cannot diagnose all the infected patients. Collectively, for chest CT scans, RT-PCR assays, and the detection of IgM/IgG antibodies, multiple and repetitive tests should be considered during different stages of the COVID-19. Further research of SARS-CoV-2 and the development of more sensitive detection methods will facilitate the diagnosis of COVID-19. In addition, the development of broad-spectrum antiviral drugs and vaccines will enhance the ability to manage future outbreaks caused by this cluster of viruses.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethics approval Not applicable.

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Review

SARS-CoV-2: an Emerging Coronavirus that Causes a Global Threat

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Abstract

An ongoing outbreak of pneumonia caused by a novel coronavirus, currently designated as the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), was reported recently. However, as SARS-CoV-2 is an emerging virus, we know little about it. In this review, we summarize the key events occurred during the early stage of SARS-CoV-2 outbreak, the basic characteristics of the pathogen, the signs and symptoms of the infected patients as well as the possible transmission pathways of the virus. Furthermore, we also review the current knowledge on the origin and evolution of the SARS-CoV-2. We highlight bats as the potential natural reservoir and pangolins as the possible intermediate host of the virus, but their roles are waiting for further investigation. Finally, the advances in the development of chemotherapeutic options are also briefly summarized.

Key words: Coronavirus, Novel coronavirus, pneumonia, SARS-CoV-2, COVID-19

Introduction

On 23 Feb 2020, the lock-down of Wuhan, a central city in China, has alarmed people all over the world of an emerging novel coronavirus that is posing a major public health and governance challenges. The novel virus, previously called the 2019-novel coronavirus (2019-nCoV), is currently designated as the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). As of 27 Feb, this emerging infection has been reported in 47 countries, causing over 82,294 infections with 2,804 deaths (Fig. 1) [1]. This novel virus is also becoming a mounting threat to Chinese and global economies.

Coronaviruses (CoVs) are members of the family Coronaviridae, the enveloped viruses that possess extraordinarily large single-stranded RNA genomes ranging from 26 to 32 kilobases in length [2]. CoVs have been identified in both avian hosts and various mammals, including bat, camels, dogs and masked palm civets, and are previously regarded as pathogens that only cause mild diseases in the immunocompetent people until the emergence of the coronavirus causing severe acute respiratory syndrome (SARS-CoV) in late of 2002 [3-6]. Currently, at least seven coronavirus species are known to cause diseases in humans. The viruses of 229E, OC43, NL63 and HKU1 only cause common cold symptoms, which are mild. Severe illness can be caused by the remaining three viruses, namely SARS-CoV, which resulted in the outbreak of SARS in 2002 and 2003 [3,4]; the coronaviruses that are responsible the Middle East respiratory syndrome (MERS-CoV), which emerged in 2012 and remains in the circulation in camels [7]; and SARS-CoV-2, the viruses emerged in December 2019 in Wuhan of China and a great effort is being undertaken to contain its spreading [8]. In this review, we will briefly introduce the outbreak history of SARS-CoV-2, the signs and symptoms of the infected patients, its transmission dynamics, the advances in the understanding on its evolutional origin and the chemotherapeutic options being developed for the treatment of its infection.

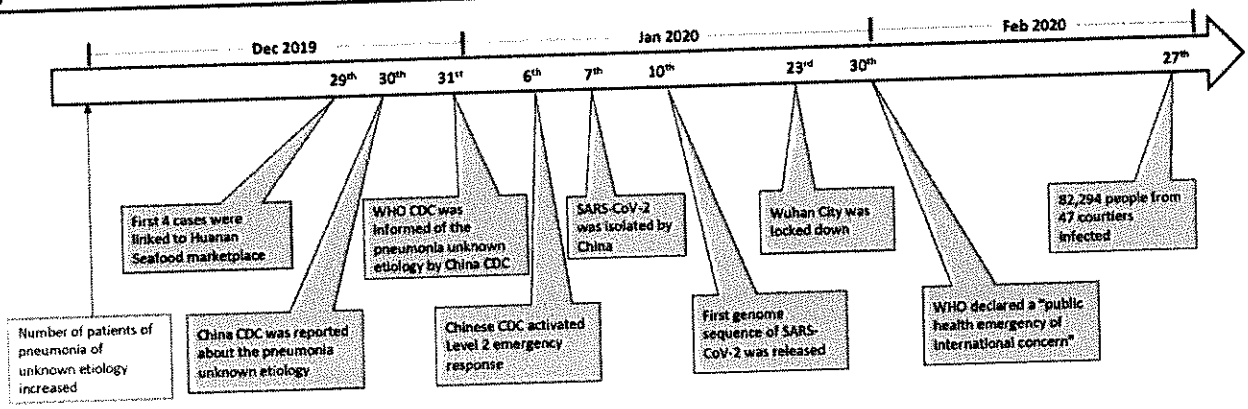

Figure 1. Key events in the early stage of SARS-CoV-2 outbreak.

The key events of SARS-CoV-2 outbreak and the pathogen characteristics

Since December 2019, an increasing number of patients with pneumonia of unknown etiology in Wuhan, a city with 11 million people, have alarmed the local hospital. On 29 December 4 cases were linked to Huanan Seafood wholesale market [9], where non-aquatic live animals, including several kinds of wild animals, were also on the sales. The local Center for Disease Control (CDC) then found additional patients linked to the same market after investigation, and reported to China CDC on 30 Dec 2019 [9]. The second day, World Health Organization (WHO) was informed of the cases of pneumonia of unknown etiology by China CDC [10]. On 6 Jan 2020, a level 2 emergency response was launched by China CDC [11].

The causal agent was not identified until 7 Jan 2020; a new type of coronavirus was isolated by Chinese authority [10]. The genome sequence of SARS-CoV-2 (WH-Human_1) was first released and shared by China on 10 Jan [12]. The isolation and identification of SARS-CoV-2 apparently facilitated the development of molecular diagnostic methods and the confirmation of the infected patients. As of 21 Jan, there are 270 cases were confirmed from Wuhan [13]. On 23 Jan, Wuhan city was locked down by local government. On 30 Jan, WHO declared a "public health emergency of international concern" (Fig. 1).

Subsequently, the viruses were successfully isolated from several laboratories [8,14,15]. The virion of SARS-CoV-2 looks like a solar corona by transmission electron microscopy imaging: the virus particle is in a spherical shape with some pleomorphism; the diameter of the virus particles range from 60 to 140 nm with distinctive spikes about 8 to 12 nm in length [8]. The observed morphology of SARS-CoV-2 is consistent with the typical characteristics of the Coronaviridae family. The genome sequence of SARS-CoV-2 from clinical samples has been obtained by several laboratories with deep sequencing [8,14-18]. The viral genome of SARS-CoV-2 is around 29.8 kilobase, with a G+C content of 38%, in total consisting of six major open reading frames (ORFs) common to coronaviruses and a number of other accessory genes [14,16]. The sequences analysis showed that the genome sequences of viruses from different patients are very conserved [14,15,19], implying that the human virus evolves recently.

Signs and symptoms of patients infected by SARS-CoV-2

A typical characteristic of the SARS-CoV-2 infected patient is pneumonia, now termed as Coronavirus Disease 2019 (COVID-19), demonstrated by computer tomographic (CT) scan or chest X -ray [3,8,18]. In the early stages, the patients showed the acute respiratory infection symptoms, with some that quickly developed acute respiratory failure and other serious complications [20]. The first three patients reported by the China Novel Coronavirus Investigating and Research Team all developed severe pneumonia and two of these three patients with available clinical profiles showed a common feature of fever and cough [8]. A subsequent investigation of a family of six patients in the University of Hong Kong-Shenzhen Hospital demonstrated that all of them had pulmonary infiltrates, with a variety of other symptoms [18]. The chest X-ray and CT imaging in a study showed that 75% of 99 patients demonstrated bilateral pneumonia and the remaining 25% unilateral pneumonia [21]. Overall, 14% of the patients showed multiple mottling and ground-glass opacity [21]. The first cases of coronavirus infection in the United States also showed basilar streaky opacities in both lungs by chest radiography. However, the pneumonia for this patient was only detected on the day 10 of his illness [22]. It is also of note that one of patients among the family of six patients did not present any other symptoms and signs, but had ground-glass lung opacities identified by CT scan [18].

Table 1. Common signs and symptoms of SARS-CoV-2 infected patients from four reports

Signs or Symptoms	Number of patients with signs or symptoms from each report				Number of patients with signs or symptoms	Total number of patients	Percentage
	Report 1 [21]	Report 2 [23]	Report 3 [24]	Report 4 [25]			
Fever	82 (n=99)	40 (n=41)	136 (n=138)	975 (n=1099)	1233	1377	90%
Cough	81 (n=99)	31 (n=41)	82 (n=138)	745 (n=1099)	939	1377	68%
Sputum production/ Expectoration	NR	11 (n=39)	37 (n=138)	370 (n=1099)	418	1276	33%
Shortness of breath/ Dyspnoea	31 (n=99)	22 (n=40)	43 (n=138)	205 (n=1099)	301	1376	22%
Headache	8 (n=99)	3 (n=38)	9 (n=138)	150 (n=1099)	170	1374	12%
Sore throat/Pharyngalgia	5 (n=99)	NR	24 (n=138)	153 (n=1099)	182	1336	14%
Diarrhoea	2 (n=99)	1 (n=38)	14 (n=138)	42 (n=1099)	59	1374	4%

NR: Not Recorded.

At least four comprehensive studies on the epidemiological and clinical characteristics of SARS-CoV-2 infected patients have been performed [21, 23-25]. The most common signs and symptoms of patients are fever and cough [21,23-25]. Fatigue was complained by 96% of patients (n=138) in one study [24], but was less outstanding (18%, n=44) in another report [23]. A combinational analysis of the common recorded signs or symptoms of the reported cases found that fever was observed in around 90% of the SARS-CoV-2 infected patients; the number of patients with cough is relatively less (68%) compared to fever (Table 1). In addition, shortness of breath or dyspnea, muscle ache, headache, chest pain, diarrhea, haemoptysis, sputum production, rhinorrhoea, nausea and vomiting, sore throat, confusion, and anorexia were also observed in a proportion of the patients [21,23-25] (Table 1).

A common feature of patients of SARS, MERS or COVID-19 is the presence of severe acute respiratory syndrome; however, the estimated fatality rate of COVID-19 (2.3%) is much lower than SARS (~10%) and MERS (~36%) [26,27]. Furthermore, the viruses responsible for above three diseases are evolutionary distinct (See below for details) [19].

Transmission of the virus

It is clear now that SARS-CoV-2 can be transmitted by human-to-human despite the majority of the early cases had contact history with the Huanan Seafood market [11,18,28]. Analysis of 425 patients with confirmed COVID-19 showed that the incubation period is 3 to 7 days. The mean was 5.2 days (95% CI: 4.1 to 7.0), and the 95th percentile of the distribution is 12.5 days (95% CI: 9.2 to 18) [11]. Notably, it was reported that the incubation period could be as long as 24 days in a rare case [25]. The basic reproductive number (R_0) up to the period of 4 Jan 2020 was estimated based on the study of 425 patients to be 2.2 (meaning that one patient has been spreading infection to 2.2 other people) [11], slightly smaller than the value of 2.68 by a modelling in another [29]. The R_0 of SARS-CoV-2 from both of these two studies is smaller than that of SRAS, which are 3 before public health measures were implemented [30]. However, subsequent investigation based on the analysis of high-resolution real-time human travel and infection data estimated that the R_0 is much larger, ranging from 4.7 to 6.6 before the control measures [31], implying that SARS-CoV-2 is highly contagious and more infectious than initially estimated. This conclusion is consistent with the wide spread of SARS-CoV-2 within a short period time and was also echoed by the finding that SARS-CoV-2 Spike (S) protein had 10- to 20-fold higher affinity to human angiotensin-converting enzyme 2 (ACE2) receptor than that of SARS-CoV based on the Cryo-EM structure analysis of S proteins [32]. Similar to SARS-CoV, the entry of SARS-CoV-2 into host cells depends on the recognition and binding of S protein to ACE2 receptor of the host cells [14,33]. The high affinity of S protein to ACE2 receptor likely contributes to the quick spreading of virus. The finding of ACE2 as the receptor of SARS-CoV-2 also indicates that human organs with high ACE2 expression level, such as lung alveolar epithelial cells and enterocytes of the small intestine, are potentially the target of SARS-CoV-2 [34].

As a new coronavirus, it is not known yet about how SARS-CoV-2 spreads. Current knowledge for SARS-CoV-2 transmission is largely based on what is known from the similar coronaviruses, particularly SARS-CoV and MERS-CoV, in which human-to-human transmission occurs through droplets, contact and fomites. SARS-CoV is predominantly transmitted through indirect or direct contact with mucous membranes in the mouth, eyes, or nose [35]. It has been shown that unprotected eyes and exposed mucous membranes are vulnerable to SARS-CoV transmission [36]. A member of the national expert panel on pneumonia was infected by SARS-CoV-2 after the inspection in Wuhan [37]. As he wore a N95 mask but not any eye protector, and experienced eye redness before the onset of pneumonia, it was thus suspected that unprotected exposure of the eyes to

SARS-CoV-2 might be another transmission pathway [37]. However, SARS-CoV-2 was not detected from the conjunctival swab sample in a confirmed COVID-19 patent with conjunctivitis [38], suggesting that more evidences are needed before concluding the conjunctival route as the transmission pathway of SARS-CoV-2. The mode of transmission by MERS-CoV is not well understood but is believed to spread largely via the respiratory close contact route [39,40].

Based on the transmission mode of SARS-CoV and MERS-CoV, a serial of preventive measures have been recommended, including avoiding close contact with people suffering from acute respiratory infections and frequent hand-washing [41]. The viruses of SARS-CoV-2 were also detected in the stool samples in some patients but not all [18,22], suggesting that a possible fecal-oral transmission occurs [42]. A systematic study showed that viruses could be detected in oral swabs, anal swabs and blood samples of the patients, and the anal swabs and blood could test positive when oral swab tested negative [43]. Furthermore, a trend of shift from more oral positive in the collected samples during the early period of patient infection to more anal positive during later period of infection was also found [43]. Therefore, a multiple shedding routes of SARS-CoV-2 might exist.

One of the challenges for preventive control of SARS-CoV-2 spreading is that the viruses are likely transmitted by asymptomatic contact. A German businessman was found infected by SARS-CoV-2 after attending a conference together with a colleague, who had no signs or symptoms of infection but had become ill due to the SARS-CoV-2 infection later [44]. This observation suggests that infected patients likely start to shed viruses before the onset of any symptom, which undoubtedly will bring great challenge to the current practice of preventive control by measuring body temperature. Despite the claim of the transmission by asymptomatic contact has been challenged [45], other asymptomatic carriers were also observed to transmit the viruses of SARS-CoV-2 [46,47]. Consistently, a study found that an asymptomatic patient had a similar vial loads in the samples of nasal and throat swabs to that of the symptomatic patients [48].

The origin and evolution of SARS-CoV-2

It is critical to identify the origin, native host(s) and evolution pathway of the virus that causes an outbreak of a pandemic. This information can help understand the molecular mechanism of its cross-species spread and implement a proper control measure to prevent it from further spreading. The association of initially confirmed SARS-CoV-2 cases with Huanan Seafood market suggested that the marketplace has played a role in the early spreading [11,23], however, whether it is the origin of the outbreak and what is the native host(s) of SARS-CoV-2 remain uncertain. In fact, the firstly documented patient was not linked to Huanan Seafood market [23].

The analysis of SARS-CoV-2 origin was firstly performed based on the genome sequence of virus isolates from six patients [19]. When compared with SARS-CoV and MERS-CoV, the nucleotide sequences of SARS-CoV-2 showed a higher homology with that of SARS-CoV while was relatively poor with that of MERS-CoV [19]. Despite some of the six major OFRs of SARS-CoV-2 genes share less than 80% identity in nucleotide acids to SARS-CoV, the seven conserved replicase domains in ORF1ab has 94.6% sequence identity in amino acids between SARS-CoV-2 and SARS-CoV [14], suggesting that these two viruses might belong to the same species. The origin of SARS-CoV has been extensively investigated. Masked palm civets were initially considered to transmit SARS-CoV to humans as a close variant of SARS-CoV was detected from palm civets [49]. This conclusion was supported by the fact that three of the four patients had the record of contact with palm civets during the two small-scale of SARS outbreaks occurred in late 2003 and early 2004 [50, 51]. However, a deep investigation based on the genome sequence of isolated viruses showed that SARS-CoV-like virus in civet had not been circulating for long [52]. Subsequently, coronaviruses with high similarity to the human SARS-CoV or civet SARS-CoV-like virus were isolated from horseshoe bats, concluding the bats as the potential natural reservoir of SARS-CoV whereas masked palm civets are the intermediate host [53-56].

It is thus reasonable to suspect that bat is the natural host of SARS-CoV-2 considering its similarity with SARS-CoV. The phylogenetic analysis of SARS-CoV-2 against a collection of coronavirus sequences from various sources found that SARS-CoV-2 belonged to the *Betacoronavirus* genera and was closer to SARS-like coronavirus in bat [19]. By analyzing genome sequence of SARS-CoV-2, it was found that SARS-CoV-2 felled within the subgenus *Sarbecovirus* of the genus Betacoronavirus and was closely related to two bat-derived SARS-like coronaviruses, bat-SL-CoVZC45 and bat-SL-CoVZXC21, but were relatively distant from SARS-CoV [15, 18, 57-59]. Meanwhile, Zhou and colleagues showed that SARS-CoV-2 had 96.2% overall genome sequence identity throughout the genome to BatCoV RaTG13, a bat coronavirus detected in *Rhinolophus affinis* from Yunnan province [14]. Furthermore, the phylogenetic

analysis of full-length genome, the receptor binding protein spike (S) gene, and RNA-dependent RNA polymerase (RdRp) gene respectively all demonstrated that RaTG13 was the closest relative of the SARS-CoV-2 [14]. However, despite SARS-CoV-2 showed high similarity to coronavirus from bat, SARS-CoV-2 changed topological position within the subgenus *Sarbecovirus* when different gene was used for phylogenetic analysis: SARS-CoV-2 was closer to bat-SL-CoVZC45 in the S gene phylogeny but felled in a basal position within the subgenus *Sarbecovirus* in the ORF1b tree [57]. This finding implies a possible recombination event in this group of viruses. Of note, the receptor-binding domain of SARS-CoV-2 demonstrates a similar structure to that of SARS-CoV by homology modelling but a few variations in the key residues exist at amino acid level [15, 19].

Despite current evidences are pointing to the evolutional origin of SARS-CoV-2 from bat virus [15, 57], an intermediate host between bats and human might exist. Lu et. al. raised four reasons for such speculation [15]: First, most bat species in Wuhan are hibernating in late December; Second, no bats in Huanan Seafood market were sold or found; Third, the sequence identity between SARS-CoV-2 and bat-SL-CoVZC45 or bat-SL-CoVZXC21, the closest relatives in their analyses, is lower than 90%; Fourth, there is an intermediate host for other human-infecting coronaviruses that origin from bat. For example, masked palm civet and dromedary camels are the intermediate hosts for SARS-CoV [49] and MERS-CoV respectively [60]. A study of the relative synonymous codon usage (RSCU) found that SARS-CoV-2, bat-SL-CoVZC45, and snakes had similar synonymous codon usage bias, and speculated that snake might be the intermediate host [61]. However, no SARS-CoV-2 has been isolated from snake yet.

Pangolin was later found to be a potential intermediate host for SARS-CoV-2. The analysis of samples from Malytan pangolins obtained during anti-smuggling operations from Guangdong and Guangxi Customs of China respectively found novel coronaviruses representing two sub-lineages related to SARS-CoV-2 [62]. The similarity of SARS-CoV-2 to these identified coronaviruses from pangolins is approximately 85.5% to 92.4% in genomes, lower than that to the bat coronavirus RaTG13 (96.2%) [14,62]. However, the receptor-binding domain of S protein from one sub-lineage of the pangolin coronaviruses shows 97.4% similarity in amino acid sequences to that of SARS-CoV-2, even higher than that to RaTG13 (89.2%) [62]. Interestingly, the pangolin coronavirus and SARS-CoV-2 share identical amino acids at the five critical residues of RBD of S protein, while RaTG13 only possesses one [62]. The discovery of coronavirus close to SARS-CoV-2 from pangolin suggests that pangolin is a potential intermediate host. However, the roles of bat and pangolin as respective natural reservoir and intermediate host still need further investigation.

Chemotherapeutic options for SARS-CoV-2 infection

As an emerging virus, there is no effective drug or vaccine approved for the treatment of SARS-CoV-2 infection yet. Currently, supportive care is provided to the patients, including oxygen therapy, antibiotic treatment, and antifungal treatment, extra-corporeal membrane oxygenation (ECMO) etc. [21,22]. To search for an antiviral drug effective in treating SARS-CoV-2 infection, Wang and colleagues evaluated seven drugs, namely, ribavirin, penciclovir, nitazoxanide, nafamostat, chloroquine, remdesivir (GS-5734) and favipiravir (T-750) against the infection of SARS-CoV-2 on Vero E6 cells *in vitro* [63]. Among these seven drugs, chloroquine and remdesivir demonstrated the most powerful antiviral activities with low cytotoxicity. The effective concentration (EC_{50}) for chloroquine and remdesivir were 0.77μM and 1.13μM respectively. Chloroquine functions at both viral entry and post-entry stages of the SARS-CoV-2 infection in Vero E6 cells whereas remdesivir does at post-entry stage only. Chloroquine is a drug used for an autoimmune disease and malarial infection with potential broad-spectrum antiviral activities [64,65]. An EC_{90} (6.90 μM) against the SARS-CoV-2 in Vero E6 cells is clinically achievable *in vivo* according to a previous clinical trial [66]. Remdesivir is a drug currently under the development for Ebola virus infection and is effective to a broad range of viruses including SARS-CoV and MERS-CoV [67,68]. Functioning as an adenosine analogue targeting RdRp, Remdesivir can result in premature termination during the virus transcription [69,70]. The EC_{90} of remdesivir against SARS-CoV-2 in Vero E6 cells is 1.76 μM, which is achievable *in vivo* based on a trial in nonhuman primate experiment [63, 69]. Encouragingly, in the first case of SARS-CoV-2 infection in the United States, treatment with remdesivir was provided intravenously to the patient on the day 7 without any adverse events observed. The patient's clinical condition was improved on day 8 and the previous bilateral lower-lobe rales disappeared, implying the remdesivir might be effective to the treatment of SARS-CoV-2 infection [22]. This result, however, should be interpreted with caution as this is only single case study and a proper trial control was lacking. In addition, baricitinib, a Janus kinase inhibitor, was also predicted to reduce

the ability of virus to infect lung cell by an analysis of BenevolentAI [71].

Currently, chloroquine and remdesivir are under phase 3 clinical trial and open-label trial for treatment of SARS-CoV-2 infection respectively (Table 2) [72]. Preliminary results showed that chloroquine phosphate had apparent efficacy in treatment of COVID-19 [73]. However, caution must be taken during clinical use of chloroquine as its overdose is highly fatal without known antidote [74]. Despite the lack of documented *in vitro* data supporting the antiviral efficacy on SARS-CoV-2, several antiviral chemotherapeutic agents have been registered for the clinical trials for the treatment of COVID-19 (Table 2) [72].

Conclusion remarks

SARS-CoV-2 is an emerging pathogen, without any effective drug available for treatment at the moment. It spreads quickly and can result in death of the infected patients. Despite the current mortality rate is 2.3% [26], the emergence of large number of infected patients within short period of time could result in the collapse of health care system, and thus the mortality rate might be elevated. Effective preventive measures must be implemented to control it from global spreading. In addition, great effort should be made on the development of vaccine and antiviral drugs. Meanwhile, the intermediate host and the molecular mechanism of its cross-species spread should be further investigated. Legislation should be employed to prohibit the trade of wild animals, the potential intermediate host(s) of various viruses, to prevent the outbreak of this and other novel viruses in future.

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Table 2. Summary of chemotherapeutic drugs under clinical trial for COVID-19

Name of Drug	Target and Mode of Action in other Viruses	*In Vitro* Antiviral Activity to SARS-CoV-2	Clinical Trial Status for COVID-19	Clinical Trial Registration Number
Remdesivir (GS-5734)	Inhibits RdRp [70]	Tested [63]	Phase 3	NCT04252664; NCT04257656
Favipiravir	Inhibits RdRp [75]	Tested [63]	Randomized trial	ChiCTR2000029544; ChiCTR2000029600
Ribavirin	Inhibits viral RNA synthesis and mRNA capping [76]	Tested [63]	Randomized trial, in combination a pegylated interferon	ChiCTR2000029387
Lopinavir	Inhibits 3C like protease (3Clpro) [77]	Not tested	Phase 3	NCT04252274; NCT04251871; NCT04255017; ChiCTR2000029539
Ritonavir	Inhibits 3Clpro [77]	Not tested	Phase 3	NCT04251871; NCT04255017; NCT04261270
Darunavir and Cobicistat	Inhibits HIV protease [78]	Not tested	Phase 3	NCT04252274
ASC09F (HIV protease inhibitor)	Inhibits HIV protease [79]	Not tested	Phase 3, in combination with oseltamivir	NCT04261270
Chloroquine	A lysosomatropic base that appears to disrupt intracellular trafficking and viral fusion events [80]	Tested [63]	Open-label trial	ChiCTR2000030054; ChiCTR2000029939; ChiCTR2000029935; ChiCTR2000029899; ChiCTR2000029898; ChiCTR2000029837; ChiCTR2000029803; ChiCTR2000029761; ChiCTR2000029740; ChiCTR2000029559; ChiCTR2000029542; ChiCTR2000029868; ChiCTR2000029826; ChiCTR2000029762; ChiCTR2000029760; ChiCTR2000029609
Arbidol (Umifenovir)	Block viral fusion [81]	Not tested	Phase 4	NCT04260594; NCT04254874; NCT04255017
Oseltamivir	Inhibit neuaminidase [82]	Not tested	Phase 3 and Phase 4	NCT04255017; NCT04261270

Competing Interests

The authors have declared that no competing interest exists.

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Proof That Face Masks Do More Harm Than Good

Dr Vernon Coleman MB ChB DSc FRSA
Sunday Times Bestselling Author

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This short monograph contains conclusive proof that face masks do more harm than good, and being forced to wear them is a form of oppression designed to have adverse physical and psychological effects upon the wearers rather than having any protective value.

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The Author

Dr Vernon Coleman MB ChB DSc FRSA was the first qualified medical practitioner in the UK to question the significance of the 'crisis' now described as covid-19, telling readers of his website www.vernoncoleman.com at the end of February that he felt that the team advising the Government had been unduly pessimistic and had exaggerated the danger of the virus. At the beginning of March, he explained how and why the mortality figures had been distorted. And on March 14th, he warned that the Government's policies would result in far more deaths than the disease itself. In a YouTube video recorded on 18th March, he explained his fear that the Government would use the 'crisis' to oppress the elderly and to introduce compulsory vaccination. And he revealed that the infection had been downgraded on March 19th when the public health bodies in the UK and the Advisory Committee on Dangerous Pathogens decided that the 'crisis' infection should no longer be classified as a 'high consequence infectious disease'. Just days after the significance of the infection had been officially downgraded, the Government published an Emergency Bill which gave the police extraordinary new powers and put millions of people under house arrest. Dr Coleman, a former GP principal, is a *Sunday Times* bestselling author. His books have sold over two million copies in the UK, been translated into 25 languages and sold all around the world. He has given evidence to the House of Commons and the House of Lords and his campaigning has changed Government policy. There is a short biography at the back of this book. Some references have been given in this book in view of the misleading information widely available online as part of the demonization process now being used to attack those questioning the 'official' line. Vernon Coleman's first book about the coronavirus, *Coming Apocalypse*, was only accepted for publication after all specific references to coronavirus and covid-19 were removed. (Careful editing worked in alternative words and phrases.) Vernon Coleman's second book about the coronavirus hoax (a collection of the transcripts of the videos broadcast between April and September) was titled, *Covid-19: The Greatest Hoax in History*. The book was banned within days of publication. A second version of the same book titled, *Old Man in a Chair* was banned within hours of publication. Vernon Coleman then succeeded in publishing an eBook version of *Old Man in a Chair* on Smashwords. This version can be downloaded free of charge by individuals and libraries.

Dedication

To Antoinette, the bravest person I know, have ever known or ever will know. If one per cent of the people had one per cent of your courage, your intuition, your imagination and your determination, this hoax would have never got off the ground, and those attempting to deceive and oppress the people of the world would by now be languishing in prison – where they belong. You can add my admiration to my love – all of which you already have, of course. You are my everyone and you mean everything to me.

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Introduction

To my horror and disappointment the shops, and indeed the streets, are full of mask-wearing muppets. In the shops everything takes an age as shopper and assistant struggle to make themselves heard through their masks. The muppets have become mumblies.

Many mask wearers keep their masks on even when out of doors, where it is not yet mandatory to do so. These over-compliant collaborators are making oppression easy for the totalitarians who will doubtless soon be demanding that we all wear our masks wherever we are and whatever we are doing – even in our own homes.

Most mask wearers have no idea of the harm they are doing by wearing masks. Indeed, many seem to understand very little about how to wear a mask. I have, on several occasions, seen people drop their mask onto the pavement – face side down of course – pick it up and put it on. Many people wear the same mask for more than two hours (which is dangerous), wear disposable masks more than once (which is dangerous), fail to wash cloth masks (which means they accumulate bacteria, fungi and viruses – all of which are breathed in) touch their mask while it is in position (which makes the mask even worse than useless), put masks into their pockets or handbags and then put them back on creased and grubby (a very dangerous thing to do since the wearer will then be breathing in whatever bugs have been transmitted to the mask. Scarves are often used as face coverings without ever being washed (an effective way to catch throat and lung infections). Nearly everyone constantly fiddles with their masks – not realising that touching a mask is something you should not do. The incidence of throat and chest infections is going to rocket. I wonder how many people will be killed by their masks. We'll never know.

What the hell has happened to people? I am appalled at how easily people have become so compliant and have accepted the Government lies. Many mask wearers now choose their masks as fashion items and wear masks designed to match their outfits. A few wear dark glasses and gloves as well as masks. I fear they probably think they look cool and well-dressed.

As I said earlier, it won't be long before the Government will order them to wear masks indoors. And they will. Some will sleep in them – and doubtless die in them.

Most mask wearers are clearly being made ill by their masks. Because their oxygen levels are low, their eyes are glazed, as though they are drugged.

When the covid-19 hoax began, authorities around the world announced that mask wearing was pointless, and it was widely agreed by experts that they could probably do more harm than good. Indeed, mask wearing was dismissed as 'virtue signalling' by Dr Fauci, the American coronavirus expert. The World Health Organisation supported this general view which was in accordance with the available scientific evidence. Medical advisors around the world agreed that there was no need to wear masks.

Later during the year the story changed.

Although there did not seem to be any scientific evidence supporting such a dramatic change, the World Health Organisation suddenly supported face mask wearing and almost instantly governments around the world, led by medical and scientific advisors, changed their views overnight and decided that we should all wear masks. The WHO's main financial supporter is the American software billionaire Bill Gates who has a number of powerful alliances with media organisations (such as the BBC), strong financial links with Monsanto and a number of drug companies and an enthusiasm for vaccination which, to put it politely, does not seem justified by the evidence.

Why, in the absence of a change in medical advice did the WHO change its mind?

Well, it seems that the campaign for masks to be worn worldwide was either founded by the World Economic Forum, which advocates a global reset and of which that well-known medical expert Prince Charles of England appears to be a leading member, or by an organisation called masks4all. The promotion of masks was supported by Goldman Sachs, the bank, in my view one of the most evil companies on earth (along with Google and Monsanto) which was once memorably described by Matt Taibbi as a vampire squid on the face of humanity. The bank is reported to have claimed that if everyone in America wore a mask, the American economy would be boosted.

I have no idea how they came to this conclusion or why they think their advice is better than medical research.

The masks4all website promotes the slogan, 'Anyone without a mask puts you and your family at risk', and masks4all is a fiscally sponsored project of something called Community Initiatives which seems to have links to a whole range of organisations I've never heard of.

As a result of the WHO's change of advice, media throughout the world also changed their advice. The well-known video sharing site called YouTube betrayed users by deleting videos made my doctors (such as myself) which offered scientific evidence proving that masks are of no value but are dangerous.

I could find no convincing scientific evidence supporting this change of heart but, as a result of the WHO's about-turn, populations everywhere were forced to wear masks – or to risk being fined. Only those prepared to self-certify that they could not wear a mask were allowed to travel on trains or buses or any other form of public transport without a face covering. And shortly afterwards, the rule was extended to cover shops and public buildings. Strangely, people in offices were not always forced to wear masks – as though the coronavirus were in some way inactive in a working environment but active in a shopping environment.

I have kept this book short and have resisted the mild temptation to include a history of mask wearing in all its various forms. The only thing that is important at the moment is whether mask wearing is useful and necessary or dangerous and being forced upon us as part of the new totalitarianism.

I repeat, I have yet to find any reliable scientific evidence proving that masks are useful, safe or worth wearing. Many doctors who are not employed by governments or public agencies, seem to agree that mask wearing is very likely to do far more harm than good.

The available scientific evidence shows that masks, whatever their form, provide a poor obstacle to infective organisms but do impede air intake and oxygen exchange.

Those who wear masks are collaborating in a massive conspiracy.

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RMG

Masks and Mask Wearing: 101 Facts You Must Know

1

Surgeons have been using surgical masks since their introduction in 1897. It has for some years been customary for surgeons and nurses to wear surgical masks in the operating theatre and to change masks part of the way through any procedure lasting more than a few hours.

The dangers associated with mask wearing were assessed by five doctors and published in the journal *Neurocirugia* in 2008.

Although it is customary for operating theatres to be fitted with air conditioning systems, the writers of the article, entitled, *Preliminary Report on Surgical Mask induced Deoxygenation During Major Surgery*, pointed out that it is known that heat and moisture are trapped beneath surgical masks and concluded that 'it seems reasonable that some of the exhaled carbon dioxide may also be trapped beneath them, inducing a decrease in blood oxygenation'.

A total of 53 surgeons, of both sexes, all employed at university hospitals and aged between 24 and 54 years of age were tested. All were non-smokers and none had any chronic lung disease. The test involved pulse oximetry before and after the course of an operation. The study showed that the longer a mask was worn the greater the fall in blood oxygen levels. This may lead to the individual passing out and it may also affect natural immunity – thereby increasing the risk of infection.

The masks used were disposable, sterile, one-way surgical paper masks. To eliminate the effect of dehydration over a several hour surgical operation, the surgeons were allowed after every hour to drink water through a straw.

The authors of the paper concluded that, 'When the values for oxygen saturation of haemoglobin were compared, there were statistically significant differences only between preoperational and post operational values. As the duration of the operation increases, oxygen saturation of haemoglobin decreases significantly.'

2.

This quote is taken from *New England Journal of Medicine*: 'We know that wearing a mask outside health care facilities offers little, if any, protection from infection. Public health authorities define a significant exposure to covid-19 as face to face contact within six feet with a patient with symptomatic covid-19 that is sustained for at least a few minutes (and some say more than 10 minutes or even 20 minutes). The chance of catching covid-19 from a passing interaction in a public space is therefore minimal. In many cases the desire for widespread masking is a reflexive reaction to anxiety over the pandemic.' The reference is: M.Klompas, C.Morris et al 'Universal Masking in hospitals in the covid-19 era' – *New England Journal of Medicine 2020*

3.

It is possible that wearing a mask for hours at a time could cause pulmonary fibrosis. In August 1988, the proceedings of the VIIth International Pneumoconioses Conference

included details of three cases of pulmonary fibrosis, thought to be due to exposure to synthetic textile fibres. The first was a woman of 52 who had a dry cough with increasing difficulty in breathing. Changes were visible on an X-ray. The woman had been working in a textile shop for 15 years where her job was measuring and cutting cloth – mainly synthetic materials. The second patient was a woman of 66 who also had difficulty in breathing. The lungs of this patient also showed X-ray changes. She was also involved in cutting and measuring synthetic fabrics. A third woman, aged 47, had bilateral pulmonary fibrosis. Studies have shown that loose fibres are seen on all types of masks and may be inhaled causing serious lung damage.

4.
People who cough and sneeze into their mask increase the risk of a build-up of fungi and bacteria – which can lead to dangerous chest infections.

5.
In 2015, the *British Medical Journal* published a paper entitled, *A Cluster Randomised Trial of Cloth Masks Compared with Medical Masks in Healthcare Workers*. The paper was written by nine authors from the University of New South Wales, the University of Sydney, the National Institute of Hygiene and Epidemiology in Vietnam and the Beijing Centers for Disease Control and Prevention in China. The aim of the study was to compare the efficacy of cloth masks to medical masks in hospital health care workers. The study, which was extensive, concluded that the results caution against the use of cloth masks.

'This is an important finding to inform occupational health and safety,' concluded the authors. 'Moisture retention, reuse of cloth masks and poor filtration may result in increased risk of infection.'

And the authors added: '...as a precautionary measure, cloth masks should not be recommended for health care workers, particularly in high risk situations, and guidelines need to be updated'.

6.
Many individuals have turned their masks into fashion items. I wonder how many wear the same mask day after day without washing them. If masks are unwashed then they become breeding grounds for bacteria, fungi and viruses. If they are washed then they become even more useless (if that is possible) than they were when new. The enthusiasm for 'fashion' masks, which match other items of clothing, is rising. But wearing a fashionable mask is akin to a slave painting their chains to look pretty.

7.
The word 'covering' is now often used in official propaganda material, having replaced the word 'mask'. It has clearly been decreed more acceptable than the more usual word 'mask' which carries worrying overtones.

8.
It is often difficult to hear what people say when they are wearing masks – particularly if the masks are close-fitting. Conversations are kept to a minimum and social interactions in shops

and other establishments are functional at best. (It is worth noting that hairdressers and others in service industries have been instructed to talk as little as possible – ostensibly to prevent the spread of the virus. Singing, a joyful activity for singers and listeners, has been banned.)

9.
Mask wearers have been encouraged by the psy-op specialists to show their hatred for mask wearers. This loathsome ploy was first promoted by Ms Dick of the Metropolitan police in London, and seems designed to make those who cannot or do not wear masks feel guilty and ashamed. The mentally and physically disabled will, therefore, be harassed and abused if they dare to go out of their homes.

10.
In October 2020, it was noticeable that when street photographs were published in the press or online, they invariably showed members of the public wearing masks – even though mask wearing out of doors was not compulsory. It was at that point clear that the public would soon be forced to wear masks out of doors – even when exercising.

11.
Symptoms caused by mask wearing are now being wrongly blamed on covid-19. It seems likely that when mask wearing starts to result in deaths (as it will do), those deaths will be blamed on covid-19 and used as a reason for politicians and advisors to demand that people wear masks for even longer hours. The vicious circle will be complete.

12.
The Occupational Safety and Health Administration in the US has decreed that any room where the carbon dioxide is present at a level or more than 5,000 parts per million is unsafe and has an environment which is toxic and dangerous. Carbon dioxide levels normally exist at between 350 and 450 parts per million. Acceptable indoor quality level is 600 to 800 ppm. Any employer who attempts to force employees to work in an environment where the carbon dioxide level is too high can be held to account. Similarly, any teacher who attempts to force children to study in such an environment would be legally responsible. If a nuclear submarine has a level of over 5,000 parts per million then it must surface because it is considered to have a threatening and dangerous environment. There is much dispute about the levels of carbon dioxide which may develop if a mask is worn. Generally, the tighter a mask fits the greater the risk that the level of carbon dioxide will rise to dangerous levels but it must be remembered that most members of the public have no training on how to wear a mask and there are few if any restrictions on mask manufacture. Indeed, members of the public are making their own masks and using bits of left over material to do so. A wide variety of masks are being designed and worn. Those dismissing the danger as non-existent might like to read HSE Contract Research Report no 27/1991, produced by the British Health and Safety Executive and entitled, *Dead space and inhaled carbon dioxide levels in respiratory protective equipment*. Those dismissing the risks associated with carbon dioxide levels should know that the amount of carbon dioxide in a small room can easily rise to levels which are dangerous enough to have a dramatic effect on decision making. At least eight studies in the last decade have studied carbon dioxide levels indoors and have found worrying levels above 1,200 parts per million.

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13.
Women giving birth in France have to wear face masks. In my opinion, this is dangerous and will put extra strain on the heart. Pregnant women should not wear a mask, not only because of the risk to themselves but because of the risk to their unborn child. There is a real risk that the baby will be stillborn or in some way damaged or poorly developed at birth.

14.
A number of those who have studied the science, regard mask wearers as collaborators – who will lead us all to damnation if we let them. Their philosophy is: 'If you've got a brain then you don't need a mask'.

15.
Research conducted by four French doctors in 2018 and reported in *Rev Mal Respir*, was designed to evaluate the effect of wearing a surgical mask during a six minute walking test. The authors of the study were E.Person, C.Lemercier, A.Royer and G.Reychler. (The six minutes walking test is regularly used in pulmonology.)

For this research, 44 health subjects were used. Each individual performed two six minute walking tests – one with a mask and one without a mask.

The researchers found that dyspnoea variation was significantly higher with a surgical mask, and concluded that the difference was clinically relevant.

The conclusion was that 'wearing a surgical mask modifies significantly and clinically dyspnoea.'

16.
Vital evidence outlining the dangers and ineffectiveness of mask wearing has been banned, blocked or deleted from the internet. Videos assessing the value of face mask wearing on the basis of the scientific evidence have been removed. Discussion and debate about the value of face masks are suppressed by politicians and the media. Research material outlining the dangers of mask wearing has been removed from the internet on the basis that 'it is no longer relevant in our current climate'. So-called 'fact-checkers' invariably dismiss medical reports published by doctors and scientists – however eminent those experts might be. The so-called 'fact-checkers' are often linked to commercial organisations or groups with commercial links. No one seems to check the 'fact-checkers' – though they should.

17.
Between 2004 and 2016, at least twelve articles appeared in medical and scientific journals showing that face masks do not prevent the transmission of infection.

18.
There are no strict rules about what constitutes a face mask, and the rules about when and where masks should be worn are constantly changing. This proves that there is no science supporting the wearing of masks. So, for example, it is clearly absurd that the coronavirus should ever be thought to spread from person to person in a shop but not in an office.

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19.
The tighter a mask fits the more likely it is to reduce blood oxygen levels and to increase the amount of carbon dioxide being inhaled. It should be noted that optimal oxygen intake in humans should, according to the US Occupational Safety and Health Administration, be between 19.5 and 23.5% and that any human-occupied airspace where oxygen measures less than 19.5% should be labelled as not safe for workers. However, the percentage of oxygen inside a masked airspace generally measures 17.4% within seconds of putting on the mask. A tighter fitting mask will result in lower oxygen levels and higher carbon dioxide levels. Lower oxygen levels and increased levels of carbon dioxide stimulate greater inspiratory flow – leading to a greater risk that loose fibres from the facemask will be inhaled.

20.
In Belgium, in September 2020, a group of 70 doctors sent an open letter to Ben Weyts, the Flemish Education Minister in which they claimed that children are badly affected by having to wear face masks. 'Mandatory face masks in schools are a major threat to their development,' they wrote. 'It ignores the essential need of the growing child. The well-being of children and young people is highly dependent on emotional attachment to others.'

(Observing facial expressions help a child's social development and so seeing those around them wearing masks must therefore delay a child's development.)

According to *The Brussels Times*, the doctors continued that 'there is no large-scale evidence that wearing face masks in a non-professional environment has any positive effect on the spread of viruses, let alone on general health. Nor is there any legal basis for implementing this requirement.'

'Meanwhile, it is clear that healthy children living through covid-19 heal without complications as standard and that they subsequently contribute to the protection of their fellow human beings by increasing group immunity.'

'The only sensible measure to prevent serious illness and mortality caused by covid-19 is to isolate individual teachers and individual children at increased risk,' they added. 'This risk assessment is not the task of the Ministry of Education but the task of the treating physicians in consultation with their patients.'

21.
Leading German virologist Professor Streeck has criticised the use of masks, which he has said are a wonderful breeding ground for bacteria and fungi. He has also criticised lockdowns.

22.
Two dentists in New York have reported seeing a number of patients with inflamed gums and other problems. The news story was reported in the *New York Post.*

'We're seeing inflammation in people's gums that have been healthy forever, and cavities in people who have never had them before,' said dentist Rob Ramondi. 'About 50% of our patients are being impacted by this, (so) we decided to name it 'mask mouth'.'

Another dentist, Marc Sclafani, told the *New York Post* that 'gum disease, or periodontal disease, will eventually lead to strokes and an increased risk of heart attacks.'

The dentists said that the problem is caused by the fact that face coverings increase mouth dryness and contribute to a build-up of bad bacteria.

'People tend to breathe through their mouth instead of through their nose while wearing a mask,' said Sclafani. 'The mouth breathing is causing the dry mouth, which leads to a decrease in saliva – and saliva is what fights the bacteria and cleanses your teeth.'

23.
Masks diminish the quality of our relationships with other people. We trust people less if they are wearing masks. We cannot see smiles and so we fear people more.

24.
When the truth finally comes out about the dangers of masks, teachers making children wear masks in schools will be sued. Bosses making their employees wear masks will also be sued. Ignorance is no defence. And as the Nuremburg defendants discovered the reply, 'I was obeying orders' is no defence.

25.
A 26-year-old man suffered a collapsed lung after running 2.5 miles while wearing a face mask. Doctors say his condition was caused by the high pressure on the man's lung, due to his intense breathing while wearing the face mask. When masks are made mandatory outdoors in the UK, joggers and cyclists will have no choice but to wear masks. Many will die.

26.
Never in history have so many people worn masks obstructing their intake of air. A considerable amount of research has been done into mask wearing. The research shows clearly that masks are ineffective in preventing the movement of infective organisms but that they reduce oxygen levels and increase levels of carbon dioxide. Most of those advocating mask wearing are either ignorant or are deliberately exposing mask wearers to danger for no reason. The side effects of excess carbon dioxide (hypercapnia) are headaches, dizziness, drowsiness, nausea, vomiting and a tight feeling in the chest. The risks are usually dismissed as irrelevant or non-existent by government spokesmen and fact checkers (many of whom are sponsored by industry) but I found it impossible to find reliable scientific evidence supporting this reassurance. It should be noted that the BBC, which claims to produce fact checking material, has financial links to the Bill and Melinda Gates Foundation (which itself has strong financial links to the vaccine industry among others) and is in my view entirely untrustworthy. The question, as always, is a simple one: who will check the 'fact checkers'?

Government defenders regard the removal of a video from YouTube as a sign that the advice in the video must have been 'wrong'. The reality, of course, is the exact opposite since YouTube takes down material which disagrees with advice from the World Health Organisation which is now heavily sponsored by the Bill and Melinda Gates Foundation.

27.

Streets are littered with discarded face masks which ought to have been incinerated as medical waste. If there really were a plague about, I can think of no better way to spread it than to litter the country with dirty face masks.

28.
In the UK, the rules seem to me to allow anyone to claim a mask wearing exemption if they have a physical or mental reason for not wearing a mask or if they feel anxious about wearing a mask. And that exemption should not be questioned.

29.
Does wearing a face mask reduce your immunity levels? No one seems to know the answer for sure but it seems possible that if people wear face masks for long periods (months or years) then the absence of contact with the real world might well have a harmful effect on immunity – if the face mask works. Do face masks prevent us developing immunity to particular diseases? This depends on many factors – mainly the effectiveness of the face mask. But if the mask isn't preventing the development of immunity then it probably isn't worth wearing anyway.

30.
Two widely acknowledged hazards of wearing a face mask are first that the mask may give a false sense of security and stop people taking other precautions – such as washing their hands. Secondly, if masks aren't worn properly (never touched and changed regularly) they can do much more harm than good.

31.
There is no doubt that face masks can be dangerous. In China, two school boys who were wearing face masks while running on a track both collapsed and died – possibly, I would surmise, because the strain on their hearts by the shortage of oxygen proved fatal. At least two other deaths due to mask wearing have been reported in Germany.

32.
A report published in the *British Medical Journal* summarised some other risks. First, when you wear a face mask some of the air you breathe out goes into your eyes. This can be annoying and uncomfortable and if, as a result, you touch your eyes you may infect yourself. Second, face masks make breathing more difficult and, as I have already pointed out, anyone who has a breathing problem will find that a mask makes it worse. Also, some of the carbon dioxide which is breathed out with each exhalation is then breathed in because it is trapped. Together these factors may mean that the mask wearer may breathe more frequently or more deeply, and if that happens then someone who has the coronavirus may end up breathing more of the virus into their lungs. If a mask is contaminated because it has been worn for too long then the risks are even greater. How long is too long? No one knows but two hours seems an accepted limit. No research has been done as far as I know. Third, there is a risk that the accumulation of the virus in the fabric of the mask may increase the amount of the virus being breathed in. This might then defeat the body's immune response and cause an increase in infections – other infections, not just the coronavirus.

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33.
Dr Russell Blaylock, a retired neurosurgeon, has reported that wearing a face mask can produce a number of problems varying from headaches to hypercapnia (a condition in which excess carbon dioxide accumulates in the body) and that the problems can include life threatening complications. Symptoms of hypercapnia include drowsiness, dizziness and fatigue. Some of the carbon dioxide exhaled with each breath is retained behind the mask and then breathed in again.

Dr Blaylock has also warned of neurological problems. 'By wearing a mask, the exhaled viruses will not be able to escape and will concentrate in the nasal passages, enter the olfactory nerves and travel into the brain,' he wrote.

And Dr Blaylock has warned of the danger to patients with cancer. 'People with cancer, especially if the cancer has spread, will be at a further risk from prolonged hypoxia as the cancer grows best in a microenvironment that is low in oxygen. Low oxygen also promotes inflammation which can promote the growth, invasion and spread of cancers. Repeated episodes of hypoxia have been proposed as a significant factor in atherosclerosis and hence increases (the risk of) all cardiovascular and cerebrovascular diseases.'

34.
The risk of side effects developing when wearing a mask depend to some extent on whether the mask is made of cloth or paper or is an N95 mask filtering out at least 95% of airborne particles. One study of 212 healthcare workers showed that a third of them developed headaches with 60% needing painkillers to relieve the headache. Some of the headaches were thought to be caused by an increase in the amount of carbon dioxide in the blood or a reduction in the amount of oxygen in the blood. Another study, this time of 159 young health workers, showed that 81% developed headaches after wearing face masks – so much so that their work was affected.

35.
An N95 mask can reduce blood oxygenation by as much as 20% and this can lead to a loss of consciousness. Naturally, this can be dangerous for vehicle drivers; masked bus drivers, for example, could be putting their passengers' lives at risk.

36.
Dr Blaylock has pointed to a study entitled, *The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence*. This study looked at 17 separate studies and concluded that none of the studies established a conclusive relationship between the use of masks and protection against influenza infection. 'When a person has TB we have them wear a mask,' concluded Dr Blaylock, 'not the entire community of the non- infected.'

Dr Blaylock has also described how mask wearing can affect immunity. '...a drop in oxygen levels (hypoxia) is associated with an impairment in immunity,' he has written. 'Studies have shown that hypoxia can inhibit the type of main immune cells used to fight viral infections called the CD4+T- lymphocyte. This occurs because the hypoxia increases the level of a compound called hypoxia inducible factor-11 (HIF-1) which inhibits T-lymphocytes and stimulates a powerful immune inhibitor cell. This sets the stage for

contracting any infection, including covid-19, and making the consequences of that infection much graver. In essence, your mask may very well put you at an increased of infections and if so, having a much worse outcome.'

37.
Visors have one important advantage over masks. The evidence shows clearly that although masks are useless at preventing the spread of infection they are potentially extremely dangerous. On the other hand, although visors are just as useless as masks at preventing the spread of infection they are at least relatively free of danger and are, therefore, the face coverings of choice for those who feel the need to wear one. Although they have not been tested extensively, visors are probably just as useless as masks but they may be less dangerous to wearers. The fact that governments allow citizens to use visors proves beyond any shadow of doubt that the whole mask wearing scam is just that – a scam. The aim is to obtain psychological control rather than to control disease.

38.
Dr Margarite Griesz-Brisson MD PhD is a leading European neurologist and neurophysiologist. In October 2020, she warned that rebreathing our exhaled air, because of wearing masks, will create oxygen deficiency and an excess of carbon dioxide in the body. 'We know,' she said, 'that the human brain is very sensitive to oxygen deprivation. There are nerve cells in the hippocampus that cannot last longer than three minutes without oxygen.' Dr Griesz-Brisson pointed out that the acute warning symptoms of oxygen deprivation are headaches, drowsiness, dizziness, difficulty in concentration and slowing down of reaction times. The real danger is, however, that when the oxygen deprivation becomes chronic, the symptoms disappear because the body gets used to them. However, efficiency remains impaired and the damage to the brain continues. 'We know that neurodegenerative disease takes years to decades to develop. If today you forget your phone number, the breakdown in your brain would have already started two or three decades ago.'

Dr Griesz-Brisson explains that while the mask wearer thinks that they are becoming accustomed to re-breathing exhaled air, the problems within the brain are growing as the oxygen deprivation continues.

She also points out that brain cells which die, because of a shortage of oxygen, will never be replaced. They are gone for ever. She goes on to argue that everyone is entitled to claim exemption from mask wearing because oxygen deprivation is so dangerous – and masks don't work.

Finally, Dr Griesz-Brisson points out that children and teenagers must never wear masks, partly because they have extremely active and adaptive immune systems but also because their brains are especially active and vulnerable. The more active an organ is the more oxygen it needs. And so the damage to children's brains is huge and irreversible.

She warns that dementia is going to increase in ten years, and the younger generation will not be able to reach their potential because of the mask wearing.

Oxygen deprivation adversely affects the heart and the lungs but it also damages the brain. And the damage will be permanent.

'My conclusion has to be that no one has the right to force us to deprive our bodies of oxygen for absolutely no good reason. Depriving individuals of oxygen is a crime perpetrated by those demanding that we wear masks. Those who let it happen and those who collaborate are also guilty. And those who wear masks in situations where they are not legally required are cooperating in a criminal activity.'

Inevitably, Dr Griesz-Brisson's interview was removed from YouTube as part of the global suppression of medical information.

39.
The nasal flu vaccine, the one given to children, contains attenuated or weakened live viruses. It is possible that if a child has a weakened immune system – as would doubtless be the case if they'd been imprisoned and kept indoors a lot or had for absolutely no good reason been wearing a mask for a long time – then a vaccine virus might conceivably cause the flu. And because attenuated viruses aren't quite dead, they could change or even become live and they could mutate and they could result in other people being infected. So it is possible that a child who has the nasal flu vaccine could transmit the flu virus to Granny – who might die as a result.

40.
Many doctors now believe that masks are being used as a conditioning tool to make us more compliant. Most people dutifully wear them, wrongly believing that their masks will protect them from the coronavirus, and without any idea of the damage that is being done to their physical and mental health. All around the world citizens have proved to be extraordinarily obedient and gullible, pathetic even, accepting the lies and deceits quite freely. Social distancing and the wearing of masks are both likely to be long-term and possibly permanent, and the physical and mental damage done is also likely to be long-term and permanent.

41.
The rules about mask wearing change from time to time and from one area to another (proving that there is no science behind mask wearing) and we never quite know what punishments to expect. In one part of America you could be sent to prison for a year if you failed to wear a mask. In another part of America you had to pay a 2,000 dollar fine but there was no prison sentence. In Texas, some people have been told that they should wear masks in their own homes. In one shop a guard pulled a gun on a man who was not wearing a mask.

42.
The Chinese wear masks routinely – to protect themselves from pollution. But the masks appeared to make no difference to the spread of the coronavirus in China.

43.
Economists, professors of anything, engineers, bankers, teachers, company directors and golf course management executives are all of one mind: we must all wear our masks. Astonishingly, and inexplicably, the media is giving yards of print space and many broadcasting hours to these people but denying space or time to experienced, well-qualified doctors who simply want to provide truth, scientific evidence and common sense. The few doctors who toe the 'party line' on the covid-19 hoax are guaranteed huge amounts of publicity.

44.

Will masks become part of the new world religion (widely known to its supporters as Chrislam)? Masks are traditionally associated with a number of repressive rituals.

45.
In a paper published in *MedRxiv.2020* entitled, *Physical interventions to interrupt or reduce the spread of respiratory viruses*, T.Jefferson, M.Jones et al concluded that compared to not wearing a mask there was no reduction of influenza-like illnesses when health care workers or the general population wore masks.

In March 2020, Dr Jenny Harries, Deputy Chief Medical Officer in the UK, warned that it is possible to trap the virus in a mask and start breathing it in. She said that wearing a mask was not a good idea.

46.
A meta-analysis published in May in 2020 by the Centers for Disease Control was entitled, *Non-pharmaceutical measures for pandemic influenza in non-healthcare settings – personal protective and environment measures*. The authors concluded that the evidence from randomized controlled trials of face masks did not support a substantial effect on the transmission of laboratory-confirmed influenza, either when worn by infected persons or by persons in the general community to reduce their susceptibility.

47.
In May 2016, a meta-analysis written by J.Smith and C.MacDougall and published in the *Canadian Medical Association Journal* concluded that both randomised controlled trials and observational studies of N95respirators and surgical masks used by health care workers, did not show any benefit against the transmission of acute respiratory infections. The authors also concluded that acute respiratory infection transmission may have occurred via the contamination of provided respiratory protective equipment during storage and through the reuse of masks and respirators during the working day.

48.
In 2019, a scientific paper written by L.Radonovich and M.Simberkoff was published in the *Journal of the American Medical Association*. The paper was entitled, *N95 respirators vs medical masks for preventing influenza among health care personnel: a randomized clinical trial*. The study involved 2,862 volunteers and showed that both surgical masks and N95 respirators 'resulted in no significant difference in the incidence of laboratory confirmed influenza'.

49.
In 2011, a meta-analysis of 17 separate studies regarding masks and the effect on the transmission of influenza found that none of the 17 studies established a conclusive relationship between mask or respirator use and protection against influenza infection. The study was conducted by F bin-Reza, V.Lopez et al.

50.

It was proved in 1920 that cloth masks fail to impede or stop flu virus transmissions. It was concluded that the number of layers of fabric required to prevent pathogen penetration would require a suffocating number of layers and could not be used. It was also recognised that there was a problem of leakage around the edges of cloth masks.

51.
A paper entitled, *Use of surgical face masks to reduce the incidence of the common cold among health workers in Japan: a randomized clinical trial* was published in the *American Journal of Infection Control* in June 2009. The authors concluded that face mask use was found not to be protective against the common cold when compared to controls who did not wear face masks.

52.
In 2009, investigators studied masks for an article published in the *Journal of Occupational Environmental Hygiene*. The authors concluded that for both N95 masks and surgical masks, expelled particles were deflected around the edges of the masks and that there was measurable penetration of particles through the filter of each mask.

53.
A paper entitled, *Face coverings, aerosol dispersion and mitigation of virus transmission risk*, written by M.Viola, B.Peterson et al, was published in 2005. The authors concluded there have been farther transmissions of virus-laden fluid particles from masked individuals than from unmasked invididuals, by means of leakage jets, including backward and downward jets that may present major hazards. All masks were thought to reduce forward airflow by 90% or more over wearing no mask; however Schlieren imaging showed that surgical masks and cloth masks resulted in a greater upward airflow past the eyebrows than occurred in individuals not wearing masks at all. Backward unfiltered air flow was found to be strong with all the masks tested, compared to individuals not wearing masks. In other words, if a person wearing a mask has an infection then the risk of being infected is high for anyone standing behind the wearer.

54.
A paper by H.Jung and J.Kim, which was entitled, *Comparison of filtration efficiency and pressure drop in anti-yellow sand masks, quarantine masks, medical masks, general masks and handkerchiefs*, was published in *Aerosol Air Qual Res* in June 2013. The paper studied 44 mask brands and found that the average penetration was 35.6%. Even most medical masks had over 20% penetration. Most importantly, the study found that general masks and handkerchiefs had no protective function in terms of aerosol filtration efficiency.

55.
A study published in 2015 in the *British Medical Journal* by C.MacIntyre, H.Seal et al, entitled, *A cluster randomised trial of cloth masks compared with medical masks in healthcare workers* found that penetration of cloth masks by particles was almost 97% while penetration of medical masks was 44%. The authors showed healthcare workers wearing

cloth masks had significantly higher rates of influenza-like illness after four weeks of using masks at work – when compared to controls.

56.
It is widely assumed that surgeons and operating theatre staff must wear masks but a paper by N.Mitchell and S.Hunt entitled, *Surgical face masks in modern operating rooms – a costly and unnecessary ritual* which was published in the *Journal of Hospital Infection* in July 1991– found no difference in wound infection rates with and without surgical masks. Other scientific research papers have established similar conclusions. There was, for example, a paper published in 2015 in the *Journal of the Royal Society of Medicine* by C DaZhou, P Sivathondan et al. The paper was entitled, *Unmasking the surgeons: the evidence base behind the use of facemasks in surgery.*

57.
No one should wear a mask while exercising. There have been several reports of masked children dying while exercising. There is evidence showing that mask wearing reduces blood oxygen levels even when the wearer is standing still. Individuals who exercise are likely to sweat. Masks then become damp more quickly and the damp promotes the growth of microorganisms.

58.
S Bae and M.Kim et al published a paper in April 2020 in the journal *Annals Internal Medicine* 2020. The title of their paper was, *Effectiveness of surgical and cotton masks in blocking SARS CoV 2: A controlled comparison in 4 patients* and they concluded that 'neither surgical nor cotton masks effectively filtered SARS-CoV-2 during coughs by infected patients'.

59.
It is not just out of politeness that surgeons and dentists traditionally remove their masks when talking to patients. They do so because they know that patients and relatives find it more reassuring, and more comforting, to see a whole human face rather than just part of one. Moreover, it is often exceedingly difficult to understand what someone is saying when they are wearing a mask.

60.
'The face mask traps warm moisture that is produced when we exhale,' says dermatologist Dr Maggie Kober. 'For those with acne, this can lead to acne flares. For many others, this warm, moist environment surrounding skin creates the perfect condition for naturally occurring yeast and bacteria to flourish and grow more abundant. This overgrowth of yeast and bacteria can produce angular cheilitis, the cracking and sores at the corners of the mouth.'

Face masks can also present a risk of contact dermatitis and can increase the risk of staph infections.

61.

In June 2020, researchers suggested that the oxygen reduction and carbon dioxide build up (hypercapnia) might put a considerable strain on the heart, lungs, kidneys and immune system. This risk has not been disproven. The paper was written by B.Chandrasekaran, S.Fernandes and entitled, *Exercise with facemask: are we handling a devil's sword – a physiological hypothesis*.

62.
Research has shown that respirators and masks contained influenza bugs found on their outer surfaces. The risk was higher the longer the masks were worn. It has also been established that bacteria accumulate on masks – and those bacteria can cause lung infections.

63.
Mask wearers are more likely to develop infection than non-mask wearers. This may be due to the fact that masks reduce blood oxygen levels and adversely affect natural immunity. It is likely that anyone who wears a face mask for long periods will have a damaged immune system – and be more susceptible to infection. Studies have shown that hypoxia can inhibit immune cells used to fight viral infections. Wearing a mask may make the wearer more likely to develop an infection – and if an infection develops it is likely to be worse. Low oxygen levels reduce T cells and therefore reduce immunity levels.

64.
'Is a mask necessary in the operating theatre?' by N.Orr, published in *Annals Royal College of Surgeons England* in 1981, found no difference in wound infection rates whether or not surgeons wore surgical masks.

65.
Thousands of years ago, it was discovered that forcing people to wear masks covering much of their faces broke their will and made them subservient. The masks depersonalised the wearers and dehumanised them too.

66.
Dr Scott Atlas, White House coronavirus advisor, claimed that face coverings are not effective in stopping the virus's spread. He tweeted, 'Masks work? NO' alongside a link to an article that argued against the success of face coverings. Twitter removed his tweet.

67.
Children are now demanding to be allowed to wear masks (so that they look 'grown up') and some are even fitting masks onto their dolls. Parents do not seem aware that children are especially vulnerable to the brain damage which will inevitably be a result of the hypoxia that is induced by mask wearing.

68.

In some parts of the world (particularly parts of the United States of America) it is compulsory to wear a mask even while exercising. This is particularly dangerous and will lead to a dramatic increase in the number of people dying while exercising.

69.
CIA torture techniques include forcing people to remain isolated (as in lockdowns), to keep their distance from others (social distancing) and to wear masks.

70.
A paper in the journal, *Ophthalmology and Therapy* (published in September 2020), written by Majid Moshirfar, William B. West Jr and Douglas P. Marx warned of an increase in dry eye symptoms among mask wearers. Those using masks regularly for extended periods are more likely to show symptoms. The condition is caused by exhaled air blowing upwards from the mask into the eyes. The increased airflow causes irritation or inflammation. The authors conclude 'this mask-associated ocular irritation raises concerns about eye health and increased risk of disease transmission in prolonged mask users'. Their advice is that lubricant eye drops should be used and goggles should be worn.

Dry eyes lead to individuals rubbing their eyes which will lead to an increase in the risk of infection.

Doctors and opticians are also reporting an increase in the number of patients complaining of persistent headaches – because of mask wearing.

71.
Those who defend mask wearing claim that the practice must be safe because surgeons and operating theatre staff wear masks. But operating theatres have a controlled air temperature, masks are replaced every couple of hours, and those working in an operating theatre do not rush around doing their shopping. It is important to remember that surgeons who wear masks (and not all do) work while standing, rather than walking, and they work in a controlled, air conditioned environment. They do not touch their masks and they change them regularly.

72.
We are told that fines for not wearing masks are going up and the military will be brought in if the police cannot cope.

73.
Mask wearing is making shopping unpleasant, and thereby destroying thousands of small businesses. This is one of the changes in society which will lead to the global reset promoted by the United Nations and its Agenda 21 and the World Economic Forum. The plan is to force us to live in sterile cities and to do all our shopping online.

74.
Mask wearing, social distancing and testing will become a permanent part of our world. The end result will be the permanent closure of schools – and the moving of education online.

Teachers who insist that pupils wear masks and maintain social distancing rules are destroying their own jobs.

75.
Fabric masks may allow viruses to enter and are not considered to be anywhere near as protective as surgical masks. A study I have seen entitled, *Optical microscopic study of surface morphology and filtering efficiency of face masks* concluded that face masks made of cloth are not very good at filtering out viruses because the pores are much bigger than the particulate matter that needs to be kept out. One study showed that face masks may have pores five thousand times larger than virus particles. If this is accurate it means that the virus will wander through the face mask much like a mouse wandering through Marble Arch.

76.
The World Health Organisation recommends that disposable masks should be discarded after one use. Few people can afford to buy two or more disposable masks for every member of their family, and so masks are frequently worn more than once. This massively increases the risk of a chest infection developing.

77.
Professor Chris Whitty, the UK's Chief Medical Officer, said in March 2020 that wearing a face mask had almost no effect on reducing the risk of contracting covid-19, and that the Government did not advise healthy individuals to wear masks. Instead, he suggested that people should wash their hands for roughly 20 seconds.

78.
Surgical masks are worn to stop respiratory droplets and human debris from the surgeon or nurse from falling into a wound.

79.
Much of the air we breathe in and out, goes around the side of the mask unless it is very tight fitting. Loose fitting masks are therefore entirely useless. Tight fitting masks may provide some filtration protection but the tighter a mask is the greater the risk of serious hypoxia and hypercapnia developing.

80.
It is sometimes said that masks should be worn to protect the elderly, the sick and those with serious health problems. It would make far more sense to suggest to such individuals that they protected themselves from society, if they chose to do so. But they should have the choice. And there is absolutely no reason to force younger, healthy members of society to endure lockdowns (which will clearly kill far more people than covid-19), social distancing (which will create massive psychological problems) or to wear masks (which will do no good but which will cause physical and mental health problems).

81.
A paper published by Boris Borovoy, Collen Huber and Q.Makeeta investigated all types of masks and discovered that 'loose particulate was seen on each type of mask'. They also noted that 'tight and loose fibres were seen on each type of mask' and warned that 'if even a small portion of mask fibres is detachable by inspiratory inflow, or if there is debris in mask manufacture or packaging or handling, then there is the possibility of not only entry of foreign material to the airways but also entry to deep lung tissue, and potential pathological consequences of foreign bodies in the lungs'. The authors draw attention to a correlation between the inhalation of synthetic fibres and various bronchopulmonary diseases such as asthma, alveolitis, chronic bronchitis, bronchiectasis, fibrosis, spontaneous pneumothorax and chronic pneumonia. The authors warn that if widespread masking continues, then the potential for inhaling mask fibres and environmental and biological debris continues on a daily basis for hundreds of millions of people. This should be alarming for physicians and epidemiologists knowledgeable in occupational hazards.' The authors warn that pulmonary fibrosis, a risk of mask wearing, cannot be cured and has a 5 to 20 year survival rate of only 20%.

82.
A mask worn by a child in school was examined in a laboratory. Tests showed 82 bacterial colonies and 4 mould colonies growing on the mask.

83.
'I'm seeing patients that have facial rashes, fungal infections, bacterial infections,' said Dr James Meehan. 'Reports coming from my colleagues all over the world, are suggesting that the bacterial pneumonias are on the rise. Why might that be? Because untrained members of the public are wearing medical masks, repeatedly in a non-sterile fashion. They're becoming contaminated. They're pulling them off their car seat, off the rear-view mirror, out of their pocket, from their countertop, and they're reapplying a mask that should be worn fresh and sterile every single time.' Dr Meehan also reported an incident where one patient wearing a mask passed out due to low oxygen while at work and fell off a ladder, resulting in serious physical injuries.

84.
If mask wearing were a science, the rules would be constant – but they are not. It is clear, therefore, that there is no science behind mask wearing. Citizens are being forced to wear masks for political reasons.

85.
It is frequently argued that Sweden, which had no lockdown and no mask requirements, has had a very high death rate. If anyone in the media were interested in the facts they would see that the average age of Swedish citizens who died was well over 80, and the great majority of deaths occurred in care homes and nursing homes. The mortality level in Sweden remained below a bad flu season. The Swedish people now seem to have a high, natural immunity. Fact checkers around the world might like to look at the Imperial College projections, which were alarming, and the actual death rate which was not. Other countries which did not make masks

compulsory (such as Japan and some African countries) also had relatively low mortality rates.

86.
A study by M.Walker in 2020 (*MedPage Today* 2020 May 20) found that 624 out of 714 people wearing N95 masks left visible gaps when putting on their masks.

87.
N95 respirators (or masks) are made with a 0.3 micron filter. Their name comes from the fact that 95% of particles having a diameter of 0.3 microns are filtered by the mask. Unfortunately, coronaviruses are approximately 0.125 microns in diameter. Still, these masks will certainly prevent snowballs, flies and other objects getting through.

88.
T.Tunevall wrote a paper called, *Postoperative wound infections and surgical face masks: a controlled study* which was published in the *World Journal Surgery* in 1991. The author found the use of masks in surgery were found to slightly increase incidence of infection over not masking in a study of 3,088 surgeries. The surgeons' masks were found to give no protective effect to the patients.

89.
In the UK, if you don't wear a mask because you have decided you are exempt – and the Government says this is a personal choice – the official advice is that you should not routinely be required to produce any written evidence to justify the fact that you are not wearing a mask. And although I'm no lawyer, I rather doubt that busy bodies, whoever they are, have any right to ask you why you have decided that you are exempt. My website www.vernoncoleman.com includes a link to a section of the Government website which provides an exemption form which can be printed out and attached to a lanyard.

90.
Nine medical authors from Australia and Vietnam studied cloth face masks and concluded that cloth masks should not be recommended for health care workers.

91.
A meta-analysis published in May 2016 concluded that masks did not have any useful effect but that reuse of contaminated masks did transmit infection. Some packs of face masks states that masks do not protect the wearer from the coronavirus.

92.
There is a risk that viruses may accumulate in the fabric of a mask – thereby increasing the amount of the virus being inhaled.

93.
Putting a mask on a baby or an unconscious patient is dangerous. The mask may result in the wearer choking on vomit. In my view, masks on babies could increase the risk of sudden infant death syndrome. No baby should be forced to wear a mask, and yet there are plenty of pictures on the internet showing masks on babies. In some parts of the world, children as young as two are forced to wear masks. Small children are more likely than adults to touch their masks, thereby rendering them useless. Also, small children are more likely to develop a weakened immune system if they wear a mask. Making children wear masks is a form of child abuse.

'It is extremely dangerous to cover a baby's mouth and nose and the design of 'cute' baby face coverings that have been brought to our attention look like they would greatly increase the risk of suffocation. I would strongly advise parents not to use any form of face covering for their baby,' said Dr Rebecca Fletcher, chair of Bury, Rochdale and Oldham Child Death Overview Panel.

94.
Some people claim that face masks give them a sore throat, reports Dr Armando Meza an infectious disease specialist in Texas. 'Humidity will let bacteria continue to grow inside the mask so if you were growing bacteria in that area and you were breathing that inside, you can potentially get an infection, especially strep or any other bacteria that can cause infection.'

95.
In some countries, quite small children are forced to wear masks on transport and even in schools. The evidence supports the view that politicians, teachers and parents who force (or even allow) children to wear masks are guilty of child abuse.

96.
A mask can substantially reduce blood oxygenation – leading to a possible loss of consciousness. At least one road crash has been blamed on a driver wearing a mask. Police reported that the driver of a single car crash in New Jersey, U.S. is believed to have passed out behind the wheel after wearing a mask for too long. Passengers would be wise to avoid travelling in public service vehicles (buses, coaches, etc.) in which the driver is wearing a mask.

97.
Surgeons and nurses are trained never to touch any part of a mask except for the nose bridge and the ear loops. If any part of a mask is touched accidentally then the mask is discarded and replaced.

98.
Over 2,000 Belgian medical professions have urged that covid-19 be prevented by strengthening natural immunity. Their recommendations include specifically to exercise in fresh air without a mask.

99.
A report by Boris Borovoy, Colleen Huber and Maris Crisler reported: 'Masks have been shown through overwhelming clinical evidence to have no effect against transmission of viral pathogens. Penetration of cloth masks by viral particles was almost 97% and of surgical masks was 44%. Even bacteria, approximately ten times the volume of coronaviruses, have been poorly impeded by both cloth masks and disposable surgical masks. After 150 minutes of use, more bacteria were emitted through the disposable mask than from the same subject unmasked. A paper by these authors entitled, *Masks, false safety and real dangers, Part 2: Microbial challenges from masks* is available on the internet and contains a list of 62 scientific journal references showing that masks have no significant preventative impact against any known pathogenic microbes. These authors conclude, 'Specifically, regarding covid-19, we have shown...that mask use is not correlated with lower death rates nor with lower positive PCR tests.' The authors add that, 'Masks have also been demonstrated historically to contribute to increased infections within the respiratory tract' and they conclude that 'the use of face masks will contribute to far more morbidity and mortality than has occurred due to covid-19.'

100.
There is much more evidence supporting the fact that masks should not be worn. Over a dozen scientific papers show clearly that masks are ineffective in preventing the movement of infective organisms and/or reduce oxygen levels, and expose wearers to increased levels of carbon dioxide. Over a dozen studies failed to show that wearing a mask provides protection against infection. In 2011, a meta-analysis of 17 separate studies proved that none of the research showed masks to be useful in preventing influenza infection. The available medical evidence proves overwhelmingly that masks do no good in preventing the spread of infection but do a great deal of harm to those wearing them.

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Conclusion

At no previous time in history have large numbers of people been forced to wear masks. The long-term physical and psychological consequences are unknown though those ordering that masks be worn are no doubt aware of the extraordinary risks and of the way that masks can be used to oppress and subjugate a population. The evidence clearly shows that mask wearing is likely to do no good but a great deal of harm. The big lie, which the WHO, governments everywhere and YouTube want to disseminate, is that wearing masks is essential to control covid-19. But the medical and scientific evidence (banned by YouTube and most mass media) shows that masks have little or no useful effect but can increase the risk of infection and can make breathing difficult. There is little doubt that masks do far more harm than good. Cloth masks are permeable to 97% of viral particles. A study by the University of East Anglia concluded that wearing masks was of no benefit and could increase infection. Experts in respiratory disease and infection protection from the University of Illinois have explained that face masks have no use in everyday life – neither as self-protection nor to protect other people. A study published in the *Annals of Internal Medicine* concluded that neither fabric masks nor surgical masks can prevent the spread of covid-19 by coughing. An article in the *New England Journal of Medicine*, published in May 2020 concluded that masks offer little or no protection and that the call for masks to be compulsory was an irrational fear reflex. A German study showed that masks had no effect on infection rates. Dr Fauci, the American covid-19 supremo, expressed real doubts about masks. On May 28th 2020, he admitted masks are little more than symbolic. Virtue signalling. A meta study on influenza, published in May 2020 by the CDC in America, found that face masks were of no help. The available evidence shows clearly that masks do not work but do have the potential to cause a variety of health problems – including short-term problems such as breathlessness and long-term problems such as brain damage and death. And yet, despite all this, there have been suggestions from various authorities that mask wearing and social distancing will need to be permanent. It has also been suggested that masks should be worn in the home. The sceptical will find it impossible to avoid the conclusion that there is far more to masks (and compulsory mask wearing) than meets the eye.

Afterword

There is absolutely no scientific reason for mask wearing under any circumstances. The covid-19 hoax is an IQ test. Anyone who wears a mask after studying the evidence has clearly failed the test.

Dear Reader

If you found this book useful I would be enormously grateful if you would post a review on social media or your preferred online site. It would help a great deal more than I can tell. And please ask everyone you know to read this book. An eBook version can be downloaded free of charge from Smashwords. There is a link on my website www.vernoncoleman.com

Thank you

Vernon Coleman

The Author

Biography and reference articles

Vernon Coleman was educated at Queen Mary's Grammar School in Walsall, Staffs. He then spent a year as a Community Service Volunteer in Liverpool where he was the first of Alec Dickson's 'catalysts'. (Ref 1 below). He studied medicine at Birmingham Medical School and qualified as a doctor in 1970. He has worked both in hospitals and as a GP. He resigned from the health service on a matter of principle. (Ref 2 below).

Vernon Coleman has organised many campaigns concerning iatrogenesis, drug addiction and the abuse of animals, and has given evidence to committees at the House of Commons and the House of Lords. For example, he gave evidence to the House of Lords Select Committee on Animals in Scientific Procedures (2001-2) on Tuesday 12.2.02

Dr Coleman's campaigns have often proved successful. For example, after a 15 year campaign (which started in 1973) he eventually persuaded the British Government to introduce stricter controls governing the prescribing of benzodiazepine tranquillisers. ('Dr Vernon Coleman's articles, to which I refer with approval, raised concern about these important matters,' said the Parliamentary Secretary for Health in the House of Commons in 1988.) (Ref 3 below).

Dr Coleman has worked as a columnist for numerous national newspapers including The Sun, The Daily Star, The Sunday Express, Sunday Correspondent and The People. He once wrote three columns at the same time for national papers (he wrote them under three different names, Dr Duncan Scott in The Sunday People, Dr James in The Sun and Dr Vernon Coleman in the Daily Star). At the same time he was also writing weekly columns for the Evening Times in Glasgow and for the Sunday Scot. His syndicated columns have appeared in over 50 regional newspapers in the United Kingdom and his columns and articles have appeared in newspapers and magazines around the world. Dr Coleman resigned from The People in 2003 when the editor refused to print a column Dr Coleman had written criticising the Government's decision to start the Iraq War. (Ref 6 below)

He has contributed articles and stories to hundreds of other publications including The Sunday Times, Observer, Guardian, Daily Telegraph, Sunday Telegraph, Daily Express, Daily Mail, Mail on Sunday, Daily Mirror, Sunday Mirror, Punch, Woman, Woman's Own, The Lady, Spectator and British Medical Journal. He was the founding editor of the British Clinical Journal. For many years he wrote a monthly newsletter called Dr Vernon Coleman's Health Letter. He has worked with the Open University in the UK and has lectured doctors and nurses on a variety of medical matters.

Vernon Coleman has presented numerous programmes on television and radio and was the original breakfast television doctor on TV AM. He was television's first agony uncle (on BBC1's The Afternoon Show) and presented three TV series based on his bestselling book Bodypower. In the 1980s, he helped write the algorithms for the first computerised health programmes – which sold around the world to those far-sighted individuals who had bought the world's first home computers. (Ref 4 below). His books have been published in the UK by Arrow, Pan, Penguin, Corgi, Mandarin, Star, Piatkus, RKP, Thames and Hudson, Sidgwick and Jackson, Macmillan and many other leading publishing houses and translated into 25 languages. English language versions sell in the USA, Australia, Canada and South Africa as well as the UK. Several of his books have appeared on both the Sunday Times and Bookseller bestseller lists.

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Altogether, he has written over 100 books which have, together, sold over two million copies in the UK alone. His self-published novel, Mrs Caldicot's Cabbage War has been turned into an award winning film (starring Pauline Collins, John Alderton and Peter Capaldi) and the book is, like many of his other novels, available in an audio version.

Vernon Coleman has co-written five books with his wife, Donna Antoinette Coleman, and has, in addition, written numerous articles (and books) under a vast variety of pennames (many of which he has now forgotten). Donna Antoinette Coleman is a talented oil painter who specialises in landscapes. Her books include, My Quirky Cotswold Garden. She is a Fellow of the Royal Society of Arts. Vernon and Antoinette Coleman have been married for more than 20 years.

Vernon Coleman has received numerous awards and was for some time a Professor of Holistic Medical Sciences at the Open International University based in Sri Lanka.

Reference Articles referring to Vernon Coleman

Ref 1
'Volunteer for Kirkby' – The Guardian, 14.5.1965
(Article re VC's work in Kirkby, Liverpool as a Community Service Volunteer in 1964-5)
Ref 2
'Bumbledom forced me to leave the NHS' – Pulse, 28.11.1981
(Vernon Coleman resigns as a GP after refusing to disclose confidential information on sick note forms)
Ref 3
'I'm Addicted To The Star' – The Star, 10.3.1988
Ref 4
'Medicine Becomes Computerised: Plug In Your Doctor.' – The Times, 29.3.1983
Ref 5
'Computer aided decision making in medicine' – British Medical Journal, 8.9.1984 and 27.10.1984
Ref 6
'Conscientious Objectors' – Financial Times magazine, 9.8.2003

Major interviews with Vernon Coleman include

'Doctor with the Common Touch.' – Birmingham Post, 9.10.1984
'Sacred Cows Beware: Vernon Coleman publishing again.' – The Scotsman, 6.12.1984
'Our Doctor Coleman Is Mustard' – The Sun, 29.6.1988
'Reading the mind between the lines.' – BMA News Review, November 1991
'Doctors' Firsts' – BMA News Review, 21.2.1996
'The big league of self publishing.' – Daily Telegraph, 17.8.1996
'Doctoring the books' – Independent, 16.3.1999
'Sick Practices' – Ode Magazine, July/August 2003
'You have been warned, Mr Blair.' – Spectator, 6.3.2004 and 20.3.2004
'Food for thought with a real live Maverick.' – Western Daily Press, 5.9.2006
'The doctor will see you now' – Independent, 14.5.2008

There is a more comprehensive list of reference articles on www.vernoncoleman.com

The Vaccine Adverse Event Reporting System (VAERS) Results

Messages:

- **VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.**
- **These results are for 532 total events.**
- **When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.**
- **Click on a VAERS ID to see a report containing detailed information for the event.**

Some measures are hidden, use Quick or More Options above to restore them.

Serious	Vaccine Type	VAERS ID	Adverse Event Description
Yes	COVID19 VACCINE (COVID19)	0913143-1	Vaccine administered with no immediate adverse reaction at 11:29am. Vaccine screening questions were completed and resident was not feeling sick and temperature was 98F. At approximately 1:30pm the resident passed away.
Yes	COVID19 VACCINE (COVID19)	0914604-1	Spouse awoke 12/20 and found spouse dead. Client was not transferred to hospital.
Yes	COVID19 VACCINE (COVID19)	0914690-1	Within 24 hours of receiving the vaccine, fever and respiratory distress, and anxiety developed requiring oxygen, morphine and ativan. My Mom passed away on the evening of 12/26/2020.
Yes	COVID19 VACCINE (COVID19)	0914805-1	RESIDENT CODED AND EXPIRED
Yes	COVID19 VACCINE (COVID19)	0914895-1	Injection given on 12/28/20 - no adverse events and no issues yesterday; Death today, 12/30/20, approx.. 2am today (unknown if related - Administrator marked as natural causes)
Yes	COVID19 VACCINE (COVID19)	0914917-1	Death by massive heart attack. Pfizer-BioNTech COVID-19 Vaccine EUA
Yes	COVID19 VACCINE (COVID19)	0914961-1	pt passed away with an hour to hour and 1/2 of receiving vaccine. per nursing home staff they did not expect pt to make it many more days. pt was unresponsive in room when shot was given. per nursing home staff pt was 14 + days post covid
Yes	COVID19 VACCINE (COVID19)	0914994-1	pt was a nursing home pt. pt received first dose of covid vaccine. pt was monitored for 15 minutes after getting shot. staff reported that pt was 15 days post covid. Pt passed away with in 90 minutes of getting vaccine
Yes	COVID19 VACCINE (COVID19)	0915562-1	pt received vaccine at covid clinic on 12/30 at approximately 3:30, pt vomited 4 minutes after receiving shot--dark brown vomit, staff reported pt had vomited night before. Per staff report pt became short of breath between 6 and 7 pm that night. Pt had DNR on file. pt passed away at approximately 10pm. Staff reported pt was 14 + days post covid
Yes	COVID19 VACCINE (COVID19)	0915682-1	Resident received vaccine per pharmacy at the facility at 5 pm. Approximately 6:45 resident found unresponsive and EMS contacted. Upon EMS arrival at facility, resident went into cardiac arrest, code initiated by EMS and transported to hospital. Resident expired at hospital at approximately 8 pm
Yes	COVID19 VACCINE (COVID19)	0915920-1	Resident received vaccine in am and expired that afternoon.
Yes	COVID19 VACCINE (COVID19)	0918388-1	Resident found unresponsive without pulse, respirations at 04:30 CPR performed, expired at 04:52 by Rescue
Yes	COVID19 VACCINE (COVID19)	0918418-1	Resident became SOB, congested and hypoxic requiring oxygen, respiratory treatments and suctioning. Stabilized after treatment and for the next 72 hours with oxygen saturations in the 90s. On 1/3/2021 was found without pulse and respirations. Resident was a DNR on Hospice.
Yes	COVID19 VACCINE (COVID19)	0919108-1	Fever, Malaise
Yes	COVID19 VACCINE (COVID19)	0920545-1	"The resident received is vaccine around 11:00 am and tolerated it without any difficulty or immediate adverse effects. He was at therapy from 12:36 pm until 1:22 pm when he stated he was too tired and could not do anymore. The therapist took him back to his room at that time and he got into bed himself but stated his legs felt heavy. At 1:50 pm the CNA answered his call light and found he had taken himself to the bathroom. She stated that when he went to get back into the bed it was ""abnormal"" how he was getting into it so she assisted him. At that time he quit breathing and she called a RN into the room immediately. He was found without a pulse, respirations, or blood pressure at 1:54 pm. He was a DNR."
Yes	COVID19 VACCINE (COVID19)	0920832-1	Vaccine 12/30/2020 Screening PCR done 12/31/2020 Symptoms 1/1/2021 COVID test result came back positive 1/2/2021 Deceased 1/4/2021
Yes	COVID19 VACCINE (COVID19)	0921481-1	Vaccine given on 12/29/20 by Pharmacy. On 1/1/21, resident became lethargic and sluggish and developed a rash on forearms. He was a Hospice recipient and doctor and Hospice ordered no treatment, just to continue to monitor. When no improvement of codition reported, doctor and Hospice ordered comfort meds (Morphine, Ativan, Levsin). Resident expired on 1/4/2021
Yes	COVID19 VACCINE (COVID19)	0921667-1	LTCF Pfizer Vaccine clinic conducted 12/29/2020 Vaccine lead received a call indicating that a staff member deceased somewhere between 1/3/2021 and 1/4/2021. Cause of death is unknown, and an autopsy is being performed.
			Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she [illegible]

Yes	COVID19 VACCINE (COVID19)	1078246-1	Death. Ruptured myocardial infarct. 178
Yes	COVID19 VACCINE (COVID19)	1078352-1	Developed fatigue, body aches, headache 1 day after vaccination on 3/3. The morning of 3/5 complained of chest pain. Took Tylenol at 8:30 am. At 10:30 am his family found him unresponsive. EMS was called and he was pronounced dead in the home.
Yes	COVID19 VACCINE (COVID19)	1079251-1	Patient died the day after she received her vaccine RM14
Yes	COVID19 VACCINE (COVID19)	1079904-1	SUBJECT WAS FOUND DECEASED ON 22 FEB 2021 AT AROUND 11:30 PM
Yes	COVID19 VACCINE (COVID19)	1079958-1	Pt found down and pulseless in home by husband. EMS called, Pt found to be in PEA arrest. Pt achieved ROSC with CPR and Epinephrin. Pt Passed away on 09/07/2021 at 1330. Pt was in multisystem organ failure.
Yes	COVID19 VACCINE (COVID19)	1079976-1	12/23/20 (Moderna #1) - Malaise, cough on 12/24, went to walk-in on 12/25 c/o cough, malaise, rx'd Augmentin x14d, Rapid covid negative (and PCR resulted negative). 12/27 slept all day, 12/28 back to work. 1/12/21 metallic taste in mouth, severe GI sx, malaise, aches, headache. 1/14 seen at walk-in and covid swabbed Negative. 1/21/21 exposed to parents who found out they were covid + on 1/22/21. 1/25/21 (Moderna #2) - Continued with persistent cough and GI sx. Then also developed urinary frequency and urgency. Seen at urgent care 2/1 c/o cough, dx URI, rx'd augmenting. Woke up morning of 2/2/21 abruptly, stood up, said something was wrong, and collapsed. CPR attempted immediately, EMS brought him to ER where he was pronounced dead.
Yes	COVID19 VACCINE (COVID19)	1080425-1	Narrative: Patient with h/o ESRD on HD MWF, HTN presented to ER on 2/20/21 with worsening dyspnea and GI symptoms; tested positive for COVID-19. Patient had received first COVID vaccination approx. 9 days prior. Patient admitted to ICU for treatment of COVID+ PNA. During admission, patient often could not tolerate removal of fluid during HD d/t tachycardia. He received dexamethasone, convalescent plasma for COVID. Patient underwent TTE which was notable for septal wall motion abnormalities and grossly reduced EF. Admission also c/b acute liver injury, possible cholecystitis, thrombocytopenia, SVT, encephalopathy. Patient then developed progressive shock and hemodynamic instability on 3/2 and passed away on 3/2/21.
Yes	COVID19 VACCINE (COVID19)	1080429-1	DEATH Narrative: no documentation regarding any immediate reaction after vaccine administration. 83 y.o. male with pmh severe pulmonary hypertension, s/p TAVR last year, severe asbestos related lung disease on chronic oxygen, recently started on palliative care. Was found by daugher deceased on the morning of 2/11/2021. Autopsy declined by family.
Yes	COVID19 VACCINE (COVID19)	1080430-1	Death Narrative: Death was not determined to be related to COVID vaccination. COVID vaccination (dose 1) occurred on 1/27/21 with no noted side effects. Death occurred on 2/14/21.
Yes	COVID19 VACCINE (COVID19)	1080431-1	Narrative: 67 year-old male received his 1st COVID vaccine dose at a clinic on 2/25/21 at ~ 11:45am. No known prior COVID infection. No history of vaccine allergies or allergies to any component of the COVID vaccine. Does have history of allergic reactions including hives, angioedema or anaphylaxis to some medications (neomycin, Neosporin, bacitracin) and environmental allergens (yellow jackets, fir trees). Patient reported previously daily use of diphenhydramine (2 caps every morning) and kept an epi-pen on hand. The afternoon of 2/26/21, patient presented to his neighbor's house requesting assistance with an epi-pen. Neighbor reported significant swelling around tongue and lips, and ability to faintly speak. Neighbor administered epi-pen, but unsure if it worked, so administered a 2nd epi-pen. Within a minute or two after the 2nd dose, patient slumped over and became non-responsive. EMS was called and neighbor began CPR. EMS reported that patient was non-responsive upon arrival. A King airway was placed and a Lucas device used for chest compressions. Three rounds of epinephrine were administered during transport to the local emergency room. Patient remained unresponsive with evidence of PEA during transport. Arrival at the ER occurred ~ 4:25pm. On arrival patient noted to be unresponsive with CPR in progress. Dose of epinephrine administered ~ 3 minutes after arrival in ER. No femoral pulse palpable, cardiac monitor did show some electrical activity. Evaluation of oral cavity showed significant swelling of tongue. Additional dose of epinephrine given. Patient remained with no palpable central pulse and showed continued evidence of PEA. Patient was estimated to have been down > 45 minutes. Patient pronounced deceased at 4:59pm.
Yes	COVID19 VACCINE (COVID19)	1080433-1	unknown cardiovascular event
Yes	COVID19 VACCINE (COVID19)	1080434-1	Death Narrative: Patient passed away on 3-2-21, patient received the vaccine on 2-24-21. Patient was obese and had several co-morbid conditions.
Yes	COVID19 VACCINE (COVID19)	1080671-1	Patient received vaccine 1/26/2021, complained of fever and chills post vaccine. Daughter reported worsening symptoms to confusion, decreased appetite, N/V and chest pain. Dry cough and SOB. Patient admitted to facility for Chest pain, AMS on 2/2/2021. Expired 2/2/2021.
Yes	COVID19 VACCINE (COVID19)	1081008-1	there were no signs of adverse reaction at the time of injections and she waited 15 minutes at the site to watch for side effects. and none were evident or reported. We were notified that she passed away on Saturday, March 6.
Yes	COVID19 VACCINE (COVID19)	1081033-1	Patient expired 2 days after receiving the vaccination. Patient had other signs of deterioration over the course of the previous month with worsening edema and difficulty breathing. Unlikely to be related according to our assessments, but wanted to err on the side of caution.
Yes	COVID19 VACCINE (COVID19)	1081155-1	Pt died on 3/6/2021. Received Vaccine on 2/12/2021. Unknown cause of death.
Yes	COVID19 VACCINE (COVID19)	1081304-1	patient passed away within 60 days of receiving a COVID vaccine
Yes	COVID19 VACCINE (COVID19)	1081305-1	Sudden death approximately 24 hours after receiving 2nd COVID vaccine - symptoms unknown - autopsy revealed cardiac disease as the cause of death
Yes	COVID19 VACCINE (COVID19)	1081547-1	NO IMMEDIATE ADVERSE EVENTS PRESENT FOLLOWING IMMUNIZATION. RESIDENT WAS ALERT, RESPONSIVE, TALKATIVE, WITHOUT COMPLAINTS, AND ENGAGING IN NORMAL ACTIVITIES AFTER IMMUNIZATION, AS WELL AS THE FOLLOWING DAY. HE WAS FOUND IN BED THE SECOND MORNING AFTER VACCINATION (AT 6:25AM) WITHOUT VITAL SIGNS AND HAD EXPIRED PEACEFULLY IN HIS SLEEP. HE WAS A DNR, NO LIFE SUSTAINING MEASURES WERE PERFORMED.
Yes	COVID19 VACCINE (COVID19)	1082467-1	Pt passed away on 3/6/21.
Yes	COVID19 VACCINE (COVID19)	1082707-1	death
Yes	COVID19 VACCINE (COVID19)	1082717-1	Patient dropped dead 24 hours after receiving the vaccine. The vaccine killed her. She received the vaccine 2/16/2021 and died 2/17/2021
Yes	COVID19 VACCINE (COVID19)	1082759-1	Death
	COVID19		

Yes	COVID19 VACCINE (COVID19)	1046613-1	patient passed away within 60 days of receiving a COVID vaccine
Yes	COVID19 VACCINE (COVID19)	1046698-1	patient passed away within 60 days of receiving a COVID vaccine
Yes	COVID19 VACCINE (COVID19)	1046795-1	Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127
Yes	COVID19 VACCINE (COVID19)	1046845-1	Deceased 02/18/2021 with an unknown cause of death
Yes	COVID19 VACCINE (COVID19)	1046881-1	Code blue called at 11:00pm. Patient had code status of Do Not Resuscitate.
Yes	COVID19 VACCINE (COVID19)	1047183-1	Pt had expired before second dose was delivered.
Yes	COVID19 VACCINE (COVID19)	1047197-1	death
Yes	COVID19 VACCINE (COVID19)	1047282-1	Patient felt fine on Friday afternoon and evening after shot. Felt fine on Saturday until the afternoon when she starte feeling fatigued and chilled. Decided to take a warm bath at about 6pm. Was found dead in bathtub at approximately 7pm with blisters on arms, legs, and face.
Yes	COVID19 VACCINE (COVID19)	1047326-1	According to patient's caregiver, patient presented with symptoms of fever (101.6 F) and purple blotches all over the body within an hour. Since patient was in hospice , caregiver called Hospice and a pharmacy and was told to give patient Benadryl and Tylenol. Patient was given both medications and the fever subsided in a few days but the purple blotches never went away. Patient passed away at the facility a week later.
Yes	COVID19 VACCINE (COVID19)	1048786-1	"Was given vaccine around 1:30Pm on 2-11-2021. He and his wife waited in the building for 15 minutes and then left. he denied complaint. (He was waiting to have both Covid shots before he went to cardiologist Re: CAD.) He had an alarm going off in his house, was going to basement to check it out. Police officer heard alarm, came into house, heard a thud when Doc fell. He was in PEA (Pulseless Electrical Activity) when brought into ER. Given 5 ""rounds of Epinephrine with no response."
Yes	COVID19 VACCINE (COVID19)	1048882-1	Vaccine was administered 2/1/2021 at approximately 9am. Due to self reporting of allergic reaction (hives) to Augmentin, patient was monitored on site for 30 minutes. After the monitoring period, she was cleared to go with no issues reported at the time. We were later informed that the patient passed away from a pulmonary embolism on 2/12/2021.
Yes	COVID19 VACCINE (COVID19)	1048947-1	Patient experienced an episode of emesis and loss of consciousness several hours after vaccine on 2/16/21. He was taken by EMS to the hospital and was noted to be hypoxic and hypotensive. He was admitted to the hospital and subsequently intubated. He was also found to have a small bowel obstruction and a nasogastric tube was placed to decompress the bowel. He required pressor support as well. He expired on 2/17/21.
Yes	COVID19 VACCINE (COVID19)	1049012-1	Patient was given vaccine on friday, one week later she passed away. The family called the pharmacy to inform us on Saturday, Feb 20, 2021. After the phone call was over, we saw in her pharmacy profile that she had received the vaccine one week prior
Yes	COVID19 VACCINE (COVID19)	1049389-1	Patient passed away Saturday at 14:04pm. Patient's wife reports his death was sudden, he passed away sitting in hi chair his heart just stopped she said. They tried to perform CPR, 911 was called and paramedics arrived at the scene and he was given medication but never had any return of vital signs and so his death was called at the scene. Wife reports he was not ill, did not have any symptoms prior to the event. They are not going to be doing a autopsy. She wanted us to know based on timing that there may be some possible correlation with his COVID19 vaccine. He obtained the vaccine on 02/09/2021 - wife reports he had no symptoms, not even arm soreness after the vaccine. Had no fever, shortness of breath. Did not complain of chest pain. We can update chart to reflect the patient is deceased and lets make a card for the family.
Yes	COVID19 VACCINE (COVID19)	1049406-1	Patient rcvd 1st covid 19 vaccine on 1/26/2021. Patient had house guests on 1/30/21. Those house guests tested positive for covid on 2/1/2021. Patient started getting symptoms on 02/2/2021. Patient tested postivie on 2/4/2021 Patient was hospitalized 2/7/2021. Patient passed away on 2/21/21.
Yes	COVID19 VACCINE (COVID19)	1049648-1	I was notified on 2/22/21 that this patient passed away over the weekend. I do not know the details, nor can I confirm anything beyond what I was told. I believe the death occurred on 2/20/21 due to a massive stroke.
Yes	COVID19 VACCINE (COVID19)	1049852-1	When calling to get billing information we were notified that patient had passed away. Patient's daughter said patien was having cvd a/s on 2.1.2021 got vaccine 2.2.2021 and passed away 2.5.2021. Cardiologist said not related
Yes	COVID19 VACCINE (COVID19)	1049963-1	Found lying face down without respiration or pulse, believed to be within 5 minutes of event. ACLS procedures unsuccessful. Unable to get autopsy. Believed to be heart attack secondary to COVID infection, but unconfirmed. Relative contribution of recent vaccination unknown.
Yes	COVID19 VACCINE (COVID19)	1049997-1	Vaccine was administered at Nursing Facility. Patient is an 89-year-old female with prior medical history of CVA with dysphagia, history of possible dementia, GERD, hyperlipidemia, and a pacemaker. She is a resident from town. She was sent for hypotension with a blood pressure of 90/52, tachypnea respirations of 54, possible aspiration pneumonia. Status post Covid vaccine earlier today. History is limited as patient is nonverbal on my exam. Death within 24 hours of vaccination
Yes	COVID19 VACCINE (COVID19)	1050137-1	Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. F pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).
Yes	COVID19 VACCINE (COVID19)	1050172-1	Individual developed severe body aches, severe shoulder discomfort, high fevers (documented max temp. 103.7 F). Daughter reported that she became non-responsive with high fevers, and when the fevers decreased she was more lucid. Her condition rapidly progressed to nausea vomiting, diarrhea and patient died on 2/9/2021.
Yes	COVID19 VACCINE (COVID19)	1050201-1	Died 7 days after receiving 2nd dose of Moderna vaccine. Had underlying hx Lung CA w/mets.
Yes	COVID19 VACCINE (COVID19)	1050281-1	Per family, patient has been feeling sick since he was vaccinated, patient went to ER on 02/15/2021, and after few hours at ER patient passed away.
Yes	COVID19 VACCINE (COVID19)	1050431-1	Since I was not with my husband I can only tell you what was told to me. He walked out of the store toward our car Someone watched him, concerned, because he was walking very slowly (normally has a slow gait because of leg braces and toe amputations so I don't know if it was unusually slow). The woman saw him fall and she ran to help- administered CPR immediately-and told me he died instantly. Medics tried to resuscitate and failed to bring a pulse. (My husband left our home around 11:15 to drop a package off at store. The store is one mile from our home. At

Yes	COVID19 VACCINE (COVID19)	1068308-1	again with a fever. He felt worse on 20Feb; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; fever; headache; stomach upset; This is a spontaneous report from a contactable consumer reporting for the father: A 75-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EL3428) at single dose at left arm on 03Feb2021 for Covid-19 immunisation. Medical history included type 2 diabetes mellitus. No known allergies. The patient had not experienced Covid-19 prior vaccination. Concomitant medication in 2 weeks included amitriptyline hydrochloride (manufacturer unknown) 10 mg, atorvastatin (manufacturer unknown) 20 mg, dutasteride (manufacturer unknown) 0.5 mg, linaclotide (LINZESS) 290 mcg, gabapentin (manufacturer unknown) 300 mg, montelukast (manufacturer unknown) 10 mg, ramipril (manufacturer unknown) 5 mg, insulin degludec (TRESIBA) 100 unit/ml, liraglutide (VICTOZA) 18 mg/3ml solution. No other vaccine in 4 weeks. The patient experienced cardiac arrest due to pericardial effusion on 21Feb2021 14:15, fever on 13Feb2021, headache on 13Feb2021, stomach upset on 13Feb2021, on 19feb, he began to feel ill again with a fever, he felt worse on 20feb on 19Feb2021, on 21feb he went to the ER after vomiting and passing out on 21Feb2021. Events resulted in Emergency room/department or urgent care. Therapeutic measures were taken as a result of cardiac arrest due to pericardial effusion. Course of events: In Feb2021, 10 days after his 1st injection, the patient developed fever, headache, and stomach upset. He went for a rapid Covid-19 test (nasal swab) and it was negative on 11Feb2021. The doctor told him he might be having a delayed reaction to the vaccination. After a couple of days, he improved. On 19Feb2021, he began to feel ill again with a fever. He felt worse on 20Feb2021. On 21Feb2021 he went to the ER after vomiting and passing out and received treatment: IV fluids, diagnostic testing at ER. Rapid Covid test (nasal swab) at ER came back negative again on 21Feb2021. His heart arrested suddenly and he could not be resuscitated. CT scan results, that came back after death, showed Covid like pneumonia and pericardial effusion. The patient died on 21Feb2021 14:15. Cause of death was cardiac arrest due to pericardial effusion. An autopsy was not performed. The outcome of cardiac arrest due to pericardial effusion was fatal, of fever, headache, stomach upset was recovering, of he began to feel ill again with a fever, he felt worse was not recovered, of he went to the ER after vomiting and passing out was unknown.; Reported Cause(s) of Death: cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion
Yes	COVID19 VACCINE (COVID19)	1068549-1	2/13/21 Patient had covid like symptoms 2/15/21 Patient admitted to Hospital with covid like sx and decreased O2 sat; tested positive for Covid on 2/15/21; treated with Remdesivir and convalesent Plasma. Sx worsened and patient died 2/26/21..
Yes	COVID19 VACCINE (COVID19)	1068700-1	Patient passed away 24 hours after receipt of 1st Dose Pfizer vaccine. Provider does not feel death was due to vaccination. but underlying conditions. No immediate side effects noted from vaccination.
Yes	COVID19 VACCINE (COVID19)	1068761-1	DEATH Narrative: patient was placed on hospice care following vaccine, unclear cause of death, not documented
Yes	COVID19 VACCINE (COVID19)	1068762-1	"DEATH Narrative: patient's wife reported he had gone in an outside hospital, had held his brilinta as advised anticipating shoulder surgery ""and he threw a big clot and died.""""
Yes	COVID19 VACCINE (COVID19)	1068850-1	Pfizer-BioNTech COVID- 19 Vaccine EUA: Wife of patient called Primary Care Physician to inform that patient had received dose #2 of Pfizer COVID vaccine, and later that evening experienced a seizure and expired.
Yes	COVID19 VACCINE (COVID19)	1068883-1	DEATH Narrative: PATIENT PASSED AWAY WHILE ON HOSPICE CARE
Yes	COVID19 VACCINE (COVID19)	1068886-1	DEATH Narrative: Pt he reports he developed chills SOB body aches the same night as receiving the COVID vaccine on 1.26.2021-pt is currently reporting CheSt tightness and SOB Admitted to hosp: ICU with Bilateral Pulmonary Emboli, LLE DVT, NSTEMI, Arrhythmia.
Yes	COVID19 VACCINE (COVID19)	1068889-1	death Narrative: no other details available, as nothing documented in record
Yes	COVID19 VACCINE (COVID19)	1069235-1	Death
Yes	COVID19 VACCINE (COVID19)	1069263-1	DIED
Yes	COVID19 VACCINE (COVID19)	1069560-1	Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at [illegible]

Yes	COVID19 VACCINE (COVID19)	1022397-1	Death 2/9/21
Yes	COVID19 VACCINE (COVID19)	1022529-1	Pt suffered Cardiac Arrest and respiratory arrest on 2/9/21 and passed away at a local hospital. He had multiple health conditions likely contributing to this. he arrested at home and CPR was attempted and unsuccessful. Pt received his Covid vaccine #1 on 1/27/21. No issues were noted after vaccine and was due for his 2nd dose next week. However, we were notified he passed away on 2/9/21. Very likely death not at all related to vaccine but wanted to document as patient was in the middle of the covid vaccine series.
Yes	COVID19 VACCINE (COVID19)	1022685-1	Received Pfizer Covid Vaccine in the AM on 2/9/21. Arrived to emergency department later the same day complaining of nausea, weakness, fatigue, Vomiting, Diarrhea. Post operative diagnosis, Ischemic colon/toxic megacolon.
Yes	COVID19 VACCINE (COVID19)	1022902-1	"death Narrative: 71 yo male who passed away on 1/29/2021, medical cause of death ""cholangiocarcinoma, interval between onset and death 14 months. Since patient passed away within 42 days of the covid19 vaccine administration, we are required to complete a report to VAERS. Vaccine (Pfizer) was administered without complications. The patient denied any prior severe reaction to this vaccine or its components or a severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy. Synopsis- 1/23 71 yo male presented to ED with upper GI bleed. PMH: DM, HTN, cholangiocarcinoma of biliary tract requiring recurrent paracentesis, COPD, perigastric and lower esophageal varices (not on beta blockers due to bradycardia). Pt has had 2 episodes of coffee ground emesis. Lactic 2.6, ammonia 52. Rec'd protonix, octreotide, and ceftriaxone in ED. Family has been previously encouraged to speak to palliative care but has never been willing to. GI consulted. 1/24 EGD completed. No signs of active bleed. MDs recommending hospice. CT + for small bowel ileus. 1/26 Requires placement of NG tube to suction. Palliative care consulted. 1/27 Paracentesis completed. 4100mls removed. 1/28 Pt changed to palliative status. 1/29 Pt passed away."
Yes	COVID19 VACCINE (COVID19)	1023803-1	Was contacted by the person's daughter on 2/5/21. Patient started vomiting 2 days after vaccination. She aspirated and passed away 1/16/21. Patient had history of stroke and swallowing problems.
Yes	COVID19 VACCINE (COVID19)	1024067-1	1/15: Pfizer vaccine dose 1 administered 1/16: Fever, chills 1/22: Sore throat, coughing w/white phlegm, taking Tylenol and Mucinex. Fever and chills from 1/16 subsided. Had telehealth consultation with PA. Per her notes, patient said he gets these symptoms annually, requested for an antibiotic. PA referred him for a COVID test. Ordered hydrocodone/chlorphen ER suspension for his cough and an antibiotic. Antibiotic was recommended if symptoms do not subside. 1/23: COVID test administered 1/25: Reported positive for COVID 1/26: Telehealth session w/PA: she informed patient of his positive test, advised to quarantine and seek medical help at hospital if symptoms worsen. Patient reported that his sore throat mostly subsided but is still coughing at night. Said that the pharmacy didn't receive the prescription order for the antibiotic, so this was re-ordered. 1/31: Partner found him dead at 8:18AM on his bed. Death certificate issued by state says cause of death: COVID. Autopsy was not performed. Buried on 2/9/21.
Yes	COVID19 VACCINE (COVID19)	1024157-1	7 days after receiving the vaccine, patient suffered excessive diarrhea and slight coughing. 9 days after vaccine, patient was tested for Covid 19, and received positive results. Patient was transported to hospital via ambulance but hospital returned her to the nursing home since chest was clear, no respiratory issues, and no fever. 10 days after receiving the vaccine, patient was turned over to hospice care but still in the nursing home. Hospice was called in to provide better physician advice and access 24/7. 14 days after receiving vaccine, patient began experiencing excruciating body aches, coughing, low oxygen levels, and no appetite. 18 days after vaccine, patient died.
Yes	COVID19 VACCINE (COVID19)	1024226-1	New onset dizziness with hypotension, tachycardia, and vomiting blood. Sent to ER - told he went into cardiac arrest and died.
Yes	COVID19 VACCINE (COVID19)	1024592-1	No adverse reactions noted. Resident is on hospice for end of life care for terminal diagnosis cerebral atherosclerosis. Experiencing respiratory distress 2/10/2021 r/t to hospice prognosis.
Yes	COVID19 VACCINE (COVID19)	1024743-1	pt became lethargic, stopped eating. No fever; no nausea
Yes	COVID19 VACCINE (COVID19)	1025579-1	Patient received the vaccine at an outside healthcare facility on 2/11/21. At approximately 1 pm she screamed out and fell out of her chair. EMS was called and patient was found to be in Vfib. ACLS was performed for approximately 42 minutes prior to arrival at ED. At that time the patient had been pulseless for 25 minutes. Patient received 450 mg of amiodarone, epinephrine x7, sodium bicarbonate x2, and 7 AED shocks. In the ED 3 more doses of epinephrine were given, one more dose of sodium bicarbonate, and 5 additional shocks. ROSC was not achieved and time of death was called at 1416.
Yes	COVID19 VACCINE (COVID19)	1025641-1	Complained of dizziness on January 18,th seen by MD this date. Passed away on 22nd.
Yes	COVID19 VACCINE (COVID19)	1026095-1	DEATH 2/12/21
Yes	COVID19 VACCINE (COVID19)	1026141-1	death 2/12/21
Yes	COVID19 VACCINE (COVID19)	1026270-1	At 10:33 am Patient pushed her pendant for staff, staff arrived to her apartment and Patient was found unresponsive in her bathroom. Patient received her second COVID-19 Pfizer vaccine about 75 minuets prior to this, she had no adverse reaction's within the first hour of receiving the second dose. CPR was started until paramedics arrived, they took over and tried to resuscitate. Patient was pronounced dead at 11:33 am at scene.
Yes	COVID19 VACCINE (COVID19)	1026362-1	Patient stated he had a migraine after the vaccine. We were advised of a change in appetite on Thursday February 4th. Patient died on February 6th.
Yes	COVID19 VACCINE (COVID19)	1026699-1	Had a stroke 3 days after round one of Covid vaccine and subsequently died the next week due to complications of stroke. Upon admission to hospital, was in afib.
Yes	COVID19 VACCINE (COVID19)	1027051-1	Few minutes post vaccination, after moving to observation area via wheelchair, the patient complained of dizziness. She took glucose tabs she had brought with her. Staff wheeled her to Triage # 1. Her eyes rolled back in her head and she lost consciousness. Staff (paramedics on site) transferred her to gurney and started compressions. AED placed, V- Fib was rhythm, Shock # 1 given, CPR resumed. Shocked again. Fire truck and additional EMT arrived on site and took over care. Epinephrine was given 3 times via intra-osseous route, Amiodarone given intra-osseous route. Additional defibrillation with on site AED for a total of 6-7 times. Patient had good chest rise with ambu-bag, no airway obstruction or peri-oral edema noted. Code called at 12:40 PM.
Yes	COVID19 VACCINE (COVID19)	1027071-1	Adverse reaction to the vaccine started with variable weakness beginning 1/29/2021. On 1/30/21 around 8:30pm, he needed assistance in the bathroom related to weakness and had what was later identified as a stroke with left side weakness and slurred speech. In accordance with his wishes, he had care at home. Due to his advanced age and frailty, a CT scan was not pursued. The 325 mg of aspirin that he was previously taking daily was discontinued. After the stroke, he needed total care. Hospice was established at home. Nursing assistant care was delivered by daughter. Death followed 9 days later (2/9/2021).
Yes	COVID19 VACCINE (COVID19)	1027503-1	Patient died on 02/08/2021
Yes	COVID19 VACCINE (COVID19)	1027619-1	Swollen leg/pain- taken to urgent care- became unresponsive - CPR initiated- expired

			care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""
Yes	COVID19 VACCINE (COVID19)	0974172-1	Resident passed away 1/25/2021 at 1048pm after the vaccine was given on 1/24/2021. Resident had been being monitored but death was not expected.
Yes	COVID19 VACCINE (COVID19)	0974422-1	Patient developed fever to 102 within 24 hours with decreased mentation. Stopped eating/drinking despite aggressively treating fever. Was DNR B status. Family agreed to a trial of IV fluids on 1/21 but was not successfully started until 1/22 after several attempts. Family wanted only comfort measures with no transfer to hospital. Patient continued to have fevers to 102-103 range. Patient passed on 1/23 . Patient did test positive for COVID in early September without significant illness. She was in usual state of health prior to vaccination.
Yes	COVID19 VACCINE (COVID19)	0974489-1	No immediate symptoms. No symptoms ever reported. Patient was found dead in her home on 1/25/2021 and last seen on 1/24/2021. Neighbor called for welfare check because they had not seen her and she had not checked mailbox. No evidence of foul play.
Yes	COVID19 VACCINE (COVID19)	0974855-1	decedent had shortness of breath and hypoxia, cardiac arrested in front of the EMS crew, ACLS initiated, arrived in the Hospital ED asystole and pronounced dead
Yes	COVID19 VACCINE (COVID19)	0975206-1	1 fall after first dose on 1/8/2021 at 1930; no injuries; 4 falls after second dose on 1/14/21 at 1545, 1/15/21 at 1700, 1/21/21/at 1220 and 1/21/21 at 1330 all falls with no injuries. Started Ceftriaxone 1 GM IM daily for 5 dyas on 1/21/21 for UTI: E. Coli
Yes	COVID19 VACCINE (COVID19)	0975382-1	01/22/20When transferring resident from bed to W/C Resident became unresponsive to voice with eyes fix open and point up to the right. Placed resident back in bed found 82% o2 sats B/P 110/106 pulse 110 resp below 16 placed o2 via non rebreather with 20 l/min 02 up to 90% then stabilized at 89% Resident following all commands encouraged to take do breathing exercises, with some compliance, continues ABT/pneumonia , no s/s adverse 1/23/2021 16:48 Discharge Summary Note Text: Resident found unresponsive with no pulse or respirations in bed with emesis on gown. Time of death verified at 1645 with LPN. Funeral Home called at 1900 and body released at 2000.
Yes	COVID19 VACCINE (COVID19)	0975434-1	"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."
Yes	COVID19 VACCINE (COVID19)	0975952-1	Narrative:
Yes	COVID19 VACCINE (COVID19)	0976032-1	Patient stated he wasn't feeling well on January 25, 2021, wasn't eating and complained of abdominal pain. Patient noted to have indigestion and was constipated. Meds provided and labs ordered. On morning of January 26, 2021, patient became weak, lethargic and hypoxic and was sent to emergency department around 0700 hours on January 26, 2021. At approximately 1100 hours, emergency physician notified this writer that patient was not going to overcome his illness and would be placed on comfort care. At approximately 1130 hours, this writer was notified that patient had passed away from multi-organ failure.
Yes	COVID19 VACCINE (COVID19)	0976111-1	"CC:full arrest HPI:HPI and ROS limited due to patient's condition. History is via EMS, medical record, and son. Per Son patient had Covid vaccine on Saturday morning. Slept all day Sunday. Woke up Sunday night a bit ""like coming out of a deep sleep per son, around 10 pm. Shortly after that patient was having a hard time breathing. Emergency called. Arrested around the time EMS arrived. King airway, I/O and CPR initiated. Patient has been in v fib. Was shocked multiple times, given 4 rounds of epi, bicarb and amiodarone. ACLS continued on arrival. Multiple rounds of epi, and attempted defib. Patient given epi, bicarb. Rhythms included fine v fib, asystole, and PEA. Unrecoverable with no cardiac motion. Time of death 11:50 pm."
Yes	COVID19 VACCINE (COVID19)	0977963-1	(Report per patients wife) Patient took his usual nap around 12pm. She found him lying in the bed unresponsvie at 2pm. EMS was not called. Patient's wife called the Funeral home.
Yes	COVID19 VACCINE (COVID19)	0978199-1	Arm hurting used his oxygen at time of bed appeared vomited.
Yes	COVID19 VACCINE (COVID19)	0978754-1	No symptoms appeared immediately after vaccination, although patient passed away around 6:00 pm unexpectedly. Staff talked with her last time at 5:30 pm and then found her at 6:00 pm passed away. Unknown at this time if death is directly related to receiving the vaccine.
Yes	COVID19 VACCINE (COVID19)	0979101-1	cardiac arrest - no warning signs
Yes	COVID19 VACCINE (COVID19)	0979155-1	Jan 3 vaccine administered, jan 4 started headaches, vomiting, pain in the back of the neck, Headaches, chills, loss of speech,
Yes	COVID19 VACCINE (COVID19)	0979255-1	Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.
Yes	COVID19 VACCINE (COVID19)	0979818-1	Patient arrived at ER with complaints of CPR in progress. Per EMS, patient became short of breath while performing yard work on 1/26/2021. At arrival, patient was in fine v fib with a total of 6 shocks delivered along with 300 mg amiodarone followed by 150 mg amiodarone, 1 amp epinephrine and 2 epinephrine drips adminstered en route to ED. CPR initiated at 1755 and EMS reports asystole at 1829. TOD 1909 pronounced by ED DO Dx: Cardiac arrest
Yes	COVID19 VACCINE (COVID19)	0979837-1	Per EMS, the patient was last seen walking and talking to wife 10 minutes prior to EMS arrival. EMS reports via patients wife, that patient was upstairs to change for his doctor appointment then patient's wife found him down. The patient received his COVID-19 vaccine on 1/25/21. EMS states they gave 5 rounds of EPI then patient moved into vfib then was shocked once but returned to asystole. In ED, the patient initially in asystole CPR was started immediately. The patient was given 3 rounds EPI, 1 round bicarb. The patient stayed in PEA throughout. Patient was given tPA. Patient continued to be in asystole and time of death was called at 11:35 am.
Yes	COVID19 VACCINE (COVID19)	0979926-1	Pt began experiencing shortness of breath 3 days after vaccine and expired later that day.
Yes	COVID19 VACCINE (COVID19)	0980107-1	Patient noted to have a change in status at 11:23PM that night. Her oxygen saturation had dropped from normal on room air to 82% and required oxygen. She was also noted to be lethargic with altered mental status and not responding verbally. She then began to mottle. Her oxygen saturation worsened to 51% on 4Liters of oxygen by the next day and she expired on 1/14/21.
	COVID19		Patient with inoperable pancreatic cancer [illegible]

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RM 15

Hoatsama /gai
(Grow Strong Together)

Parties Represented: REPUBLICAN PARTY OF SOUTH AFRICA, AFRICAN HEALTH ASSURANCE (AHA), KHOISAN REVOLUTION (KSR), PEOPLE'S AFRICAN PARTY (P.A.P.), INDEPENDENT PARTY (IP), SOUTH AFRICAN FIRST (SAF), PEOPLE'S RIGHTS PARTY (PR), TRUE FREEDOM PARTY (TFP), MAGOSHI SWARANANG MOVEMENT, SISONKE PEOPLES FORUM, AFRICAN CONGRESS OF DEMOCRATS (A.C.D) & YOUTH OF THE WORLD (YOW).

27 April 2020

The President of the Republic of South Africa
His Excellency, Mr Cyril Ramaphosa
Union Buildings
Pretoria

By e-mail

Dear President Ramaphosa,

REQUEST FOR INFORMATION

The letter is addressed to you, by myself, in my capacity as national co-ordinator of a conglomerate of small political parties.

1. In accordance with the relevant provisions of the Promotion of Access to Information Act of 2000 ("the Act") this is a formal legal request for information in respect of the following:
    a. All information that formed the basis and motivation of the executive decision to declare a state of disaster and subsequently impose the lockdown effective from 26 March 2020, in particular the epidemiological mathematic model and accompanying data, reports, etc.

    b. All information that formed the basis of the decision to extend the lockdown, for a further period of two weeks until 30 April 2020, e.g. the indicators and or measures, that necessitated the decision for the extension;

c. Actual figures and measures of the pandemic, in particular the death rate, the formula used in calculating the rate and what standard or evidence is used to indicate Covid-19 as the direct and immediate cause of a death;

d. Actual measures of infection, what is the method used to test for Covid-19, what test device is used, does the test particularly tests for Covid-19 or is it inferred and what is the reliability of the test and how was it determined.

2. The reasoning and basis for our request for information is as follows:

a. SA is a constitutional democracy, founded on the principles of open and accountable government sensitive to the civil liberties of its citizens and exercised a transparent and rational manner;

b. citizens therefore have the right to access information in order to discharge their constitutional right;

c. The Act gives citizens the right to access information and government the obligation to supply information to the public; and

d. Due to the probabilistic nature of the disaster declared, it is important to release the model that informed the decision to declare a national disaster, for independent review.

Failure by the Executive to release this information, would result in us having the right in seeking judicial relief provided for in the Constitution and in the Act, in particular.

This request is made in a quest to detect, discourage and avoid abuses of power and to ensure accountability.

Yours sincerely,

Mr. R. Maarman (MA) - **National Co-ordinator**

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THE PRESIDENCY
REPUBLIC OF SOUTH AFRICA

OFFICE OF THE CHIEF OPERATIONS OFFICER

Private Bag X1000, PRETORIA, 0001

Enquiries: Mr Justice Hlungwani
Tel: 012 300 5376
Email: Justiceh@presidency.gov.za

Our Ref: PAIA/02/2020/21

The Information Officer
The Department of Co-Operative Governance & Traditional Affairs
Pretoria
0001

Per email: ThinavhuyoN@cogta.gov.za

Dear Sirs

Re: Transfer of request for access to information in terms of the Promotion of Access to Information Act, 2 of 2000 (the Act)

The above matter has reference.

The Presidency received a request for access to information wherein the requestor, requested access to the following information:

"All information that formed the basis and motivation of the executive decision to declare a state of disaster and subsequently impose the lockdown effective from 26 March 2020 in particular the epidemiological mathematic model and accompanying data, report,etc"

We attach hereto a copy of the said request.

I have considered the request and I am of the view that your department is the relevant department to respond to the attached request.

I therefore transfer the attached request to your department in terms of section 20(1)(b) of the Act for further handling and response thereto.

Yours faithfully

L Mxenge

Ms Lusanda Mxenge
Acting Deputy Information Officer
Date: 18/06/2020

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RMS

THE PRESIDENCY
REPUBLIC OF SOUTH AFRICA

OFFICE OF THE CHIEF OPERATIONS OFFICER

Private Bag X1000, PRETORIA, 0001

Enquiries: Mr Justice Hlungwani
Tel: 012 300 5376
Email: Justiceh@presidency.gov.za

Our Ref: PAIA/02/2020/21

Mr R Maarman
50 Jeannette Street
Ext 4, Ridgeway
Johannesburg
2091

Per email: rainbownation2020@yahoo.com

Dear Sir

Re: Your request for access to information in terms of the Promotion of Access to Information Act, 2 of 2000

The above matter has reference.

In the abovementioned request, you requested access to the following information:

" All information that formed the basis and motivation of the decision to declare a state of disaster and subsequently impose the lockdown effective from 26 March 2020, in particular the epidemiological mathematic model and accompanying data, reports,etc"

As you might be aware after having first been identified in Wuhan,China, during December 2019, a novel coronavirus ("SARS-CoV-2) has spread globally, resulting in an international pandemic of the novel coronavirus disease (Covid-19).

On 15 March 2020, the Minister of Co-Operative Governance and Traditional Affairs, Dr Nkosazana Dlamini –Zuma declared a National State of Disaster in terms of section 27(1) of the Disaster Management Act.

Section 27(2) of the Disaster Management Act empowers the Minister to make regulations and to issue directions, subject to section 27(3) and after consulting the responsible cabinet members concerning the matters listed in paragraphs (a) to (o).

Having considered the above, I am of the view that the information is more closely related to the functions of the Department of Co-Operative Governance. In light of the above I have made the decision to transfer your re quest in terms of section 20(1)(b) of the Act to the Department of Co-Operative Governance and Traditional Affairs.

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Am15

Hoatsama /gai
(Grow Strong Together)

Parties Represented: REPUBLICAN PARTY OF SOUTH AFRICA, AFRICAN HEALTH ASSURANCE (AHA), PEOPLE'S AFRICAN PARTY (P.A.P.), PEOPLE'S RIGHTS PARTY (PR), MAGOSHI SWARANANG MOVEMENT, THE NATIONALS OF SOUTH AFRICA (NSA) ,ECONOMIC SOCIAL DEMOCRATS (ESD), UNITED PEOPLE OF SOUTH AFRICA (UPSA) & YOUTH OF THE WORLD (YOW).

25 May 2020

The President of the Republic of South Africa
His Excellency, Mr Cyril Ramaphosa
Union Buildings
Pretoria

By e-mail

Dear President Ramaphosa,

REQUEST FOR INFORMATION

This letter is addressed to you, in my capacity as national co-ordinator of a conglomerate of small political parties. Mr. President, in your recent televised address to the nation, you mentioned that you receive "guidance" from the WHO (World Health Organisation) and it has also been broadcasted that Mr Bill Gates met with you to discuss the Covid-19 pandemic.

1. In accordance with the relevant provisions of the Promotion of Access to Information Act of 2000 ("the Act") this is a formal legal request for information in respect of the following:
    a. Please explain and make public what guidance the WHO has been giving you, in the form of transcripts, minutes and or directives, et cetera?

    b. Please inform us who the person/s representing the WHO were that communicated with you or your representatives and if that person/s was or were vetted in terms of our national security protocols?

c. Please explain and make public what standing the WHO has in our sovereign constitutional republican order, which warrants or justifies taking their guidance and which grants it any authority in or over our Republic?

d. Please explain if and what measures were taken to safeguard our national security in your interactions with the WHO, as they are a foreign extra-constitutional entity?

e. Please explain in what capacity did Mr Gates meet with you? Was he or is he a representative of the WHO or the United States of America (US) government, et cetera?

f. If Mr Gates met with you in his capacity as a representative of WHO or US government , please release and explain the credentials Mr Gates presented?

g. Was Mr Gates vetted in terms of our national security protocols?

h. Please release the transcript/s of your meeting/s with Mr Gates with respect to COVID 19?

2. The reasoning and basis for our request for information is as follows:

a. South Africa is a constitutional democracy, founded on the principles of open and accountable government sensitive to the civil liberties of its citizens and exercised in a transparent and rational manner.

b. Citizens therefore have the right to access information in order to discharge their constitutional right.

c. The Act gives citizens the right to access information and the government the obligation to supply information to the public.

d. Mr. President, you have suspended many fundamental and constitutional rights, in your declaration of a national disaster, as you have deemed the COVID 19 pandemic a great risk to our national security, hence we seek clarity on the

consistency and rationality in your dealings with foreign agents and entities on this matter vis-à-vis our national security protocols.

e. Ours is a Constitutional Democratic Republic and Mr President you are duly invested with sovereign authority by the people to govern in accordance with the Constitution of South Africa, hence the reassurance sought to establish the standing of the WHO constitutionally and the credentials of Mr. Gates.

f. A natural disaster such as the one you have declared, leaves our nation vulnerable, a situation which can easily be exploited by foreign adversaries, hence the need for an abundance of caution in all dealings.

g. Any extra-constitutional authority granted to foreign agents and foreign entities would jeopardise the integrity of our democratic and constitutional order, upon which rests the legitimacy of our system of government, the soundness of our sovereignty and the well-functioning of our society.

Failure by the Executive to release this information, would result in us having the right in seeking judicial relief provided for in the Constitution and in the Act, in particular.

This request is made in a quest to detect, discourage and avoid abuses of power and to ensure accountability.

Yours sincerely,

Mr R Maarman (MA)
National Co-ordinator

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AM 15

THE PRESIDENCY
REPUBLIC OF SOUTH AFRICA

OFFICE OF THE CHIEF OPERATIONS OFFICER

Private Bag X1000, PRETORIA, 0001

Enquiries: Mr Justice Hlungwani
Tel: 012 300 5376
Email: Justiceh@presidency.gov.za

Our Ref: PAIA/06/2020/21

Mr R Maarman
50 Jeannette Street
Ext 4, Ridgeway
Johannesburg
2091

Per email: rainbownation2020@yahoo.com

Dear Sir

Re: Your request for access to information in terms of the Promotion of Access to Information Act, 2 of 2000

Your letter dated 25 May 2020 attached to the abovementioned request setting out the information you seek access to, has reference.

As you may be aware South Africa is a member of the World Health Organisation (WHO). As a member state of the WHO, South Africa is bound to follow technical guidance issued by the WHO in combating the spread of Covid19. The guidance offered by the WHO to the member states is available on the WHO website.

The President did not meet Mr Bill Gates, but had a telephonic conversation with him. For the issues discussed between the President and Mr Bill Gates we refer you to a tweet posted on the President's twitter account. According to the tweet posted on the President's twitter account, the Gates Foundation offered assistance to the country on mass-based testing kits and research.

We wish to draw your attention to the provisions of section 74 and 75 of the Act in relation to the appeal process.

Yours faithfully

Ms Lusanda Mxenge
Acting Deputy Information Officer

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Hoatsama /gai
(Grow Strong Together)

Parties Represented: REPUBLICAN PARTY OF SOUTH AFRICA, AFRICAN HEALTH ASSURANCE (AHA), PEOPLE'S AFRICAN PARTY (P.A.P.), PEOPLE'S RIGHTS PARTY (PR), MAGOSHI SWARANANG MOVEMENT, AFRICAN CONGRESS OF DEMOCRATS (A.C.D), THE NATIONALS OF SOUTH AFRICA (NSA) AFRICAN NATIONAL FREEDOM PARTY (ANFP), ECONOMIC SOCIAL DEMOCRATS (ESD) & YOUTH OF THE WORLD (YOW).

06 May 2020

The President of the Republic of South Africa
His Excellency, Mr Cyril Ramaphosa
Union Buildings
Pretoria

By e-mail

Dear President Ramaphosa,

REQUEST FOR INFORMATION

The letter is addressed to you, by myself, in my capacity as national co-ordinator of a conglomerate of small political parties.

1. In accordance with the relevant provisions of the Promotion of Access to Information Act of 2000 ("the Act") this is a formal legal request for information in respect of the following:
    a. The complete details of the total financial obligations in respect of the Lockdown-Debt, which you have committed this country to e.g. Loans & Borrowings, et cetera.

    b. The terms and conditions of these financial obligations, e.g. interest rates, currency, loan repayments, maturity dates, monetary and fiscal policy restraints.

    c. The collateral used to secure these financial obligation, e.g. land and or our deposits of natural resources.

d. Who were these Loans & Borrowings taken out with e.g. the International Monetary Fund (IMF), etc.

e. Please provide a detailed plan of the intended use of these funds reconciling to the total Financial obligation (to ensure accountability).

2. The reasoning and basis for our request for information is as follows:

a. South Africa is a constitutional democracy, founded on the principles of open and accountable government sensitive to the civil liberties of its citizens and exercised in a transparent and rational manner;

b. citizens therefore have the right to access information in order to discharge their constitutional right;

c. The Act gives citizens the right to access information and government the obligation to supply information to the public; and

d. Although you have incurred this vast and burdensome financial obligation, it is the taxpayers that shall have to honour the obligation. In case we default on the loans and if collateral was indeed pledged, we stand to lose valuable resources and impair or lose our sovereignty.

Failure by the Executive to release this information, would result in us having the right in seeking judicial relief provided for in the Constitution and in the Act, in particular.

This request is made in a quest to detect, discourage and avoid abuses of power and to ensure accountability.

Yours sincerely,

Mr. R. Maarman (MA) - **National Co-ordinator**

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THE PRESIDENCY
REPUBLIC OF SOUTH AFRICA

OFFICE OF THE CHIEF OPERATIONS OFFICER

Private Bag X1000, PRETORIA, 0001

Enquiries: Mr Justice Hlungwani
Tel: 012 300 5376
Email: Justiceh@presidency.gov.za

Our Ref: PAIA/03/2020/21

The Information Officer
National Treasury
40 Nkomo Street
Pretoria
0001

Per email: paia@treasury.gov.za / dgregistry@treasury.gov.za

Dear Sirs

Re: Transfer – Request for access to information in terms of the Promotion of Access to Information Act, 2 of 2000 ("The Act")

The above matter has reference.

The Presidency received a request for access to information from a Mr Ricardo Maarman in his capacity as national co-ordinator of a conglomerate of small political parties wherein he seeks information regarding details of total financial obligations in respect of the lockdown debt.

The full details of the information sought is set out in the request attached hereto.

The President on 21 April 2020 in his address to the nation made it clear that the Minister of Finance will provide details and other related tax announcements relating to the Covid 19 economic and social relief measures. The President also made it clear in his address that other details will be announced in the adjustment budget tabled by the Minister of Finance.

The Presidency has considered the request and we are of the view that the information sought is more closely related to the functions of the National Treasury.

In light of the above, I have made the decision to transfer the request to your department in terms of section 20(1)(b) of the Act.

We therefore transfer to your department the attached request for access to information in terms of section 20(1)(b) of the Act for further handling.

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We have provided the requestor with a copy of this letter.

Yours faithfully

Ms Lusanda Mxenge
Acting Deputy Information Officer
Date: 18/06/2020

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THE PRESIDENCY
REPUBLIC OF SOUTH AFRICA

OFFICE OF THE CHIEF OPERATIONS OFFICER

Private Bag X1000, PRETORIA, 0001

Enquiries: Mr Justice Hlungwani
Tel: 012 300 5376
Email: Justiceh@presidency.gov.za

Our Ref: PAIA/03/2020/21

The Information Officer
National Treasury
40 Nkomo Street
Pretoria
0001

Per email: paia@treasury.gov.za / dgregistry@treasury.gov.za

Dear Sirs

Re: Transfer – Request for access to information in terms of the Promotion of Access to Information Act, 2 of 2000 ("The Act")

The above matter has reference.

The Presidency received a request for access to information from a Mr Ricardo Maarman in his capacity as national co-ordinator of a conglomerate of small political parties wherein he seeks information regarding details of total financial obligations in respect of the lockdown debt.

The full details of the information sought is set out in the request attached hereto.

The President on 21 April 2020 in his address to the nation made it clear that the Minister of Finance will provide details and other related tax announcements relating to the Covid 19 economic and social relief measures. The President also made it clear in his address that other details will be announced in the adjustment budget tabled by the Minister of Finance.

The Presidency has considered the request and we are of the view that the information sought is more closely related to the functions of the National Treasury.

In light of the above, I have made the decision to transfer the request to your department in terms of section 20(1)(b) of the Act.

We therefore transfer to your department the attached request for access to information in terms of section 20(1)(b) of the Act for further handling.

We have provided the requestor with a copy of this letter.

Yours faithfully

Ms Lusanda Mxenge
Acting Deputy Information Officer
Date: 18/06/2020

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RMIG

THE PRESIDENCY
REPUBLIC OF SOUTH AFRICA

OFFICE OF THE CHIEF OPERATIONS OFFICER

Private Bag X1000, PRETORIA, 0001

Enquiries: Mr Justice Hlungwani
Tel: 012 300 5376
Email: Justiceh@presidency.gov.za

Our Ref: PAIA/04/2020/21

The Information Officer
The National Department of Health
Pretoria
0001

Per email: matsoP@health.gov.za **and** gerrit.wissing@health.gov.za

Dear Sir

Re: Transfer of a request for access to information in terms of the Promotion of Access to Information Act, 2 of 2000 ("the Act")

The above matter has reference.

The Presidency received a request from a Mr Ricardo Maarman wherein he sought access to information regarding the tracking and surveillance systems in relation to the contact tracing for Covid-19 infections.

We attach hereto a copy of the said request.

The Presidency has considered the contents of the request and I have made the decision to transfer the request to your department as the information sought is more closely related to the functions of the Department of Health.

We therefore transfer to your department the attached request in terms of section 20(1)(a) and (b) of the Act.

We have provided the requestor with a copy of this letter.

Yours faithfully

Ms Lusanda Mxenge
Acting Deputy Information Officer

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AM15

THE PRESIDENCY
REPUBLIC OF SOUTH AFRICA

OFFICE OF THE CHIEF OPERATIONS OFFICER

Private Bag X1000, PRETORIA, 0001

Enquiries: Mr Justice Hlungwani
Tel: 012 300 5376
Email: Justiceh@presidency.gov.za

Our Ref: PAIA/04/2020/21

Mr Ricardo Maarman
50 Jeanette Street
Ridgeway Ext. 4
Johannesburg
2091

Per email: rainbownation2020@yahoo.com

Dear Sirs

Re: Your request for access to information in terms of the Promotion of Access to Information Act, 2 of 2000 ("the Act")

Your request for access to information dated 19 May 2020 has reference.

In the abovementioned request, you attached thereto a letter detailing the information you request to be given access too. We attach hereto a copy of your letter for your ease of reference.

The Presidency has considered the content of your request and has noted that the information you seek is not in a record format as set out in the Act.

We wish to highlight that on 26 March 2020, Minister Ndabeni-Abrahams issued directions in the government gazette a set of directions dealing with the allowance for using phone data to assist with the tracing of persons who came into contact with someone who has tested positive with Covid-19. The data was intended to assist the Department of Health trace others who came into contact with persons who have tested positive with Covid-19. The directions you will note are intended solely to save lives and to combat the spread of the Covid19.

The Department of Justice and Correctional Services went further to appoint a Covid-19 Judge whose role is to safeguard the privacy of Covid-19 patients and contacts.

In light of the above, I have made the decision to transfer your request to the Department of Health in terms of Section 20 (1)(a)and(b) of the Act.

We attach hereto a copy of the letter of transfer.

We wish draw your attention to the provisions of section 74 and 75 of the Act in relation to the appeal

Yours faithfully

Ms Lusanda Mxenge
Acting Deputy Information Officer
Date: 18/06/2020

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THE PRESIDENCY
REPUBLIC OF SOUTH AFRICA

OFFICE OF THE CHIEF OPERATIONS OFFICER

Private Bag X1000, PRETORIA, 0001

Enquiries: Mr Justice Hlungwani
Tel: 012 300 5376
Email: Justiceh@presidency.gov.za

Our Ref: PAIA/04/2020/21

The Information Officer
The National Department of Health
Pretoria
0001

Per email: matsoP@health.gov.za **and** gerrit.wissing@health.gov.za

Dear Sir

Re: Transfer of a request for access to information in terms of the Promotion of Access to Information Act, 2 of 2000 ("the Act")

The above matter has reference.

The Presidency received a request from a Mr Ricardo Maarman wherein he sought access to information regarding the tracking and surveillance systems in relation to the contact tracing for Covid-19 infections.

We attach hereto a copy of the said request.

The Presidency has considered the contents of the request and I have made the decision to transfer the request to your department as the information sought is more closely related to the functions of the Department of Health.

We therefore transfer to your department the attached request in terms of section 20(1)(a) and (b) of the Act.

We have provided the requestor with a copy of this letter.

Yours faithfully

Ms Lusanda Mxenge
Acting Deputy Information Officer
Date: 19/11/2020

IN THE HIGH COURT OF SOUTH AFRICA
(WESTERN CAPE DIVISION, CAPE TOWN)

Case NO: 5852/2021

In the matter between:

RICARDO MAARMAN	Applicant
And	
THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	First Respondent
THE MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS	Second Respondent
PROFESSOR SALIM ABDUL KARRIEM obo THE GOVERNMENTAL COVID-19 ADVISORY COMMITTEE	Third Respondent
THE NATIONAL DEPARTMENT OF HEALTH	Fourth Respondent

FILING NOTICE

KINDLY TAKE NOTICE THAT the Respondents herein file their Answering, Confirmatory ant Explanatory Affidavits evenly herewith.

SIGNED AT **CAPE TOWN** ON THIS 25th DAY OF **MAY** 2021

THE STATE ATTORNEY

Per: M Nkabini

First to Fourth Respondents' Attorneys
4th Floor

THE STATE ATTORNEY
Per: Mr M Nkabini
Tel: 021-441-9200

22 Long Street
CAPE TOWN
Ref No: 891/21/P6

TO: **THE REGISTRAR**
Western Cape High Court
CAPE TOWN

AND TO: **T VICTOR & ASSOCIATES**
24 Viola Road
BLOUBERGSTRAND
CAPE TOWN
Tel: 077078168

C/o **ROB GREEN ATTORNEYS**
Room 305
Benzal House
3 Barrack Street
CAPE TOWN

IN THE HIGH COURT OF SOUTH AFRICA
(WESTERN CAPE DIVISION, CAPE TOWN)

Case No: 5852/2021

In the matter between:

RICARDO MAARMAN	Applicant
and	
THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	First Respondent
THE MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS	Second Respondent
PROFESSOR SALIM ABDUL KARRIEM obo THE GOVERNMENTAL COVID-19 ADVISORY COMMITTEE	Third Respondent
THE NATIONAL DEPARTMENT OF HEALTH	Fourth Respondent

RESPONDENTS' ANSWERING AFFIDAVIT

I, the undersigned,

PROFESSOR ADRIAN J PUREN

do hereby make oath and say:

INTRODUCTION

1. I am an adult male and employed as the Acting Executive Director: of the National Institute for Communicable Diseases ("NICD"). I am carrying out my principal duties at 1 Modderfontein Road, Sandringham, Johannesburg, Gauteng Province.

2. The NICD is a national public health institute of the South Africa, providing reference to microbiology, virology, epidemiology, surveillance, and public health research to support the South African Government's response to communicable disease threats. The NICD thus serves as a resource of knowledge and expertise of communicable diseases to the South African Government, Southern African Development Community countries and the African continent. The main goal of the NICD is to be the national organ for South Africa for public health surveillance of communicable disease.

3. Before commenced my employment with the NICD: I graduated as a medical doctor from the University of the Witwatersrand and obtained a Medical degree (1986) and a Ph (1993). I received further training at the University of Oxford and University of Colorado Health Sciences Center in the fields of immunology and Cytokines.

4. I was appointed at the NICD to implement a HIV diagnostic and vaccine laboratory in July 1999. Subsequently, I was appointed as a Deputy Director for Virology Division that included several sections including Centres for Respiratory Diseases

and Meningitis, Centre for Vaccines and Immunology and Centre for HIV and STIs, I have thus gained extensive experience and practical knowledge in virology, virology diagnostics and surveillance.

5. I serve as the technical manager for quality assurance at the NICD and have a knowledge and understanding of the matters relating to requirements for providing accurate and key results in line with the ISO standards.

6. I am accordingly duly authorised to depose to this affidavit on behalf of the Fourth Respondent. In the interest of simplicity, the first, second and fourth Respondents will be referred to, herein, by their abbreviated title (the first Respondent as "the President", the second Respondent as "CoGTA" and the fourth Respondent as "the NDOH" or the Respondents.)

7. The facts set out in this affidavit are within my personal knowledge or are derived from documents and information under my control, unless the context indicates otherwise, and are true.

8. As will appear from the allegations (including the annexures thereto) in the founding affidavit, the Applicant's application turns, to a large extent, if not exclusively, on the documents he attached to his founding affidavit, the authenticity and contents whereof are disputed and which I have perused.

9. Where required, the facts set out in this affidavit are supported and confirmed by affidavits depose to by the appropriate persons in CoGTA or NDOH or both, with

personal knowledge of the relevant facts and will be filed together with this affidavit. Where legal submissions are made during this affidavit, they are based upon the advice of my legal representatives. I believe such advice to be correct.

10. I have read the founding affidavit of the Applicant and respond thereto as follows:

POINTS *IN LIMINE*

11. At the outset I point out that there are several legal issues which arise from the averments set out in the Applicant's founding affidavit, which requires comment before I deal with the balance of the averments, therein.

12. The comments below will be raised by way of legal objections/points *in limine* in relation to three issues, viz: non-compliance with the regulations, self-created urgency and no prima facie or strong case for the relief sought.

THE FIRST POINT IN LIMINE:

Non-compliance with the National Health Act, 2003

13. In terms of paragraph 2 of the Notice of Motion the Applicant seeks an order that the Respondents "*produce the isolated and purified physical SARS-COV-2 virus, not a culture isolate or any mixture within which the supposed virus is, nor a*

photograph or the RNA sequence only, to the Applicant at the place in terms of their safety measures of choice, within 7 days".

14. NDOH contends that on the face of the relief in paragraph 2, *supra*, the Applicant's request amounts to, *inter alia*, an acquisition or importation or handling of human pathogens. Because the Applicant requested the Court to order that the Respondents "produce" the isolated and purified physical SARS-CoV2 to him within 7 days.

15. The NDOH contends that any, one (or more) of the processes, contemplated in paragraph 2, above, seem to fall within the scope of the National Health Act, 2003, Regulations relating to the registration of microbiological laboratories and the acquisition, importation, handling, maintenance, and supply of the human pathogens ("the NHA Regulations"). Put differently, to give effect to his relief, he would, amongst others, be required to "acquire" "receive" or "handle" human pathogens, as contemplated in the NHA Regulations.

16. Accordingly, the NDOH contends that the Applicant, before, he can claim that he has a right to the relief under paragraph 2, *supra*, he must comply with the express requirements of the NHA Regulations.

17. Section 1(a) of the NHA Regulations defines "human pathogen" means-

> *"an infectious substance (b) the toxin of an infectious substance, or (c) any diagnostic specimen, vector or other material that contains, or that is*

reasonably suspected to contain an infectious substance or a toxin of an infectious substance",

"infectious substance" means- (a) a micro-organism, virus or parasite that is capable of causing human disease, or (b) an artificial produced hybrid or mutant micro-organism that contains genetic components of any micro-organism capable of causing human disease."

"microbiological laboratory" means a laboratory which handles human pathogens capable of colonising in humans, irrespective of whether or not the laboratory undertakes specific culture of such human pathogens or merely receives and handles tissue and other specimens potentially infected or infested which such human pathogens, and including laboratories which handle infected or infested, or potentially infected or infested, indigenous vectors of human pathogens, or exotic vector species irrespective of whether they are infected or infested."

18. Section 3 of the NHA Regulations 2003 provides that-

No person shall:

"*(a) acquire, receive or import human pathogens; or*

(b) *handle, manipulate, maintain, store, culture or in any way process, issue or in any way dispose of human pathogens so acquired, received, or imported, unless the person -*

(i) is registered with the department as a microbiological laboratory in terms of regulation 6(1)(a)(ii);

(ii) is assigned a BSL code in terms of regulation 6(1)(a)(iii)

(iii) Is in possession of permit issued in terms of regulation 6(1)(b) to conduct the activities referred to in paragraph (a) or (b) in respect of human pathogens in accordance with the BSL code of the laboratory indicated in the permit; and

(iv) conduct an activity referred to in (a) or (b) as the case may be, in accordance with the provisions of these regulations and the standards."

19. The NDOH contends that the Applicant, on his own case, he is not competent nor permitted to request the relief sought referred to in paragraph 2 above. Accordingly, the NDOH contends that the Applicant on, at least, two grounds would be disqualified to request the relief in his Notice of Motion.

19.1. Firstly, in paragraph 2 of the founding affidavit the Applicant merely describes himself as "an adult male, Ricardo Maarman who holds an MA International Politics obtained at the University of Leicester in the UK. He specialises in post-cold World Order, International Security Intelligence and

Security & US Foreign Policy". Thus, on his own description he would not qualify.

19.2. Secondly, his founding affidavit contains no positive or other averments which indicates or show that he, was registered as a microbiological laboratory with the Department, as contemplated in section 3(a) of the NHA Regulations. In addition, it not suggested by the Applicant that he is in the process or doing so. In any event, even if he was (which is denied) his expertise or lack thereof would still preclude him from requesting the relief sought.

20. In all the circumstances, the NDOH the contends that the Applicant's relief sought in paragraph 2 of his Notice of Motion appears to be unlawful, in that, it is contrary to the requirements of the NHA Regulations.

21. In the premises his application fell to be dismissed with costs. Should the Court nevertheless consider his application, then the NDOH contends that his applications must be dismissed on the grounds set out, below.

THE SECOND POINT IN LIMINE

Whether the Applicant has made out a case for urgency in his affidavit

22. In paragraph 1 of the Notice of Motion (read with paragraphs 10 to 24 of the founding affidavit) the Applicant prays for an order along the following lines:

> *"That this application is heard as a matter of urgency and that the Applicant's failure to comply with the time limits imposed by the Rules of this Honourable Court be condoned in terms of Rule 6(12)."*

23. In support of his urgent application the Applicant in paragraphs 10 to 21 of the founding affidavit set out the purported grounds which he asserted renders this matter urgent. To avoid unnecessary repetition, herein, I will only refer some of the Applicant's averments set out in his founding affidavit, below. In doing so, I do not thereby concede and/or acknowledge the correctness or otherwise of his averments set out below (or those expressly excluded, herein). I turn to the Applicant's averments, below:

> *"I respectfully submit that this matter cannot wait to be dealt with in the ordinary course, as such, I ask the Court to dispense with the forms and service provided for in the Rules and in my non-adherence with the normal rules procedure as set out in Rule 6.*
>
> *This matter is of such urgency that it simply cannot wait for the normal procedure to be complied with. I respectfully submit that this application should be heard other than in the normal course, otherwise the relief which we seek will be rendered ineffective.*
>
> *Currently the entire state is under lockdown level 1, which is a serious violation of the citizens' fundamental rights. To date, the Minister of Health has uttered and there are circulating discussions that the lockdown*

measures will be tightened which begs for those measures to be scrutinised.

There is a massive nationwide rollout of a vaccine claimed by the Respondent that must be used in the prevention of being infected by the alleged virus.
This vaccine rollout has begun in other countries and it has resulted in deaths and vaccine injuries.
The National disaster has been declared and is ongoing for almost a year affecting the entire nation with dire consequences.

The outcome of the order could very well mean a quick recovery to normal circumstances for the entire nation.
In South Africa, there is vast unemployment and poverty. As such, the question of the very cause threatens to drastically increase the already desperate circumstances must at least be thoroughly investigated and with utmost haste.

...And each week of continual lockdown will, in the long run, cause more loss of lives than the virus itself."

24. The Respondents (CoGTA and NDOH) contend that the Applicant's application fell to be dismissed, in that, he failed to, amongst other factors, show that he will not otherwise be afforded substantial redress at a hearing in due course. The Respondents (CoGTA and NDOH) contend that the Applicant *faintly* asserted in paragraph 11, without more, that "*this matter is of such urgency that it simply cannot wait for the normal procedures to be complied with*". Apart from the latter statement, no material facts or circumstances are advanced in his founding

affidavit wherein he claims that he will not be afforded substantial redress at a hearing in due course.

25. The Respondents contend that the only reasonable inference which could be drawn from the lack of any particularity or facts, in the founding affidavit, about the substantial redress, stems from the fact that the Applicant, in essence, is seeking *final* relief in this matter. In other words, the granting of an interdict, in the manner framed by the Applicant, would be dispositive of any matter between the parties. This is so because the Applicant is not seeking the relief in paragraph 2 of the Notice of Motion *pending* the resolution of the main (or other) proceedings.

26. Thus, the Applicant in paragraph 2, *supra*, is seeking final relief or relief with final effect. In any event, the Applicant is not suggesting that he is seeking (through the interdict) any "freezing" of existing rights which are threatened by irreparable harm.

27. The above, notwithstanding, the Respondents contend that the urgency in this matter appears to be self-created. Although it lacks the requisite factors to show urgency, the only allegation in the founding affidavit which contains some '*elements*' of alleged urgency appears in paragraph 20, where he alleged that:

> *"In South Africa, there is vast unemployment and poverty as such, the question of the very cause threatens to drastically increase the already desperate circumstances must at least be thoroughly investigated and with utmost haste".*

28. The Respondents contend that the above allegation should be read against, amongst others, the allegations contained in paragraph 62 where the Applicant asserted that he *has a reasonable suspicion about the existence of SARS-CoV-2 virus*". On the Applicant's version, if the SARS COV 2-virus does not exist then, amongst other restrictions, the lockdown restrictions are unlawful or irregular and as such violates his fundamental rights.

29. The Respondents contend that the Applicant commits an elementary error, in that, no right is absolute and may in appropriate circumstances be limited in terms of section 36 of the Constitution.

30. In any event, the Respondents contend that there appears to be a disconnect, on the one hand between the claim for urgency and on the other, the allegations in paragraph 10 to 21 of the founding affidavit, in support thereof. Put differently, the allegations in the founding affidavit do not support the Applicant's cause of action.

31. Nevertheless, the Respondents contend that if the Applicant failed to comply with the requirements of section 3 of the NHA Regulations then this Court may, in any event, not exercise its discretion in favour of the Applicant. In addition, the relief sought contains the risk that the Court, in granting the relief sought, might thereby enters, into the exclusive domain of the Executive or organs of state (in circumstances where no case is made out that the Executive or the organ of state commit an irregularity or violate the Constitution.)

32. I turn to the self-created urgency which emerge from the allegations in paragraphs 51 to 57 of the founding affidavit. Due to the repetition of the latter allegations, I only restate the gist of the allegations set out in the founding affidavit, below:

32.1. The Applicant knew about the National Lockdown restrictions, at least since 15 March 2020.

32.2. On the Applicant's own version, he knew or reasonable should have known that in or during January 2020 the world became aware of the so-called Coronavirus.

32.3. He knew or reasonably should have learnt about the vaccination rollout programs in this country, since March 2021 or earlier.

32.4. In addition, the reported case of infected persons in the country are in the public domain, on a daily or weekly basis.

32.5. The instances when the President address the citizens of the country about restrictions is, similarly, in the public domain. The President mostly recently in or during the beginning of April 2021 address the citizens of the country.

33. Despite all the above information at his disposal, at the time, the Applicant now wishes to leapfrog the court procedures and insist that he must be heard on an urgent basis, whilst no discernable case is made out in his founding affidavit.

34. More importantly, the Applicant rushes to Court, despite, the fact that he on his own case has an alternative remedy. This is evident from paragraph 132 of his affidavit that *"the applicant has a right to access to information in terms of section 32 of our Constitution, and that is what he is essentially requesting here."*

35. The Applicant put up no grounds or facts why he omitted to invoke his right to access to information. The Respondents contend that it is, in any event, not suggested by the Applicant in his affidavit that he in or during March or April 2021 submitted a request for information and his request was declined by the Respondents.

36. Accordingly, the Respondents contend that it is plain, that on his own version, the Applicant has an alternative remedy which he should have invoked *before* launching this urgent application.

37. In the circumstances, the Respondents contend that the Applicant's failure to do so, should be regarded as an abuse of the Court process. This is so because, not only is he requesting relief with far reaching consequences for how the Executive and organs of state should positively comply with their constitutional obligations

(by protecting the population and the health resources) but the net effect of his relief might very well place the lives of millions at risk. Because the Applicant establishes no factual basis how he will come with the provisions of the NHA Regulations. Accordingly, the handover the physical virus to him, as requested, poses serious dangers for the effective protections of the population.

38. In the premises the Respondents contend that this Applicant's application fell to be dismissed on this ground also. Should the Court, nevertheless, be amenable to consider his application (which ought to be rejected) then the Respondents contend his application should be dismiss on the ground set out below.

THE THIRD POINT IN LIMINE

39. The Respondent contends that the Applicant's application for a mandatory interdict is not an *ordinary interdict*. The Respondents contend that it is common cause that the Applicant is seeking a mandatory interdict against the Executive and organs of state (first, second and fourth Respondents).

40. The Respondents contend that in the absence of *mala fides* on the part of the Respondents, the Court does not readily grant such an interdict. Moreover, the Respondents contend that the Court only grants an interdict, such as that sought by the Applicant in the present instance upon a strong case being made out for

that relief. The Applicant failed to make out such a string case and for the reason(s) referred to above and hereunder.

41. In terms of the Notice of Motion (read with paragraphs 129 to 141) of the founding affidavit the Applicant seeks the following relief:

> *"That the Respondents "produce" the isolated and purified physical SARS-COV-2 virus (not a culture isolate of any mixture within which the supposed virus is, nor a photograph or the RNA- sequence only) to the Applicant at a place in terms of their security measures of choice, within 7 days."*

42. The Respondents contend that in terms of paragraph 2 of his Notice of Motion, if the relief is granted, they would be obliged to perform a positive act, *viz.*: to "produce" the isolated and purified SARS-COV-2 virus to the Applicant" even if the Applicant failed to comply with the provisions of section 3 of the NHA Regulations. The Respondent contend that since the Applicant has no legal basis to request the relief, this should be end of the matter. However, for consistency I, nevertheless, deal with the grounds advance in the founding affidavit, below.

Whether the Applicant has made out a prima facie case in the founding affidavit

Ad paragraphs 129 to 141 of the founding affidavit

43. The Applicant in his founding affidavit sets out the alleged basis for the relief sought in the Notice of Motion. The Applicant in paragraph 129(a) to (i) to thereof, alleged that he (and the public have the following undisputed *prima facie* rights, viz.:

Prima facie right

43.1. **Ad paragraph 129**

"The Applicant and the public have the following undisputable prima facie right to (a) to human dignity; (b) life; (c) bodily and psychological integrity; (d) to make decisions concerning the security and control over their body; (e) freedom to practice their trade, occupation and professional; (f) not to be treated in a cruel, inhumane and degrading way; (g) the right to have access to health care services; (h) freedom to movement; and (i) just administration."

43.2. **Ad paragraph 130**

"Not to have limitations imposed on their rights entrenching the Bill of Rights and if so, that it must be restrictively interpreted, so as to impose minimum limitation on those rights, in accordance with section 36 of the Constitution."

43.3. **Ad paragraph 131**

"That the Bill of Rights be applied to all law, including the DMA."

43.4. **Ad paragraph 132**

"The Applicant has a right to access to information in terms of section 32 of our Constitution, and that is what he is essentially requesting here."

43.5. **Ad paragraph 133**

"From the above it is clear that a strong case has been made out by the Applicant and those it is acting on behalf of, have at least prima facie right."

44. The Respondents contend that there appears to be a disconnect between the relief sought in paragraph 2 of the Notice of Motion and the fundamental rights claimed in the paragraphs set out, in paragraphs 129 to 133, *supra*. Because the Applicant failed to show which, if any of the rights referred to above, is/are threatened by an impending or imminent irreparable harm. In addition, the Applicant failed whether any member of the public (which he claims to represent) right(s) was/were threatened by an impending or imminent irreparable.

45. The Respondent contend that on the Applicant's case the prima facie right which he must establish is not merely a catalogue of rights, as envisage in paragraph 129 (a) to (i), *supra*, in order, for the Court to grant an order in terms whereof the Respondents would be compelled *"to produce of the isolated and purified physical*

SARS-COV-2 virus." The Respondents contend that the prima face right must be a right to which, if not protected by an interdict, irreparable harm would ensue. I have already pointed out in paragraph 44, *supra,* no such case is made out on the papers by the Applicant.

46. In any event, the Respondents contend that the allegations contained, *inter alia,* in paragraphs 129 (read with 134 to 138) of the founding affidavit failed to demonstrate a *prima facie* right that is threatened by an impending or imminent irreparable harm. Alternatively, the above facts in the founding affidavit failed to demonstrate a prima facie case for the relief sought in the Notice of Motion.

47. Similarly, the facts set out in, *inter alia*, paragraphs 129 (read with paragraph 134 to 138) of the founding affidavit failed to demonstrate a clear right that is threatened by an impending or imminent irreparable harm.

Reasonable apprehension of irreparable and imminent harm

48. In paragraph 134 the Applicant in support of the assertion of reasonable apprehension of irreparable and imminent harm alleged that:

48.1. **<u>At paragraph 134</u>**

"I submit that harm is apparent in this instance, as set out throughout this founding affidavit."

48.2. **Ad paragraph 135**

"Without the relief sought to prevent further harm the Applicant and the rest of South Africa will continue to suffer irreparable financial, material, physical and psychological harm."

48.3. **Ad paragraph 138**

"From the above it is clear that a strong case has been made out by the Applicant and those it is acting on behalf of the existence of the reasonable apprehension of irreparable and imminent harm."

49. The Respondents contend that there is another difficulty with the Applicant's assertion that he has prima facie right to an interim urgent interdict against the Respondents, is this: He is seeking the interim interdict ostensibly to protect the catalogue of rights set out in paragraph 129(a) to (i) of the founding affidavit. However, the difficulty with the Applicant's case is that he established no facts or circumstances how the "production" of the isolated and purified physical SARS-COV-2 virus would protect those fundamental rights. To this end he commits an elementary error by not establishing facts or circumstances to support his cause of action.

50. What is, however, plain from paragraph 136 to 137 of the founding affidavit is that he is, essentially, complaining about the lockdown restrictions. If this is the case, then, the Respondents contend no case is made out for an attack on those restrictions. Put more accurately, no case is made out to show the declaration of a national state of disaster (RM7) and the subsequent regulations ad directive were/are unconstitutional. Because it is not suggested in his founding affidavit (in addition to the interdict) that he complains that the lockdown restrictions are unlawful or otherwise offend the provisions of the Constitution.

51. The allegations on paragraphs 136 to 137 reads:

52. **Ad paragraph 136**

"The public further stands severely prejudiced with the arbitrary infringements of their fundamental rights should the Respondents continue to ignore their rights."

53. **Ad paragraph 137**

"At the current rate, the South African Government will run out of money to pay the salaries of state employees, it is submitted that if South Africa's present economically restricted lockdown measures are not discontinued immediately, the Respondents may cause 29 times more deaths with the measures aimed to prevent the spread than the virus itself."

54. In all the circumstances, the Respondents contend that there is misalignment between the relief sought for an interdict and *source* of the harm.

55. The Respondents further contend that it is plain from the structure of the Notice of Motion, the Applicant seems to pray for final relief or a mandatory interdict with final effect. This is evident from prayers 1 and 2 of the Notice of Motion. It is also evidence from allegations in paragraphs 129 to 141 of the founding affidavit. Put differently, the Applicant is not seeking a provisional order which is designed to protect his rights pending an (the main) application to be brought to establish his rights. That is the purpose of the interim interdict is to freeze the position until the Courts decides where his rights lie.

56. In the premises, the Respondents contend that the Applicant's application fell to be dismissed with costs.

Hearsay evidence

57. The Respondents contend that the Applicant's application is largely, if not, exclusively founded on statements and documents, the authenticity of which are disputed. Notwithstanding the dispute about the authenticity of those documents, the Respondents contend that a large, if not, the entire case in support of the relief sought under paragraph 2 of the Notice of Motion, appears to consist of hearsay evidence.

58. I will, accordingly, not deal with those individual paragraphs and documents which offend the rules of evidence and the Uniform Rules of Court in this affidavit. The Respondents intend to launch an interlocutory application in this regard. Accordingly, my responses below will be confined to those allegations which invite a scientific response.

59. I will, similarly, not expressly deal with those averments which relates to CoGTA. In this regard, a supporting affidavit, explanatory and confirmatory affidavits will be deposed to by the relevant employees.

THE AVERMENTS CONTAINED IN THE FOUNDING AFFIDAVIT

60. **Ad paragraphs 1 to 2 thereof**:

61. Denied.

61.1. As is evident from paragraph 2 of the founding affidavit, the Applicant's expertise falls within the domain of 'social science'. In particular, he appears to specialise in, amongst others, Post-cold war world order, international security, intelligence, and US foreign policy.

61.2. Whereas the subject matter of SARS-COV2 seems to fall within the broader branches of microbiology, virology, and epidemiology. There is no evidence that the Applicant is a specialist or had otherwise gain expert knowledge in

any of the branches of science. To this end, the NDOH dispute the Applicant's claim about his personal knowledge and his expertise in the relevant branch of science.

61.3. I am advised that the documentary material attached to his founding affidavit constitutes hearsay evidence. The NDOH denies that it consented to the submission or use of those documents.

61.4. Save as aforesaid, the balance of the allegations contained in this paragraph are denied.

62. **Ad paragraphs 3 to 5 thereof**:

The allegations contained in these paragraphs are noted but not disputed.

63. **Ad paragraphs 6 to 9 thereof**:

64. Denied.

64.1. The NDOH denies that this matter is urgent. The NDOH repeats the submissions set out in paragraphs 22 to 38, *supra*.

64.2. The NDOH denies that the Applicant is entitled to the relief sought in paragraph 7 (read with paragraph 2 of his Notice of Motion). The grounds

upon which the NDOH claims that the Applicant is not entitled to the relief sought are more fully traverse in paragraphs 13 to 21 and 39 to 56, *supra*.

64.3. In particular, the NDOH denies that the Applicant is registered as a microbiological laboratory. The NDOH avers that there are minimum requirements which must be met before a person or laboratory can be registered. For ease of reference, I attached hereto a copy of the minimum requirements for laboratories, marked ("**AP1**").

64.4. When a person/laboratory is so registered the NDOH issued a permit to the laboratory. I also attached hereto, a flow chart of how a permit is obtained, marked ("**AP2**").

64.5. Save as aforesaid the balance of the averments is denied.

65. **Ad paragraphs 10 to 24 thereof**:

66. Denied.

66.1. The NDOH repeat the submissions in paragraphs 23 to 23, *supra*.

67. **Ad paragraphs 25 to 31 thereof**:

The allegations herein are noted, but not admitted.

68. **Ad paragraph 32 thereof**:

The allegations herein are noted.

69. **Ad paragraph 33 thereof**:

70. Denied.

71. The NDOH avers that the allegations in this paragraph amounts to a statement which are not supported by any material facts or circumstances.

72. In any event, there are no corroborating evidence in support of the Applicant's claim that he acts for or in the interests of the public.

73. **Ad paragraphs 34 to 39 thereof**:

The allegations contained herein are noted, but not admitted.

74. **Ad paragraphs 40 to 44 (read with paragraphs 46, 47, 48 and 49) thereof**:

75. Denied.

76. The NDOH avers that the allegations contained in the above paragraphs are argumentative and fell to be struck from the affidavit.

77. In any event, the NDOH denies that the Applicant could have any personal knowledge in respect of the matters set out in paragraphs 40 to 42, above.

78. **Ad paragraphs 45 thereof**:

79. Denied.

79.1. The NDOH dispute the basis upon which the Applicant advance the submission in this paragraph.

79.2. It is common cause that he is not qualified as an expert or otherwise expertise in the fields of microbiology or epidemiology.

79.3. Despite the patent lack of the requisite expertise the Applicant seeks to venture deep into branches of science, without the benefit of a qualified expert.

79.4. More importantly, despite the grave knowledge deficits, the Applicant persist with this application on an urgent basis.

79.5. The NDOH avers that the Applicant does not only (through this application) place the Court a great disadvantage, in that, the Court is not qualified nor possess the requisite scientific knowledge. But, in doing so, I am advised, he also contravene the Rules of this Court, in particular Rule 36(9).

80. **Ad paragraph 50 thereof**:

The allegations contained herein are noted but not admitted.

81. **Ad paragraphs 51 to 60 thereof**:

The NDOH avers that these averments are dealt with in the supporting affidavit deposed to by Deputy-Director General from CoGTA.

82. **Ad paragraphs 61 to 63 thereof**:

83. The NDOH avers that in lockdown restrictions were lawfully impose in the context of the prevailing COVID 19 pandemic to, amongst others, to save lives and control the rapid spread of infections in the country.

83.1. The NDOH avers that assertions by the Applicant that "some disruption is lives may only be necessary if we are assured beyond doubt of the existence of the SARS-COV2, appears to be baseless.

83.2. It is not plain what is the source of the opinion advanced in paragraph 61 of the founding affidavit, in particular, his claim that such disruptions depend on an assurance beyond doubt. In addition, the Applicant failed to provide any qualified expert opinion or any peer review which supports his claim.

83.3. In any event, he is not qualified as an expert in the relevant field, it is accordingly unclear on what basis, if any, he advanced his findings.

83.4. Save as aforesaid the balance of the allegations is denied.

84. **Ad paragraphs 64 to 71 thereof**:

85. Denied.

86. In amplification of the aforesaid denial the NDOH avers as follows:

86.1. Protocols for isolation and culturing of "physical virus" are now well established. There are many clear review manuscripts to support this statement. It is not done routinely for diagnosis, as it will be impractical and will not be conducive to patient management.

86.2. The nature of the SARS COV-2 has been established not only through RT-PCR in sequencing but also in electron microscopy.

86.3. I confirm that this has been achieved by the NICD where I carry out my principal duties. I refer below to certain criteria/methodologies use, viz. Koch and the Bradford-Hill criteria/methodologies.

The Koch criteria

86.4. Koch postulates that the following needs to be satisfied to determine causation of a disease:

(a) the organisms must be regularly associated with the disease and its characteristic lesions.

(b) the organisms must be regularly associated with the disease host and grown in culture.

(c) the disease must be reproduced when a pure culture of the organism is introduced into a healthy susceptible host.

(d) the same organisms must be re-isolated from the experimentally infected host.

86.5. There have been significant advances with new diagnostic methodologies and sequencing, and further associations are made:

86.5.1. A nucleic acid sequencing belonging to a putative pathogen should be present in most cases of an infectious disease. Microbial nucleic acids should be found preferentially in those organs or gross anatomic sites known to be diseased and not in those organs that lack pathology. Fewer, or no, copy numbers of

pathogens-associated nucleic acid sequences should occur in hosts or tissues without disease. With resolution of disease, the copy number of pathogen-associated nucleic acid sequence should decrease or become undetectable. With clinical relapse, the opposite should occur.

86.5.2. When sequence detection predates disease, or sequence copy number correlates with severity of disease or pathology, the sequence-disease association is more likely to be a causal relationship.

86.6. The nature of the micro-organism inferred from the available sequence should be consistent with the known biological characteristic of that group or organisms.

86.7. Tissue-sequence correlates should be sought at the cellular level: efforts should be made to demonstrate specific in situ hybridization of microbial sequence to areas of tissue pathology and to visible micro-organisms or to areas where micro-organisms are presumed to be located. These sequence base forms with evidence for microbial causation should be reproducible.

The Bradford-Hill criteria

86.8. Causation may also be determined by the Bradford-Hill criteria (Koch postulates are not possible for all pathogens):

86.9. Strength (effect size): the association between SARS COV-2 infections and COVID-19 presentation is strong.

86.10. Consistency (reproducibility): consistent findings observed by persons in different places with different samples strengthens the likelihood of an effect. This has been done for SARS-COV-2 and COVID-19 in many ways by many different groups around the world.

86.11. Specificity: causation is likely if there is a very specific population at a specific site and disease with no other likely explanation. The more specific an association between a factor and an effect is, the bigger the probability of a causal relationship. These criteria may be a bit problematic for COVID-19.

86.12. I think one supporting evidence here is that one Island that is free from COVID-19 and no SARS COV-2 detected.

86.13. Temporality: the effect is to occur after the cause (and if there is an expected delay between the cause and the expected effect, then the effect must occur after the delay. COVID-19 was not reported before the emergence of SARS COV-2.

86.14. Biological gradient (dose-response relationship): greater exposure should generally lead to greater incidents of the effect.

86.15. I think the effect of lockdown measures etc. can be named here, i.e., reduced risk, reduced cases, this is but one example there are many other examples which could be identified.

86.16. Plausibility: a plausible mechanism between cause and effect is helpful (but Bradford-Hill noted that knowledge of the mechanisms is limited by current knowledge).

86.17. We know from SARS and MERS that zoonotic coronavirus is involved in respiratory illness.

86.18. Coherence: coherence between epidemiological and laboratory findings increased the likelihood of an effect. This has also been found now many times.

86.19. Experiment: occasionally it is possible to appeal to experimental evidence. This is where the animal models can come in. For ease of reference, I attached a recent article which comments on: Animal models for SARS-Cov2/COVID 19 research- A commentary, marked ("**NM3**")

86.20. Analogy: the use of analogies or similarities between the observed association and any other associations. SARS and MERS sets' the precedent for zoonotic coronaviruses emerging to cause respiratory diseases in humans, although no difference in epidemiology/clinical spectrum.

87. **Ad paragraphs 72 to 128 thereof**:

88. The NDOH avers that the allegations (including the annexures thereto) constitute hearsay evidence and as such fell to be strike out from this affidavit.

89. The NDOH further avers that the complaint about the hearsay evidence forms part of an interlocutory application (which will be heard with this application).

90. Save as aforesaid the allegations contained in paragraphs 72 to 79 are denied, as if specifically, traverse, herein.

91. **Ad paragraphs 129 to 141 thereof**:

92. Denied.

93. The NDOH repeats the submission set out in paragraphs 42 to 56.

94. Save as aforesaid the balance of the averments contained in paragraphs 129 to 141 are denies, as if, specifically, traverse, herein.

95. **Ad paragraphs 134 to 138**:

The allegations contained herein are denied.

96. **Ad paragraph 142 thereof**:

97. Denied.

97.1. The NDOH avers that the Applicant is not permitted and/or competent to received, and/or handle and/or otherwise deal with this or any other infectious virus.

97.2. The NDOH repeats the grounds set out in paragraphs 13 to 21, supra, in support of the aforesaid averments.

97.3. Save as aforesaid the balance of the averments is denied.

98. **Ad paragraph 143 thereof**:

99. Denied.

100. The NDOH avers that on the Applicant's own case, he established in paragraph 132 that he does have an alternative remedy.

101. In any event, the NDOH avers that the must first overcome the hurdles referred to in paragraphs 13 to 21, supra, before he could possibly assert any claim to the existence of a right.

102. Save as aforesaid the balance of the averments is denied.

Professor Adrian J Puren

I certify that:-

The deponent signed this affidavit and swore, and acknowledged that he/she: -

a) knew and understood the contents thereof;

b) had no objection to taking the oath; and,

c) considered the oath to be binding on his/her conscience.

The deponent then uttered the words, "*I swear that the contents of this declaration are true, so help me God*".

COMMISSIONER OF OATHS

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SUID-AFRIKAANSE POLISIEDIENS
SANDRINGHAM
CSC
25 MAY 2021
CSC
SOUTH AFRICAN POLICE SERVICE

"AP1"

Annexure A

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001 Civitas Building, c/o Struben and Thabo Sehume Streets
Enquiries: send to emails: registrationlaboratories@health.gov.za & DOH.COVID19@nhls.ac.za

MINIMUM REQUIREMENTS FOR LABORATORIES CONDUCTING SARS CoV-2 DIAGNOSTIC TESTING

AUGUST 2020

Introduction

Diagnostic Laboratories in South Africa are required to comply with a number of legislative requirements in order to perform diagnostic testing for human subjects. A set of minimum requirements were drafted for laboratories who wish to conduct SARS-CoV-2 diagnostic testing in consultation with the National Health Laboratory Service (NHLS), including the National Institute for Communicable Diseases (NICD) and National Institute for Occupational Health (NIOH) for the National Department of Health (NDoH). The minimum requirements checklist takes into consideration the legislative requirements as set out by the Department of Health (DOH), the Department of Employment and Labour (DEL), the Council for the Non-Proliferation of Weapons of Mass Destruction (NPC) and the Health Professionals Council of South Africa (HPCSA).

One of the major regulations relevant to laboratories that wish to embark on clinical diagnostic testing, is Regulation 178. This Regulation stipulates that all laboratories that acquire, receive or import human pathogens; or handle, manipulate, maintain, store, culture or in any way process, issue and/or dispose of human pathogens, must be in possession of a permit issued by the Department of Health (DoH), authorizing the laboratory to conduct the work as described above.

Scope

This checklist is relevant to all South African laboratories, in both the public and in the private sector, that perform diagnostic testing in response to the current SARS-CoV-2 pandemic.

Instructions to Laboratories:

1. *All laboratories intending to do diagnostic SARS COV-2 testing should complete the checklist; this checklist represents the minimum requirements to be met by laboratories, that will be allowed to conduct diagnostic testing for SARS COV-2;*
2. *First step is to ensure the laboratories are compliant with the requirements described in the checklist (**Annexure A**);*
3. *Complete the checklist providing descriptions of compliance in the "comments" section, and return the completed checklist to registrationlaboratories@health.gov.za and copy the DOH.COVID19@nhls.ac.za within seven (7) working days of receiving the checklist;*
4. *Should you fail to return the minimum checklist within the allotted time, your laboratory will be removed from the testing & reporting register,*

5. *Regardless of the information presented in the initial checklist, the laboratory will be afforded a period of one (1) calendar month to achieve compliance with the minimum requirements listed.*
6. *If compliant, an application form for authorisation to handle the SARS CoV-2 will be sent to the laboratory/facility. If non-compliant after this one month period, the laboratory may request an extension of an additional 1 month, but may not provide SARS-CoV-2 testing until compliance is achieved. Laboratories that still fail to show compliance will be required to cease with their SARS-CoV-2 testing.*
7. *The laboratory/facility will be allowed to report results and will be issued with a permit (valid for one year), to conduct SARS-CoV-2 diagnostic testing.*

Conclusion

Patient specimen testing is a highly valued capacity for South Africa during this pandemic and these minimum requirements are not intended to be restrictive or hindering on the country's response efforts to this global pandemic. This unique and previously uncharted territory has highlighted opportunities for the enhancement and strengthening of biosafety and biosecurity regulations to better serve the country and its people. This ultimately brings us closer to 2021 International Health Regulations (IHR) requirements and will ultimately ensure that the diagnostic results are of the highest standard. It also paves a way to a legally compliant medical laboratory sector and greater government oversight regarding patient testing and pathogen security.

Annexure A: Minimum requirements to be met by laboratories conducting SARS-CoV-2 testing

1.	**Personnel**	**Requirement**	**Yes/No**	**Comments**
1.1	• A minimum of one Health Professions Council of South Africa (HPCSA) registered person working in the lab • Registration with the HPCSA in any medical laboratory discipline e.g. Microbiology, Virology, Chemical Pathology, Haematology, Cytology etc. • Provide registration numbers for people working in the laboratory/facility.	Person must have physical presence in the lab –; There has to be a physical presence of an HPCSA registered person in the testing laboratory;		
2.	**Quality requirements**			
2.1	Participate in External Quality Assessment/ Proficiency Testing (PT) program/s for existing test(s), if laboratory is already participating in PT for SARS-CoV-2, please provide proof)	Once approved – register for SARS-CoV-2 testing in first month		
2.2	Must undergo a quality assurance audit	Applicants will be required to provide evidence of a quality management system in effect at the laboratory.		
2.2.1	Proof of accreditation If laboratory is accredited.	NOTE: Even though accreditation is not a requirement it will guide the audit process mentioned above		
2.2.2	Provide proof that the laboratory was testing for other coronaviruses before March 2020.	Example of a test results showing method excluding personal patient identifiers and information		
3.	**Occupational Health and Safety requirements**			

3.1	Must have a valid documented risk assessment that includes but is not limited to biological, chemical, physical and ergonomic risks.	Include emergency procedures, training decontamination, Personal Protective Equipment (PPE), Occupational Health and Safety Policies		
3.2	The risk assessment must include control measures to be implemented to minimise the risks identified.	All control measures to be considered, engineering, administrative and PPE		
3.3	A record of control measures implemented and where relevant including any maintenance validation records to be provided	Risk assessment control measure e.g. Equipment service vertification/validation		
3.4	If the employer has assigned any duties in terms of the Occupation Health & Safety (OHS) Act, a copy of the assignment in terms of Section 16.2 of the OHS Act to be provided.	E.g. Assignment letter describing the delegation of responsibilities for occupational health and employee safety.		
3.5	Provide proof of a process for the appointment of health and safety representative(s) HSR and the appointment thereof. Provide evidence that health and safety committees have been established and meetings are held, where applicable (number of HSRs dependent on the number of employees i.e. 1 HSR per < 50 laboratory employees)	Establish a Committee if more than one HSR		
3.6	Emergency procedures in place	Documented procedures		
3.7	Access control to facility	Photograph of the facility main lab access signage		
3.8	Provide details of the manager appointed as the COVID-19 Compliance Officer	Appointment letter		
4.	**Requirements for transport of dangerous goods**			
4.1	The vehicle on registration should be registered as a transporter of "Dangerous Goods". Vehicles should be appropriately marked and monitored by tracking devices.	Registration – license disc		

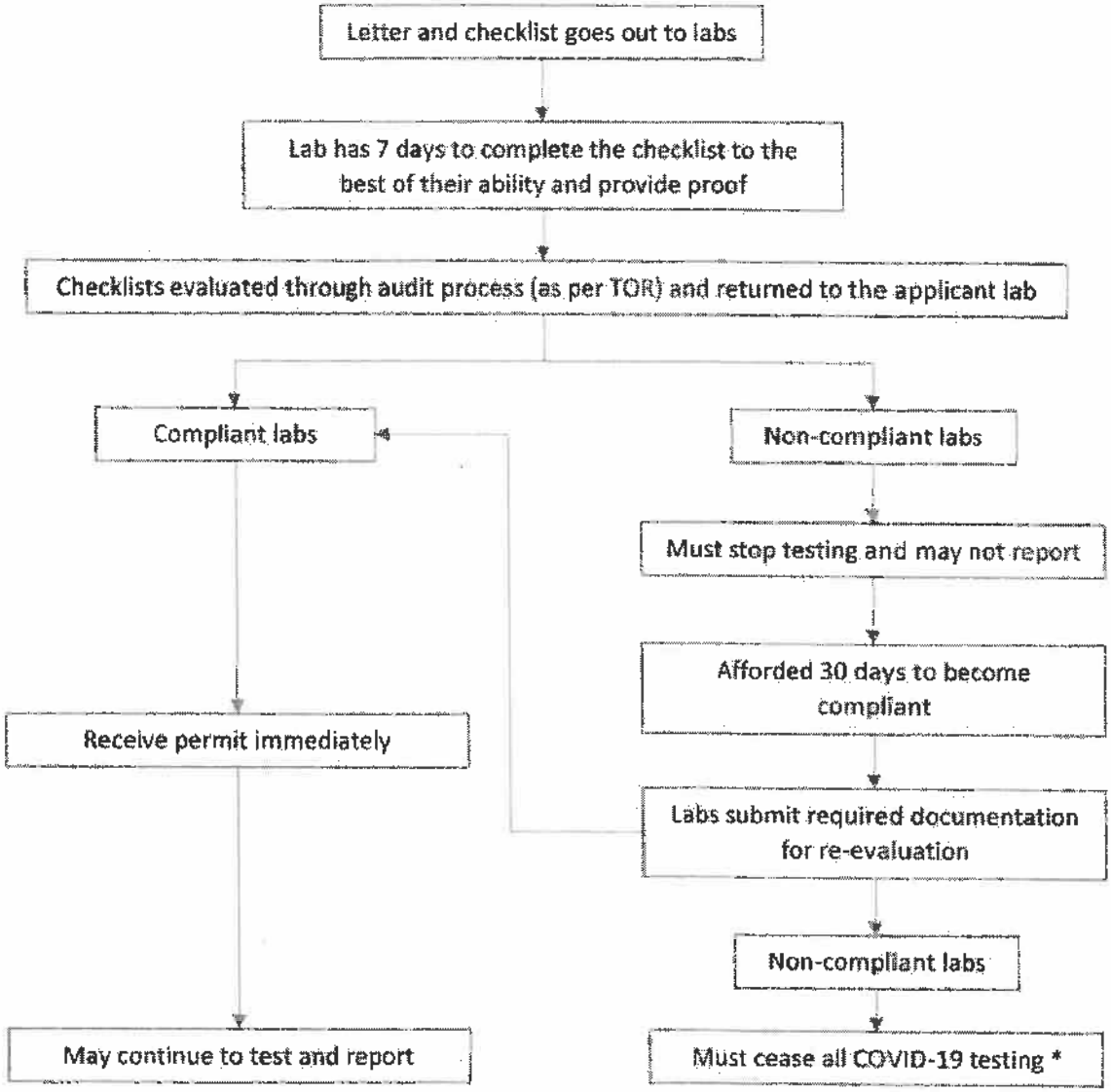
AM
AM

4.2	Licensed driver trained to transport UN3373 Category B biological substances by training organisation that is registered with the Transport & Education Training Authority (TETA)	Public Drivers Permit Certificate with TETA full registration number		
5.	**Waste Management**			
5.1	Provide details of registration of either the Provincial or National Waste Information System in terms of the National Waste Information Regulations as a generator of waste	Copy of registration Online process put link		
5.2	Provide proof of an agreement between the facility and a registered health care risk waste management service provider for the removal, treatment and/ or disposal of chemical waste.	PO for company to safely remove waste.		
6.	**Laboratory registrations and permits**			
6.1	Laboratory is in possession of a permit issued in terms of Regulation 178 to conduct the activities as described in Regulation 178 in respect of **human pathogens** in accordance with the Biosafety Level (BSL) code of the laboratory indicated on the permit; (i.e. BSL2)	Regulation 178 Permit or temporary approval		
6.2	Laboratory issued with a permit from the National Department of Health as a Microbiological Laboratory that handles SARS-CoV-2 (excluding normal labs that test for other coronaviruses) – relevant for all labs that do not regularly test for coronaviruses)	Expiry date of permit – valid for one year from date of issue of permit and will then be reviewed		
7.	**Information Technology for Reporting Data to NICD**			
7.1	Laboratory Information Management System (LIMS) sin place to submit data to NICD/NHLS/NDOH	Access to a LIS system to submit data		
7.2	Able to submit result data (negative and positive) to SOAP web. service	All results must ultimately be reported to the NICD as SARS-CoV-2 is a notifiable medical condition. For more information on the process please see:		

		https://www.nicd.ac.za/nmc-overview/		
7.3	Data submitted per XML specification			
7.4	Quality data in line with requirements as stipulated in NMC regulations	Must have quality checks in place		

"AP2"

Annex B – Process flow for obtaining a Permit to conduct SARS-CoV-2 diagnostic testing



** extra month extension may be granted at the discretion of the evaluator – i.e. if there is a legitimate reason that criteria cannot be met in the allotted first month, possibly outside the control of the lab e.g. advertising and recruitment of an HPCSA registered person*

This would only be based on exceptional circumstances if there is a legitimate reason for the extra time, AND on condition that the lab does not conduct testing until the permit is in hand

hw
KM.

IN THE HIGH COURT OF SOUTH AFRICA
(WESTERN CAPE DIVISION, CAPE TOWN)

Case No: 5852/2021

in the matter between:

RICARDO MAARMAN	Applicant
and	
THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	First Respondent
THE MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS	Second Respondent
PROFESSOR SALIM ABDUL KARRIEM obo THE GOVERNMENTAL COVID-19 ADVISORY COMMITTEE	Third Respondent
THE NATIONAL DEPARTMENT OF HEALTH	Fourth Respondent

CONFIRMATORY AFFIDAVIT

I, the undersigned,

SABELO SIYABONGA SANDILE BUTHELEZI

do hereby make oath and say:

555
M.C

1. I am an adult male and employed as the Director-General in the office of the Fourth Respondent.

2. I am duly authorised to depose to this affidavit on behalf of the Fourth Respondent.

3. The facts contained herein are within my personal knowledge, and are both true and correct, unless the context indicates otherwise.

4. I have read the main answering affidavit deposed to by Professor Adrian J Puren on behalf of the Fourth Respondent, the supporting affidavit on behalf of CoGTA and/or the National Disaster Management Centre and I confirm that the facts set out therein, insofar as they pertain to the Fourth Respondent and such facts fall within my knowledge or are based on institutional knowledge of the Fourth Respondent gained in the course of my work as the Director-General and from documents now under my control, unless the context indicates otherwise, and are true and correct.

Sabelo Siyabonga Sandile Buthelezi

I certify that the deponent has acknowledged that he knows and understand the contents of this affidavit, which was signed and deposed to before me at Pretoria on this the 25 day of **MAY 2021** and the provisions of the regulations contained in the Government Gazette Notice R1258 of 21 July 1972, as amended, and the government Gazette Notice R1648 of 19 August 1977, as amended, have been complied with

SUID-AFRIKAANSE POLISIEDIENS
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DIVISION: VISIBLE POLICING
SOUTH AFRICAN POLICE SERVICE

COMMISSIONER OF OATHS

IN THE HIGH COURT OF SOUTH AFRICA
(WESTERN CAPE DIVISION, CAPE TOWN)

Case No: 5852/2021

In the matter between:

RICARDO MAARMAN	Applicant
and	
THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	First Respondent
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PROFESSOR SALIM ABDUL KARRIEM obo THE GOVERNMENTAL COVID-19 ADVISORY COMMITTEE	Third Respondent
THE NATIONAL DEPARTMENT OF HEALTH	Fourth Respondent

EXPLANATORY AFFIDAVIT

I, the undersigned,

PROFESSOR KOLEKA MLISANA

do hereby make oath and say:

1. I am an adult female. The principal place where I carry out my duties is at 1 Modderfontein Road, Sandringham, Johannesburg.

2. I am duly authorised to depose to this affidavit on behalf of the Government Covid 19 Advisory Committee.

3. The facts set out in this affidavit are within my personal knowledge and are derived from documents and information under my control, unless the context indicates otherwise and are true.

4. I have read the affidavits of the Applicant, including the answering affidavit of Professor Adrian J Puren and the supporting affidavits thereto and I confirm the correctness of the contents thereof insofar as it relates to the recommendations of the Ministerial Advisory Committee on COVID-19.

5. The purpose of this affidavit is to explain the position of Professor Salim Abdool Karim, the Third Respondent, who is cited in his official capacity as the head of the Ministerial Advisory Committee on COVID-19 (the Committee). I confirm that Professor Karim resigned as chairperson of the Committee on 26 March 2021.

6. I confirm that I am the chairperson of the committee and that I am duly authorised to deal with all matters pertaining to the Committee.

PROFESSOR KOLEKA MLISANA

M-C

I certify that the deponent has acknowledged that she knows and understand the contents of this affidavit, which was signed and deposed to before me at Pretoria on this the 25 day of **MAY 2021** and the provisions of the regulations contained in the Government Gazette Notice R1258 of 21 July 1972, as amended, and the government Gazette Notice R1648 of 19 August 1977, as amended, have been complied with

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W/O MAKGALE
MAKGALENG MAKGWALE CHARITY
COMMISSIONER OF OATHS
WARRANT OFFICER
MALUPA NUGA BUILDING

IN THE HIGH COURT OF SOUTH AFRICA

(WESTERN CAPE DIVISION, CAPE TOWN)

CASE NO.: 5852/2021

DATE: 2021.05.27

In the matter between

RICARDO MAARMAN	Applicant
and	
THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	First Respondent
THE MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS	Second Respondent
PROFESSOR SALIM ABDOOL KARIM obo the GOVERNMENTAL COVID ADVISORY COMMITTEE	Third Respondent
THE DEPARTMENT OF HEALTH	Fourth Respondent

BEFORE THE HONOURABLE MRS ACTING JUSTICE NZIWENI

ON BEHALF OF THE APPLICANT	: ADV SIBANDA
	: ADV VILJOEN
	: MS T VICTOR
ON BEHALF OF THE RESPONDENTS	: ADV TSEGARI

PROCEEDINGS ON 21 MAY 2021 [10:46]

COURT: Counsel, if I can ask you a question?

MR VILJOEN: Yes?

COURT: You intimated earlier on that you intend to lead at the bar?

MR VILJOEN: M'Lady, in short is that we've brought an urgent application. The State then requested a postponement which was granted to them and ...[intervenes]

COURT: The State?

MR VILJOEN: Yes, we're for the applicant – Mr Maarman. The State is the respondent.

COURT: State referring to?

MR VILJOEN: There's four respondents. The State President, the Council for the Covid, the Minister of Health and the Minister of Cooperative Governance.

They then asked for a postponement. There was a court order by agreement that they were supposed to file their replying affidavit on 7 May. They didn't.

COURT: So they contacted you ...[intervenes]

MR VILJOEN: Yes, and they ...[intervenes]

COURT: ... yes, then in the interim.

MR VILJOEN: ... they then contacted us, M'Lady, and asked for an extension which we gave them. They still missed that date and they filed late, M'Lady. So we're going to ask the Court; they didn't apply to uplift the bar then, the automatic

bar; so we'll ask the Court to just listen to that and if the Court doesn't grant them bar or condonation to file late, then I don't know if we'll still have time in the day then. Then I'll apply for a default judgment stating that our papers is in order, M'Lady.

COURT: Alright.

MR VILJOEN: But it's all in my directive note there, M'Lady.

COURT: No, I need to read the file.

MR VILJOEN: Of course, M'Lady.

COURT: It's just that ...[intervenes]

MR VILJOEN: And I did put in my directive what the Court needs to read, because their response is quite technical, but at this stage I don't believe the Court needs to read it, because we haven't consented to receive it, because it's late.

COURT: Alright.

MR VILJOEN: Thank you, M'Lady.

COURT: [Indistinct], Mrs Kock?

MRS KOCK: It's just that we haven't had the chance to read the files.

COURT: You are kidding me.

MRS KOCK: I'm not kidding, M'Lady.

COURT: And those which we've read are not ready?

MRS KOCK: Ja.

COURT: Which ... how many matters are those?

MRS KOCK: I can't say, M'Lady.

COURT: I need to read. I need to read. So is it the right

time to adjourn then?

MRS KOCK: Yes.

COURT: Court then adjourns. Also seeing that we're adjourning, this early, right, it won't be at 2 now, after 2. I'll ... you see, perhaps I should start with yours. Are there others? Legal representatives who were earlier?

MRS KOCK: Yes before them.

COURT: Oh before them. Oh unfortunately.

MR VILJOEN: M'Lady, we're set for the whole day and we'll wait until the Court's ready.

COURT: The whole day. Alright. Okay.

MR VILJOEN: And, M'Lady, I'll inform to say that we're sitting and that we're proceeding. They're well aware, I don't know where they are at the moment.

COURT: Alright.

MR VILJOEN: But I'll let them know, M'Lady.

COURT: Alright.

MR VILJOEN: Thank you, M'Lady.

COURT: Court then adjourns.

COURT ADJOURNS [10:50]

COURT RESUMES [12:17]

COURT: Counsel, I'm not trying to get you away from the people. There's something which I would like to address with you. It appears the matter is drawing some interest, people

are here.

MR VILJOEN: Yes, M'Lady.

COURT: Why was that not addressed in the practice note? Because the directions there is especially stated that:

> "Parties should inform the Court how many people are they expecting."

MR VILJOEN: M'Lady, we wasn't aware that so many people will pitch up and according to our client, there's media as well and he's asked us... the Court permission if they can record, M'Lady. But unfortunately we were focussing on the matter, we didn't know about the media attention or that there will be public attending, unfortunately. Otherwise we would have informed the Court.

COURT: How do we deal with the situation now? Because this is a very small court.

MR VILJOEN: M'Lady, we're willing to lead from the Court, M'Lady. If the Court wants the people to wait outside then it will actually suit us, because then we can focus on the matter. It's... M'Lady, it's in the hands of the Court.

COURT: Obviously, we cannot accommodate everyone.

MR VILJOEN: Of course, M'Lady. I agree. Maybe we'll ask that the... our client enters the court and ask the other people to wait outside, M'Lady. That's not an issue for us. We're here to focus on the matter, M'Lady.

COURT: Ja. Ironically this matter deals also with COVID

matters.

MR VILJOEN: Yes, M'Lady.

COURT: So, ja. Alright then counsel, we are ready now to hear your matter.

MR VILJOEN: M'Lady, what should I tell the... the public? The media?

COURT: No, they were supposed to ask for permission.

MR VILJOEN: Yes, M'Lady. We only found out now. So, I am making application from the bar if some members ...[intervenes]

COURT: For whom now?

MR VILJOEN: ... if the media can be allowed, M'Lady.

COURT: To... to sit?

MR VILJOEN: Yes.

COURT: Obviously, yes. No, but not to record.

MR VILJOEN: Thank you, M'Lady. I don't know now who is here from the media. I'm going to ask my attorney to ...[intervenes]

COURT: Okay, I cannot bar the media from coming.

MR VILJOEN: Yes, M'Lady.

COURT: The proceedings are not *in camera* ...[intervenes]

MR VILJOEN: M'Lady, then ...[intervenes]

COURT: ... but not recording.

MR VILJOEN: If we're then proceeding, my co-counsel will argue first. I'm, not aware where the respondents are. They

haven't communicated with us.

COURT: I'm not really surprised that they are not here. I'm really not surprised that they are not here.

MR VILJOEN: Thank you, M'Lady.

COURT: You can go and do some housekeeping outside.

MR VILJOEN: I'll ask my attorney to go so we can continue, M'Lady.

COURT: Thank you, thank you.

MS VICTOR: As you wish, M'Lady.

MR SIBANDA: Sorry, M'Lady. Advocate Sibande is my name.

COURT: Advocate?

MR SIBANDA: Sibanda.

COURT: Sibanda.

MR SIBANDA: Yes, Your Ladyship.

COURT: Let me just record your name on my side. Very hectic today. Counsel, you are also for the applicant?

MR SIBANDA: Yes, I am also for the applicant, Your Ladyship.

COURT: Alright.

MR SIBANDA: I am just wondering, Your Ladyship, as regards the people who are here with Mr Maarman, how many is the Court comfortable with sitting inside the courtroom?

COURT: There were indications, so we cannot accommodate everyone.

MR SIBANDA: Yes, this is... so that we know that they can

basically amongst themselves ...[intervenes]

COURT: Decide, indeed.

MR SIBANDA: ... decide as to who is coming in.

COURT: Indeed.

MR SIBANDA: What sort of number are we looking at here, M'Lady?

COURT: Check there Counsel, I don't know.

MR SIBANDA: Oh, the yellow spots.

COURT: Yes.

MR SIBANDA: So it is about 15, Your Ladyship.

COURT: Fifteen?

MR SIBANDA: Sorry?

COURT: Fifteen is too much.

MR SIBANDA: Fifteen is too much? How about ten?

COURT CLERK: It is between the demarcations.

COURT: Oh. So, can you count for us then, Mrs Cooper? So the yellow spots are demarcations?

COURT CLERK: Yes.

MR SIBANDA: Oh, okay. I thought the yellow spots is where they sit. I apologise, Your Ladyship.

MS VICTOR: M'Lady, as the Court the pleases. We'd like to ... there are five interested parties.

COURT: Perfect.

MS VICTOR: It is the ...[indistinct] media and then the rest, we have our expert here, we have the applicant, his wife and

Jerry Els which is also ...[intervenes]

COURT: Alright then, it should be fine then. It should be fine. Please sit at the demarcated area. Make sure. Thank you, counsel, you may proceed.

MR SIBANDA ADDRESSES COURT: Thank you very much, Your Ladyship.

COURT: But before you proceed, counsel, urgency. Urgency of this matter?

MR SIBANDA: Yes, Your Ladyship. Your Ladyship, this matter, as already stated by the applicant in his founding affidavit is a letter that comes before court on a basis of urgency.

COURT: Yes.

MR SIBANDA: The urgent element, Your Ladyship, being the fact that we are faced with a scenario whereby people 's liberties are at stake.

COURT: Alright.

MR SIBANDA: And being at stake on the basis of a virus that is supposed to be out there and ...[intervenes]

COURT: Okay. Hold on. Hold on, counsel, I've got a question for you. Unfortunately, the virus has been with us for a quite a while now, it started last year, isn't it?

MR SIBANDA: Your Ladyship, we have been told since last year that there is a virus.

COURT: We have been told.

MR SIBANDA: This is why the application is on the basis that the applicant is requesting for the respondents to produce the isolated virus.

COURT: Ja, ja.

MR SIBANDA: Because that aspect has never been conclusively established and it means, this is what raises the urgency, regardless of the time factor, Your Ladyship. The aspect that arises is that more and more measures are being cast. For example ...[intervenes]

COURT: Ja, the lockdowns.

MR SIBANDA: ... the lockdowns. We have heard from Government through the media that there is a third wave that is coming and that raises urgency, because necessarily as soon as Government arrives at the conclusion that there is a third wave, then they will start taking measures which are aimed, supposedly, at curtailing the adverse effects of that particular third wave. And this then necessitates an understanding as to the nature of a virus that can be predicted by man as to when exactly it will hit, because we are being given precise timelines.

COURT: Alright.

MR SIBANDA: So that becomes urgent in the sense that if government is afforded an opportunity, particularly the first respondent to address the nation and say we are putting in punitive measures to protect you from the third wave, then we

will be caught in a situation where we have to approach the Court again, seeking for a remedy in that particular regard ...[intervenes]

COURT: Okay.

MR SIBANDA: ... whereas that can be curtailed by an order, which simply says first respondent, second, third, fourth produce the virus.

COURT: You've made reference to the impending.

MR SIBANDA: I beg your pardon, Your Ladyship?

COURT: You are making reference to the third wave?

MR SIBANDA: Yes, I am Your Ladyship.

COURT: We had a second wave. There was mention of a second wave.

MR SIBANDA: There was mention, yes, Your Ladyship.

COURT: There was mention of a first wave.

MR SIBANDA: Yes, there was, Your Ladyship.

COURT: Now it appears that there are talks that we're going towards a third wave. And according to you, you say because of those talks, those references to the third wave, that creates urgency. Are you saying that, counsel?

MR SIBANDA: What we're saying, Your Ladyship, is according to paragraph 30 of the applicant's affidavit, amongst the aspects that establish urgency, is the serious violation of the citizens fundamental rights and that violation of itself becomes urgent in the sense that if the virus is not produced,

the respondents are going, according to them; we saw it's even given the Easter period where they introduce measures which took away the liberties of the nation.

COURT: Ja.

MR SIBANDA: And now when they declare that a third wave is coming, they are going again do the same thing. The history has basically confirmed how they behave.

COURT: Aren't you... you are being pre-emptive. You are... aren't you being pre-emptive now?

MR SIBANDA: Your Ladyship, the pre-emptive ...[intervenes]

COURT: And aren't you being speculative?

MR SIBANDA: It's not speculation, Your Ladyship, because we have already seen how exactly this scenario has played itself out. Your Ladyship made it clear that there was a first wave, there was a second wave. And we have seen what accompanies these waves in as far as the manner in which the respondents behave and in as far as the manner in which there is heavy-handedness against the fundamental rights of the citizens of the nation. Hence the stand that has been taken by the respondents to say we intend to protect the nation from this happening again in the absence of there being a virus.

But note the respondents is also saying Your Ladyship, if indeed this virus exist, then definitely we can take measures which are in keeping with the nature of the virus because we now have it.

COURT: Let's go to page 7 of the bundle, notice of motion. Page 7, paragraph 7. Can you read that aspect for record purposes, flowing from your submission?

MR SIBANDA:

> "That the respondents produce the isolated and purified physical SARS-CoV-2 virus, not a culture or any mixture within which the supposed virus is, nor a photograph or the underlying sequence only to the applicant at the place of their choice and under the security measures as preferred by the respondents."

COURT: Tell me if I'm correct, counsel?

MR SIBANDA: Yes, Your Ladyship.

COURT: That's the essence. That's the essence of the application.

MR SIBANDA: Absolutely, Your Ladyship.

COURT: Absolutely.

MR SIBANDA: The isolated virus to be produced.

COURT: Yes. Yes, that's the essence. It's not the essence of the application that they are impending perhaps lockdowns, impending restrictions, that's not really that.

MR SIBANDA: Your Ladyship ...[intervenes]

COURT: The backbone of this application is contained in paragraph 7 of page 7. Isn't it?

MR SIBANDA: In as far as the order that the applicant is

seeking ...[intervenes]

COURT: Yes, counsel?

MR SIBANDA: That is ...[intervenes]

COURT: The essence.

MR SIBANDA: ... the essence of the application.

COURT: Indeed.

MR SIBANDA: The affidavit of the applicant then goes to further give justification as to why it is necessary for this virus to be produced. Otherwise, who is to tell whether the measures that are being taken; whether the measures to be taken; whether the measures that have been taken are in keeping with the exact nature of the virus that we do not know? We are told, Your Ladyship, that it's a novel Coronavirus.

COURT: We've been told. We're told since last year, isn't it?

MR SIBANDA: Absolutely and this is the ...[intervenes]

COURT: We've been told since last year.

MR SIBANDA: This is the whole point, Your Ladyship.

COURT: Ja. Novel

MR SIBANDA: And we are told that it has variants and we are told that novel as it is, it has different waves. So, it... that is why it becomes necessary to identify this ...[intervenes]

COURT: Is it really urgent, counsellor? I'm sorry to sound like a broken record, but I'm stuck there. I can't move from that. Isn't this urgency self-created?

MR SIBANDA: No, it's not self-created, Your Ladyship. The unemployment of the people of this country is not self-created; the closure of businesses is not self-created; the death of people is not self-created.

COURT: No.

MR SIBANDA: The number of people, Your Ladyship, who are denied access to the hospital on the basis that wards are being reserved for Coronavirus patients, is not self-created.

COURT: And graves being dark.

MR SIBANDA: Graves being dark at the behest of the respondents and how many of those graves have been used, Your Ladyship?

COURT: But my question was not referring to that. My question was not referring to that. Is it correct that this is not the first time this matter has enrolled?

MR SIBANDA: It is correct, Your Ladyship.

COURT: It was last enrolled when? In March?

MR SIBANDA: It was in April, Your Ladyship.

COURT: Was it in April?

MR SIBANDA: 20 April, Your Ladyship, yes.

COURT: And then subsequent to that, what happened?

MR SIBANDA: Subsequent to that, Your Ladyship, the respondents did not meet the timelines which had been made an order of the Court. The respondents proceeded to request for indulgence from the applicant's attorneys, which indulgence

they were given and the primary reason why they are being this indulgence is because, Your Ladyship, this is a matter of State interest. This is a matter of national interest to every citizen of this country and even with having been given that particular indulgence, today they are not here. They filed their papers out of time, they don't apply for condonation and today they are not here. They have been informed, even this morning that ... reminded about this matter coming to court and still they are not here.

COURT: So in actual fact, it's for the third time the matter is on the roll, not the second time?

MR SIBANDA: It is the second time as far as I'm aware, Your Ladyship, which is the 20th and the 27th.

COURT: Can you help me, sir? Sorry.

MR SIBANDA: Thank you. Your Ladyship, my co-counsel informed me, I sincerely apologise. I was not aware of that particular date. But at that time the applicant had come before the Honourable Court in his personal capacity ...[intervenes]

COURT: Ja, it doesn't matter, it's still the same applicant.

MR SIBANDA: It's the same applicant.

COURT: Still the same applicant.

MR SIBANDA: I just say that particular aspect and Your Worship... Your Ladyship, I apologise, the mere fact that the applicant came before this Honourable Court on 8 March and now we're at the 27th of May, does not take away from the fact

that it's still an urgent application.

COURT: But counsel, people have already been vaccinated, lockdowns have already happened.

MR SIBANDA: Your Ladyship, if I may, with all due respect and humility correct that position. Some people have been vaccinated.

COURT: People. It doesn't matter ...[intervenes]

MR SIBANDA: And we ...[intervenes]

COURT: It doesn't matter, it's people.

MR SIBANDA: The important thing, Your Ladyship, is that those who have not been vaccinated still have a right to know about this virus, whereby it indeed exists or not ...[intervenes]

COURT: Counsel ...[intervenes]

MR SIBANDA: ... because they are being vaccinated against something that has not been proved. We are against something that the respondents are incapable of producing, because all that has to happen is for the respondents to simply say, here is the virus. That's the ...[intervenes]

COURT: Yes.

MR SIBANDA: ... end of the equation, My Ladyship.

COURT: Don't get me wrong.

MR SIBANDA: Yes, Your Ladyship.

COURT: I'm not dealing with the merits of the matter. I'm merely dealing with urgency.

MR SIBANDA: Absolutely, Your Ladyship.

COURT: As the applicant has got an onus to show that this matter warrants to be heard on urgent basis. Isn't it, counsel?

MR SIBANDA: Absolutely, Your Ladyship.

COURT: It's not a matter of making assertion that the matter is urgent, then it's going to be dealt with on urgent basis.

MR SIBANDA: Absolutely, Your Ladyship.

COURT: Yes. So don't misunderstand me, counsel. Any further submissions pertaining to urgency, counsel?

MR SIBANDA: Your Ladyship, the more critical aspect really as regards urgency, is that it is of national interest as a matter of urgency that people be freed from this fear that is daily instilled upon them. That people be allowed to think outside the media that on a daily basis will bring figures which necessarily end up with their psychological integrity being compromised, because they are now living in a state of fear; and, Your Ladyship, that is absolutely critical.

And Your Ladyship, further, the urgency is that the young children who are at school, who are being subjected to masking without any evidence of the efficacy of the mask in protecting them against this so-called virus against the... their rights to breath natural fresh air. That is urgent, Your Worship... Your Ladyship, I apologise; and it becomes absolutely critical that regardless of the period 8 March up to now, the protection of the nation of South Africa in as far as this lockdowns are concerned, be given serious attention.

COURT: So ...[intervenes]

MR SIBANDA: And there has been actually ... so we've actually produced evidence to the effect that this is costing the economy.

COURT: Essentially you are saying, counsel, there is inherent urgency in this matter.

MR SIBANDA: Absolutely, Your Ladyship.

COURT: Alright. One last question ...[intervenes]

MR VILJOEN ADDRESSES COURT: M'Lady, if I may address the court on one aspect on the urgency?

MR VILJOEN: M'Lady will notice from our annexures that this is not a self-created urgency, M'Lady. M'Lady will see since the lockdown has started, the applicant has engaged in emails with the State President, with the ministers, asking them to produce this virus, which they simply ignored. Then he brought an application in terms of the PAYA Act, which was ignored, M'Lady. And then out of desperation, he approached the Court himself. Unfortunately, that shows the urgency and that he wasn't creating this urgency. He was simply a layman trying to find his way in the legal and the political system to have his voice heard, M'Lady.

So there was no delay or self-created urgency, M'Lady. The urgency here was created by the respondents not reacting to his enquiry and all he's asking is show us the virus, M'Lady. And the urgency is that there is no end in sight to this

lockdown and there's simply talk that it's going to continue and it's seriously damaging the entire nation's economy and people's health by wearing masks and people getting vaccinated and reports of people dying afterwards, M'Lady. So it needs to be addressed urgently. Thank you, M'Lady.

COURT: So socially, before you sit counsellor, before you sit. Essentially, what you are saying, the WHO does not have any credibility as far as the applicant is concerned?

MR VILJOEN: M'Lady, we're not asking the Court or making ...[intervenes]

COURT: No.

MR VILJOEN: ... any submissions on that.

COURT: No, I'm asking. No, I'm asking.

MR VILJOEN: M'Lady ...[intervenes]

COURT: I'm asking because the WHO and which we happen to be part of, isn't it?

MR VILJOEN: Yes, M'Lady.

COURT: Yes, said there is a virus.

MR VILJOEN: They said so, M'Lady.

COURT: Please ...[intervenes]

MR VILJOEN: And, M'Lady, there's a saying ... I can't... I'm not allowed to swear in court but it says, assumption is the mother of all f-ups, M'Lady, and that's what we're all doing here. We can't go on assumption because somebody told us. We need to have the evidence produced and it's part of our

legal system, M'Lady.

COURT: Okay.

MR VILJOEN: If you allege you must show.

COURT: What about the powers of the executive to govern the country?

MR VILJOEN: M'Lady, we're also not asking for that. And it's a simple fact, the next step is to actually determine whether this virus really exist. From there, M'Lady, other court cases may follow, but for this specific one, we've got a right to information, M'Lady. The Government says this virus exist; we're asking them show us. That's all, M'Lady.

COURT: Can't this issue be adjudicated in the normal way?

MR VILJOEN: It can't, M'Lady. We've tried and it's too urgent, M'Lady, and if we go in the normal way, when will we get onto the post draw? How many people will still die from the vaccinations? How many children will become asthmatic because of the mask, M'Lady? It's very urgent. M'Lady, we're not asking the Court to make a finding on anything. We're simply asking the Court to instruct the respondents to follow the rule of law by producing something they say they have and we have that right to access the information.

COURT: Thank you, counsel.

MR VILJOEN: And from there, other cases might follow with determination on scientific facts etcetera, M'Lady.

COURT: Thank you, counsel.

MR VILJOEN: Thank you, M'Lady.

COURT: Anything further, counsel?

MR SIBANDA: Your Ladyship, you asked the question as regards the applicant's attitude towards the World Health Organisation. Your Ladyship, one of the reasons why the applicant is before the Honourable Court is founded on the fact that the World Health Organisation, for one, changed the definition of pandemic to enable a situation like what we have right now. And at the same time, the World Health Organisation, according to its own website, has conceded the fact that the PCR test, which is supposed to be the test establishing the existence of COVID-19, is actually giving false positives. It's there on their website.

The Centre for Disease Control in the United States has confirmed the position of the World Health Organisation. That is why the applicant has found it necessary to come before the Honourable Court and say, if this is what the World Health Organisation is saying, an organisation that we trusted and believed in and thought is looking after our best interest, but they are the one saying this test is not accurate, then there must be something wrong. If the CDC is also supporting that position, then there must be something wrong. Hence, the applicant saying hold on, maybe our Government can assist us here and show us this virus that is leading to these policies. And further, Your Ladyship, the World Health Organisation is

the same entity that tells the world that no autopsies must be done when it comes to death supposedly related to COVID. How then do we know that this is the virus causing this thing called COVID-19 deaths if no autopsies are being done?

Because it is trite, Your Ladyship, that one of the co-fundamentals behind an autopsy is to establish the cause of death. Hence, the reason why the doctors in Italy decided to define the World Health Organisation and came instead with thrombosis according to their autopsies. Hence, the reason why the applicant is saying there must be something out there that is killing our people and we need to find out what it is. If it's this SARS-CoV-2 virus, let's see it, so that we can help each other to be able to respond as to how exactly we protect ourselves as a nation. Because we are caught in a situation where literally on a daily basis, Your Ladyship, people are being compromised left, right and centre and, Your Ladyship, amongst the issues that has concerned the applicant, is the research that shows the dangers of sanitisers. And we are caught literally, Your Ladyship, in a scenario whereby at national level, at international level, at World Health Organisation level, no one has basically been able to say this is the virus.

And, Your Ladyship, Your Ladyship mentioned the issue of the vaccine. One of the reasons why the applicant has found it necessary, Your Ladyship, is because none of these

vaccines are premised on an attenuated natural virus. Some of these so-called vaccines, Your Ladyship, are actually premised upon genetically modified organisms. They got aborted foetal cells in them, Your Ladyship, and it goes against the ethics of some people, it goes against the religious beliefs of some people in this country and the respondents are not coming clean to the nation to say these are the issues. And further, we've seen it in the media, Your Ladyship, where one of the unions representing the health workers, is saying they are being gagged in as far as reporting the adverse effects. Hence, the reason why the respondents finds it necessary to come before the Honourable Court and say this is our last port of call, this is our last hope as a nation.

COURT: Sorry, sorry to do it to you counsellor. It has been brought to my attention that the respondent has finally graced us with their presence.

RESPONDENTS' ATTORNEY: Morning Judge.

COURT: Good morning, sir.

RESPONDENTS' ATTORNEY: Sorry to interrupt the proceedings.

COURT: Yes, the bus is already in motion.

RESPONDENTS' ATTORNEY: My apologies, judge. I am representing the first to the fourth respondents in this matter. I've been communicating with my colleague for the applicant and we are under the impression that he would advise us when

the matter would be heard. We ... I'm quite surprised that our matter is proceeding, that he didn't revert to us to tell us that our matter is proceeding, because he have indicated in the morning that the matter was not on the court roll. He is taking the file to bring it to you, judge.

COURT: Perhaps it's something which you should canvass between yourselves. I was not privy to that. I was only informed that they do not know where you are. As I said, the horses have already boarded and not that you cannot join us, if you wish, we are busy with the aspect of urgency. I asked the parties to address the Court on urgency.

RESPONDENTS' ATTORNEY: Thanks judge. The counsel who is assisting us in respect of Advocate Tsegari, he is on standby. He is also waiting to be alerted by my colleague.

COURT: How ...[intervenes]

RESPONDENTS' ATTORNEY: So if the matter may stand down, judge, so that I can contact him to rush to court.

COURT: Counsel, I am on urgent duties. There is another counsel waiting for me. I would like to hear the respondents. I would like to hear the respondents and I cannot really shut the door at the respondents, but I don't have the luxury of time. I've got a stack of files waiting for me for tomorrow, which I need to read. I'm not really amenable to adjourning. I'm not sure. I'm really between the rock and the hard place. Counsel, what do you say?

MR VILJOEN: M'Lady, the matter was a court order to be at court today. M'Lady, I met my colleague at the steps this morning and I said to them the matter is not on roll; I'll find the file and I'll put it before the judge and we'll be waiting in court. M'Lady, I can't run the case for them. If they decided that they'll be on standby until whenever they feel it's convenient, M'Lady, there's rules of court. The matter has been set down today and if they decide it's not convenient to wait in court until the matter is being heard, M'Lady, and the matter has already started as the Court said, M'Lady. And there's no good grounds for them to come in now, M'Lady, and for us to delay the entire process. This is an urgent matter, M'Lady, and it's clear that the State is just playing games in their response.

COURT: I ...[indistinct]

MR VILJOEN: Ja.

COURT: You don't know whether they would concede to urgency. But even if they concede to urgency, if I'm not convinced that that concession is correctly made and I may overrule that concession.

MR VILJOEN: Exactly, we don't know, M'Lady, but we'll object for the Court to bring them in at this late stage, M'Lady. There's rules of court and there's procedure and we can't just come to court whenever we feel it's convenient, M'Lady. Thank you, M'Lady.

COURT: I'll... no, I'll give you an opportunity now, counsel.

Yes, counsel?

MR SIBANDA: Your Ladyship ...[intervenes]

COURT: Are you still continuing?

MR SIBANDA: Yes, I'm continuing on that.

COURT: Now there's something which is interjecting now. Let's deal with that issue first.

MR SIBANDA: No, it's the issue of their being in court ...[intervenes]

COURT: Oh alright.

MR SIBANDA: ... in the first place, Your Worship.

COURT: Alright. Alright.

MR SIBANDA: Your Ladyship, it is my humble opinion that before the Court can basically determine the issue as regards at which point they get into the proceedings, the critical question to be answered is who are they in as far as this proceedings are concerned? Necessarily meaning from the papers that they can file regardless of the extensions given and agreed upon, they were still out of time and did not apply for condonation. That is the first part.

Secondly, Your Ladyship, according to the papers that they have been submitted, there are four respondents. There is no answering affidavit for the first respondent, no answering affidavit for the second respondent, the third respondent is represented by the person who has taken over, Mr Ndizana, who has taken over and all he has filed is an explanatory

affidavit explaining his stepping into the shoes of Mr Karim.

COURT: Alright.

MR SIBANDA: And the fourth respondent is represented by one Professor Poolen, who according to him, says in paragraph 5 of their papers:

> "I serve as the technical manager for quality assurances."

And proceeds to say he is duly authorised to depose to the affidavit, not necessarily saying, Your Ladyship, that he is duly authorised to represent the fourth respondent. And there is nothing that has been submitted to confirm this assertion on his part. No documentation to say that this quality assurance manager has the authority to come and stand in court and ...[intervenes]

COURT: No, I heard you, counsellor.

MR SIBANDA: Thank you, Your Ladyship.

COURT: From the matter you are saying you don't have a problem if this court disposes of this issue of the respondents?

MR SIBANDA: Absolutely, Your Ladyship.

COURT: And after all, the onus is upon the applicant to convince this court that there is urgency.

MR SIBANDA: I appreciate that as per Your Ladyship.

COURT: That the Court *mero moto* raise the issue of urgency. So you say you're happy if we can proceed without the respondents if this matter of urgency can be addressed without

the respondents?

MR SIBANDA: Yes, that we are saying, Your Ladyship. But however, which way the Court decides on the issue, there's no problem.

COURT: Alright.

MR SIBANDA: But the most fundamental aspect is that we are not at this stage going to condone the respondents ...[intervenes]

COURT: It's the Court's duty ...[intervenes]

MR SIBANDA: ... coming ...[intervenes]

COURT: ... to ...[intervenes]

MR SIBANDA: No, that's what I'm saying, M'Lady, they have not applied for condonation. So we are not amenable to suggesting that of our own we will open the door and say they should come in ...[intervenes]

COURT: Alright.

MR SIBANDA: ... and participate in the proceedings.

COURT: You've made your point, counsel. You made... otherwise we're going to be here for the entire day. Thank you.

MR SIBANDA: Thank you, M'Lady.

COURT: You may be seated, counsel. Counsel, we are in not even in the middle. We're at the end of the urgency aspect. You may sit down counsel, and listen, alright. It's too late now. It seems as if you've got reservations.

RESPONDENTS' ATTORNEY: Judge, may I just draw this to your attention the conversations I referred to earlier were actually ... not only when we met with Advocate... counsel in the morning. However, we also communicated over the phone where he indicated that if there's any progress in the matter, he would revert to me and advise me accordingly.

COURT: So ...[intervenes]

RESPONDENTS' ATTORNEY: So now the matter proceeding without my colleague reverting to me to alert me to that ...[intervenes]

COURT: Ja.

RESPONDENTS' ATTORNEY: ... is like misleading in a sense, because he had indicated that he would revert to us. The recordings are in the phone, M'Lady, and M'Lady, the advocate who assisted us in preparing the opposing papers, is not present. It would serve ...[intervenes]

COURT: Where is the advocate?

RESPONDENTS' ATTORNEY: In chambers. In chambers.

COURT: Here?

MR TSEGARI: That's correct.

COURT: Around.

RESPONDENTS' ATTORNEY: Around here. In Keerom... Keerom 60 something. I'm not sure. I think it will take him about 10 minutes to come here. I'll just call him now.

COURT: It's going to be lunchtime now. It's important... not

that I'm going to condone, I'll love to hear from the counsel why should this Court hear him or her on this aspect of urgency which we've... we were almost done with it. Right, on that aspect.

RESPONDENTS' ATTORNEY: [Indistinct]

COURT: So now, it's 4 minutes to 1. We might as well take our lunch break. We are going to come back at quarter past 2. Right? Quarter past 2.

RESPONDENTS' ATTORNEY: That would be sufficient.

COURT: Thank you.

MR SIBANDA: I am indebted to Your Ladyship.

COURT: Court then adjourns.

COURT ADJOURNS [12:58]

COURT RESUMES [14:20]

COURT: Why are you standing, counsel?

MR VILJOEN: M'Lady? I had a good think about the allegations by the State, M'Lady, and I realised that I didn't know when the matter is going to be called because the ... M'Lady said we'll be heard and I... but later in the day and I relayed that message. And then we waited outside, M'Lady. We didn't know whether we're going to be called and when. So, it's not that I deliberately not informed my colleagues that we've been called, M'Lady.

COURT: No. If you were in contact with them, perhaps you

could have said let's wait, let me get into contact.

MR VILJOEN: Yes, M'Lady, I could have done that, yes. Thank you, M'Lady.

COURT: Yes, counsel?

MR TSEGARI: M'Lady ...[intervenes]

COURT: But counsel how can you rely on the other party?

MR TSEGARI: M'Lady, that is the most difficult part which I had to deal with. If I may... if you receive this ...[intervenes]

COURT: No.

MR TSEGARI: (Playing call recording.)

COURT: It is not necessary, counsel. It's not necessary to do that.

MR TSEGARI: I don't have to do that? But the problem is, M'Lady, if you have collegiality amongst colleagues and you know that the matter is opposed and you know that you have told your colleague when the matter will be called, you do not call your colleague to say that you will deal with the matter, but you went ahead anyway. I do not know what inference one can draw from that. And that is the disappointing part is that, you know, it's not a situation that we say that we try to ambush each other. It's just, I think it's collegial to notify your colleague that the matter is about to be called. Have you... can you be here in two minutes. I'm two minutes away.

The only thing which I hear is my learned... and my attorney comes gasping to me to say that we're in trouble, that

the matter has already been heard and the persons have addressed the Court. So what do you do in a situation like that? So I'm here and the respondents was always ready to deal with the matter.

And what makes it worse, M'Lady, is the fact that this morning we received what is referred to a practice note, argument to be postponed on 27 May 2021, which I'm not sure it's part of your bundle. But those are the communications which up until this morning before the matter has actually even gone into court and before that message came, that was the information which was conveyed to us.

So we have no reason to believe that the matter will continue in our absence. That is the problematic part, M'Lady. But I'm here now and I would like to address you on... if I may ...[intervenes]

COURT: Ja.

MR TSEGARI: ... when I have my opportunity to address you on the respondents' position in this matter.

COURT: Are you aware where are we?

MR TSEGARI: I have no idea where we are, because I... I miss ... I'm not even sure how long my learned friend was on his feet to address you, what he have covered.

COURT: We were about to finish their arguments pertaining to urgency because the Court requested them to address the Court regarding urgency.

MR TSEGARI: Yes. Are they finished with that?

COURT: Not yet.

MR TSEGARI: Okay.

COURT: I'm sure they're about to finish. So we'll take it from there.

MR TSEGARI: We can take it from there. I'll... ja, I'll assess the... sorry, I'll assess the argument as I go along.

COURT: Yes, counsel?

MR SIBANDA: Thank you, Your Ladyship. Your Ladyship, we maintain basically in summing up that indeed this matter is urgent. And the aspect of urgency has to be viewed from basically a perspective that speaks to each own situation in the sense that in this particular instance, we are dealing with a continuous process which basically has the potential to compromise much more than have already been compromised.

COURT: Yes. As you said earlier on, counsel, that you're relying on inherent urgency.

MR SIBANDA: Absolutely. If I could just draw another to Your Ladyship, a scenario where someone is assaulted, bashed to the ground, that for all intends and purposes would be classified as a crime. If that person is on fire and you bashed him and rolled him on the ground to switch out a fire, you are actually saving their lives, because there is a fire.

COURT: Ja. But is it an appropriate analogy under the circumstances of this matter?

MR SIBANDA: It is very appropriate, Your Ladyship. In the sense that if you vaccinate someone or you lock down or you pass different protocols, supposedly to save lives and there's nothing there, then it's an assault against that particular individual, but if it's done and there is actually something, then you are protecting them, which is why the applicant is then simply saying just to produce this item, so that even for those people within the nation who might be called anti-vaxxers or called sceptics or whatever, they themselves will also take an informed position and say, yes, this thing does exist and for that particular reason, I must also be part of the process that saves the entire nation.

COURT: Isn't the ... I said earlier on, we should try not to delve into the merits of this matter.

MR SIBANDA: Absolutely.

COURT: But now that you are addressing that, isn't there scientific proof to that effect, scientists?

MR SIBANDA: That is what we are asking the respondents to show us; the scientific proof that there is a virus called themselves COV-2. That is the science that we are asking for, Your Ladyship and that is the urgency.

COURT: Thank you.

MR SIBANDA: Thank you.

COURT: Counsel, I do understand that you are handicapped. Do you need to address the Court pertaining to urgency?

MR TSEGARI: M'Lady, let me try my best. I will address you.

MR SIBANDA: M'Lady ...[intervenes]

COURT: Stop, stop, stop.

MR SIBANDA: Can I just repeat it? Your Ladyship, before we broke for lunch, we had raised an issue about the right of the respondents to be heard. Has Your Ladyship made a ruling on that for the respondents to address the Court?

COURT: Meaning they are not supposed to address the Court based on late filing of the documents?

MR SIBANDA: Meaning, Your Ladyship, that on one aspect there's the issue of late filing.

COURT: Yes.

MR SIBANDA: On another aspect there is the issue of who exactly is before the Honourable Court in the sense that the first respondent, there are no papers for the first respondent. Second respondent, there are no papers for the second respondent. The third respondent simply files an explanatory affidavit and then the fourth respondent is represented by one referred to as a technical quality assurance manager without any authority ...[intervenes]

COURT: Okay. Counsel, aren't you defeating your own argument?

MR TSEGARI: Yes.

COURT: Because you are asserting that this is an urgent application.

MR SIBANDA: Yes, Your Ladyship.

COURT: And consequent to that, the rules of the Court should not be adhered to.

MR TSEGARI: Yes.

MR SIBANDA: Absolutely.

COURT: Now you say the Court should penalise them because of a, b, c. Yet, on the same breath you say this is an urgent application where normally the rules of the Court are not adhered to.

MR SIBANDA: This is why, Your Ladyship, when I rose I asked the Honourable Court to confirm if a ruling has been made on that particular aspect.

COURT: Remember when you are ... when you made those assertions there was no one from the side of the respondents, whether it's for the first respondent, second respondent or whatever. You said those assertions in their absence. Perhaps you should repeat them so that they can hear you, so that they can answer to that.

MR SIBANDA: The instructing attorney was present, but for the sake of the counsel, I will repeat. But it's basically what I've already said now, that the issues, even the affidavit deposed to by Professor Purinis very clear, that he says:

> "I am accordingly duly authorised to depose to this affidavit on behalf of the fourth respondent."

There is no affidavit that has been submitted to say it's on

behalf of the first respondent. Nothing to say on behalf of the second respondent.

There's another affidavit from one Mr Buthelezi who says he is also deposing to an affidavit on authority for the fourth respondent. And then there is an affidavit from Mr Ndizana who says he is deposing to an affidavit for the third respondent, purely on an explanatory aspect, not for purposes of being heard, because all that the respondents says in this affidavit, in the interest of simplicity, the first, second and fourth respondents are referred to here by their abbreviated title. It doesn't say that he is now also representing them. He is purely confined to the fourth respondent. So there is the aspect of condonation which they have not applied for regardless of the agreed timelines they still file their papers out of time.

COURT: Yes.

MR SIBANDA: Yes, they will argue that they sent an email, but that particular email was only sent at 20 to 5 in the afternoon or thereabouts, but the papers were actually filed the following day. So on that ...[intervenes]

COURT: But did they cause ... are they dealing with urgency?

MR SIBANDA: I beg your pardon, Your Ladyship?

COURT: Are they dealing with urgency?

MR SIBANDA: Yes, their papers are dealing with the... their filing notice, everything. It was emailed and yes they raised

some point *in limine*.

COURT: No, no, counsel. No, no, we are not on the same page. Are the papers dealing with urgency? We are currently dealing with urgency.

MR SIBANDA: Yes, their papers do deal with the aspect of urgency. Their points *in limine*, their first point *in limine* actually talks to the aspect of urgency.

COURT: Alright. I think you said enough, counsel. Thank you very much. Thank you, counsel?

MR TSEGARI ADDRESSES COURT: M'Lady, as it may please you. May I apologise for the fact that I could not introduce myself. M'Lady, Cecil Tsegari, I'm a member of the Cape Bar and may I, with your leave, hand up these – these documents?

COURT: Which documents are those, counsel?

MR TSEGARI: This is a, what we would be referred to as service document and a note and the heads of argument by the respondents.

COURT: In doing so, you intend to reply to the latter part of the submissions?

MR TSEGARI: It will... my reply is contained in, amongst others, the note which is annexed to the heads of argument. But before I do that, M'Lady, may I just say, for purposes of my address, I would like to follow the full instruction.

The first thing I would like to address you on the procedural steps taken by the applicants thus far and

thereafter I would like to address you on the first point *in limine*, which the respondents contend is dispositive of the matter.

And the second point is the issue relating to the question of urgency and whether a case has been made out. Remember, the urgency or the interdict which is sought here, is seek against the executive or the organ of state. There is different requirements which apply and I would take to the notice of motion where the relief is set out in the applicant's papers.

And the third point I would like... I would take you which is connected to the second point, is the issue relating to whether a *prima facie* grounds has been set out for the relief sought. And then I'll deal, obviously, if necessary, with the other points. But because ...[intervenes]

COURT: No, counsel, you are moving very fast.

MR TSEGARI: Ja.

COURT: We are still at the stage of urgency before we get to any other thing.

MR TSEGARI: M'Lady, I would be, amidst as an Officer of the Court to not tell you the sequence, since my learned friend has referred to the alleged lateness of the filing of the papers, I would have to deal with those aspects. And we've done so by way of an affidavit, the affidavit of Mr Mgabene.

COURT: Unfortunately, the record is not ...[intervenes]

MR TSEGARI: It is a stapled document which I've just handed up to you now, M'Lady.

COURT: Alright. Amongst these. Alright.

MR TSEGARI: The Court will see that ... may I interrupt myself before I address you on that point?

There is an assertion made without justification that there is no affidavits or the respondents are not properly before you. M'Lady, if you have proper regard to the second paragraph, the relief in prayer 2 of the applicant's notice of motion, you would note that what they're seeking there is in essence issues which relates... of which... issues of a scientific matter.

As far as you know and it's public knowledge that the President is not a scientist and that within the Government there are organisations or institutions who deals with these particular aspects. So, it's appropriate that we don't place hearsay evidence before the Court, but we place the information before the Court with the persons who can properly respond thereto. But I will in the process of my address deal with that particular aspect. You'll see this is where they ask for, they say that:

> "The respondents must produce the isolated and purified physical SARS-COVID 2 virus."

They don't want a photograph. They don't want any mixtures. They don't want sequencing, RNA sequencing.

> "To the applicant at the place and in terms of the security measures of choice within 7 days."

That's the relief which they seek. And then turning back, they ask then for the urgent relief.

I'll address you properly on the issue of urgency. May I then return to this... the procedural steps which then transpired subsequent. On the 18th in paragraph 3.1; on the 18th there was an email correspondence which is referred to in their affidavit as MM1, which was correspondence between the attorney and Mr Viljoen or Advocate Viljoen, dealing with the indulgence, a request for filing the papers at – at a later stage.

You'll see, if you refer, return to MM2. MM2 is a response coming back from Mr Viljoen or from Carlo & Victor Attorneys saying that, he say:

> "Dear Mr Mlungisi,
>
> Thank you for the update. We will grant you until next week Tuesday, which is the 25th. Please keep in mind that we will still need to reply and both parties need to submit heads of argument."

Now, if you look at ... there was an email then sent subsequently, MM3, where the answering affidavits and the annexures and the confirmatory affidavits was then forwarded by email and I must also state that the parties have agreed they can serve by way of electronic means, i.e. sending of an email and that's precisely what the attorney has done in

relation to MM3.

And then if you take it to MM4, basically deals with the same thing. But then if you go to MM6 where Attorney Victor came back and say that:

> "Dear sirs,
>
> We received it."

With reference to the documentation which was sent to them. So, what my learned friend, I hope, was also ... was supposed to be before you, was then on the 25th or the 21st, the applicant was serving, what is referred to, a notice of bar. And in the notice of bar, and I'll address whether or not that is proper; in the notice of bar they say, on their own notice, they say that:

> "You are called upon to delivery your answering affidavit to the applicant before 12 o'clock on the 25th."

Again, with reference to the date of the 25th.

> "And within one day of service of this notice you will file it, which the respondents will then be *ipso fictio* barred."

In other words, they would be barred if they do not do so. If you have a look at that notice, you will see that it's dated the 21st of May 2021, which was last Friday. If you take a literal reading of the notice, it means in essence that the respondents was supposed to comply on the Saturday, which is not a court

day. But if you take a more generous approach and you say that their five days, which was supposed to be, and they with reference they referred to Rule 26. And Rule 26 makes it very clear. It says that the party is supposed to, if you put... if you request a party to deliver further pleadings, that must be done in a period of five days. But if you take the court days, it then will be from the Monday up to the 5th – the five days will at least run out on the 28th of this month.

But be that as it may, the respondents submit that there is no procedure and I could not find any law that you can in motion proceedings use a notice of bar. Notice proceedings accurately belongs in action proceedings. What, if the applicants have failed to do, is that they have omitted to utilise a process which is set out in practice note. And I refer to that more fully in the note which I have also attached to you at paragraph 8.

So on the face of their own notice of bar that how, request for complying with for filing the papers is premature. But be that as it may, we then find that in motion proceedings a party can use a chamber book application and that chamber book application practice directive 37-19 provides that you can apply in chambers compelling the respondents to comply, failing which you can then set the matter down on the unopposed motion, on an unopposed basis. That is the procedure which is open to you. They have not done so.

It's a flagrant disregard for not only the rules, but also for the practice directive. Now may I turn against that background, we then say that there is no basis to say factually or otherwise that the respondents were either out of time or that their papers were not properly before you. You sit with a notice of intention to ... a notice to oppose. You receive the papers, you've never rejected it on the 25th when you received it. On the 26th you also receive the court issued papers.

Now, on that score, now let me take ... and on that basis we say there's no basis to say that we... that the respondents are not properly before you. They are parties to these proceedings and they are properly... they've properly complied with the requirements which is set out in the rules. And the Court must, as a matter of law and in terms of the rules, ignore that notice of bar, because the notice of bar is incompetent for the proceedings which the applicant seeks to enforce.

Now may I then turn to the issue which you say we should lastly address you. And the reason why I would like to take a slight detour from this process is for the following reasons. And then may I take you to the respondent's heads of argument. Again may I interrupt myself, is that, in terms of that arrangements or the agreement between the parties, the parties were supposed to submit their heads of argument by Wednesday, which was yesterday. We still await the respondents' heads of argument, nothing has forthcoming and

the respondents receive the ... the applicants received the respondents heads of argument yesterday, which was sent to them via email.

Now, may I then turn to page 4 of my heads of argument? M'Lady, may I request that you keep your finger on and just turn to the notice of motion, paragraph 2. Paragraph 2, as I read earlier on, there is... the applicants are seeking that:

> "The respondents must produce the isolated and purified physical Sars-Covid-2 virus to them within 7 days."

Now, as any democratic country would have done it, is that there are regulations and procedures which regulate issues relating to such sensitive matters.

So, I would like the Court to view the first point *in limine* against paragraph 2 that the respondents contend that there is non-compliance with the Health Act of 2003, the regulations with reference to paragraph 2. And they say, and specifically and I have taken the liberty in attaching the regulations to my heads of argument. You'll find at the very end. There is, what is referred to and I'm not going to deal with the definitions. But may I take you to paragraph 15, then?

COURT: Paragraph?

MR TSEGARI: Paragraph 15 on page 6 of the heads of argument. Paragraph 15 say that:

"Section 3 of the NHI Regulations 203 provides as follows"

They say:

"No person shall acquire, receive in court human pathogens or handle, manipulate, maintain, store, culture or in any way process issue or in any way dispose of any human pathogens or so acquired receive imported, unless..."

There's the qualification.

"... the person is registered with the Department as a..."

Page 7.

"... a microbiological laboratory, in terms of Regulation 6(1)(a)(ii)."

MR VILJOEN: M'Lady, I feel ...[intervenes]

COURT: You may sit, counsel. Counsel, you may sit, I want to hear your colleague.

MR VILJOEN: I feel ...[intervenes]

COURT: Counsel, you may sit. Yes?

MR VILJOEN: I feel obliged to object to this line of arguing. There's no relevance towards the urgency that the Court asked my learned counsel to address the Court, M'Lady. I don't know when... if we're going to get there, but ...[intervenes]

COURT: Ja, you are a bit premature. Let's hear him out.

MR VILJOEN: Thank you, M'Lady.

COURT: Yes. May you proceed, counsel?

MR TSEGARI: M'Lady, the relevance is self-explanatory. If your... if the Court were to... amenable to even consider the relief which they seek on an urgent basis, then the Court will have to deal with the regulation, Regulation 3. And you'll see in ... the applicant, Mr Maarman, is not a scientist or arranges the person as required by the regulations. For that reason we say they're not even getting out of the starting blocks with their application and the Court must have regard to the regulations.

And that regulations has been set out in paragraph 15 and 16 where it's clearly stated that if you... if you turn the page, M'Lady, at paragraph 17.1. That facts are, which are stated in there is common cause and at paragraph 17.2, it is clear that the founding affidavit contains no possible other averment which indicates or to show that he was registered as required by the regulations. In any event, there's no permit to substantiate that. The short point is this, M'Lady, is that for the Court to comply with the question of legality and for the Court to provide the relief which they seek, the Court cannot ignore the requirements of the regulation. The Court must have regard to that, even before ...[indistinct].

But let's then deal with the second leg, which I will deal at paragraph... at page 9, which is the second point *in limine* and the question which my learned friend would like to urge me

to, to get to. The question there was is whether a case of urgency has been made out in the affidavit. Now the respondent say:

> "It is trite that in accordance with the uniform rules and case law, the applicant must make out a case for urgency in his founding affidavit."

That is trite. Then the above ...[intervenes]

COURT: Sorry, counsellor, to interject.

MR TSEGARI: Yes?

COURT: Before you move on, are you done now with the aspect of whether you are properly before the Court? Are you done with that aspect?

MR TSEGARI: I didn't hear the last part?

COURT: Are you done with the aspect that you are properly ... if ... whether you are properly before the Court?

MR TSEGARI: The respondents are properly before the Court, M'Lady.

COURT: Alright.

MR TSEGARI: And I'll say... and perhaps if the question which M'Lady would like to address with regards to urgency, I would be compelled to go into... to the merits of the matter. And I'm not sure whether the Court would like me to address you on the merits of the matter ...[intervenes]

COURT: Not.

MR TSEGARI: ... as to why that is the case.

COURT: Not.

MR TSEGARI: And the Court would know that the affidavits constitute the evidence which is before the Court. We cannot place hearsay evidence before the Court. We will have to place ... and the reason why the affidavits were structured in this manner, the Court will know that there are certain individuals which are implicated. For example, Dr Tau was implicated in his capacity as the head of the centre. There's no... and as the head of the centre, he then give an explanation of the supporting affidavit setting out his position.

Now, it would be amiss to say that if we would like to ask the first respondent where there's no allegations which directly or indirectly implicate the first respondent in the affidavit, that we ask the first respondent to deal with questions of science, for example. So for that reason, if the Court will have regard to ... before I deal with that issue, if the Court will have regard to the affidavit by Professor Purin, right?

COURT: Is it contained in your bundle?

MR TSEGARI: It's in the... it's part of the answering affidavit, M'Lady. The answering papers were filed, but if... it was filed ...[intervenes]

COURT: Professor? Professor?

MR TSEGARI: Professor Purin. He sets out a comprehensive part in paragraph 2 where he say that:

"The NICD..."

Which were reference to the National Institute of Communicable Diseases, which is referred to here in his abbreviated form or title.

"... is a National Public Health Institute of South Africa providing reference to microbiology, virology and epidemiology and it provides a surveillance in public health research in support to the South African government."

So here he's not ... we're dealing with the institution which actually deals with the matter which were are called upon to answer.

COURT: In this affidavit?

MR TSEGARI: In this affidavit. Ja, in this affidavit we are called upon to say produce these isolated purified. But the best person who can give not hearsay evidence, who is in fact dealing with this particular subject matter, not only as a profession, but on a daily basis, he is best placed to give that evidence. And for that reason he is the person who is supposed to give a... the answering affidavit and answer the allegations which are made, which relate to the scientific matter.

So therefore it is ... it's not a question, there's no question of *locus standi*. It is plain that the persons have made out a case for that. And he also attach the minimum

requirements and macro requirements for dealing with that.

But if we turn... if ... the following paragraph will then be obviously the affidavit of Dr Tau. Now, if the Court will have regard to page 3, paragraph 8, 9 and 10 and even if we go to the first part of his affidavit where he say:

> "I'm the Head of the National Disaster Management Centre."

And why he say that, is that the Court will see there are certain paragraphs in the founding affidavit which implicate him or refer to him in his official capacity. So we cannot ask Dr Purin or Professor Purin or anyone else to deal with those matters other than that. We cannot ask the minister to say why are you not dealing with this if there is a head appointed? And this person is directly implicated.

The second respondent as a minister or an executive in an official capacity is not implicated. So while we have information or an affidavit before the Court which does not ... which will related in essence to hearsay evidence. So this is, because it is trite that the affidavit constitute the evidence which is before the Court. And they form the evidence which is supposed to be led. So the person who is with personal knowledge, is the person who is supposed to depose to the affidavit. And reference is also made to Professor Salim Abdool Karim on behalf of the Governmental Covid-19 Advisory Committee.

Now, there is an explanatory affidavit which deals with the fact that the Professor has resigned from this. So the co-chair is setting out the position and she deals with the particular aspects which are being set out or required. No express implication is made against Professor Abdul Karim in his capacity at the time, that he must give evidence by way of affidavit. He is just cited in the same way that the President is just cited. They're just cited as parties, but no specific relief is sought against them.

It is on that basis, M'Lady, that if you make allegations in your founding affidavit and you implicate certain persons in that affidavit, the persons who are appropriately in possession of the knowledge or access to that, those are the people who's supposed to give evidence by way of an affidavit. To that extent, M'Lady, it is submitted that there is no merit in the submission to say that the respondents are not properly before you. The respondents are before you.

In any event, there is no affidavit... replying affidavit to counter that. To say, well, you don't have to give, other than submissions from the bar, to say that, that to take that particular point. So there's no evidence before you as matter of law.

So may I then, and that is the point, M'Lady, the point is that the respondents are properly before you and they answered the allegations which are raised against those

particular respondents.

COURT: And the affidavits are properly before the Court?

MR TSEGARI: The affidavits are properly before the Court as I've explained and I've set out in that service affidavit that you can't say the order in the first place was taken by agreement. The parties have an agreement, you can file your papers by a certain date. You then file your papers by a certain date and now the parties are ... the agreement ... you're not permitted to do that. There's nothing in the email, MM2 from Victor to say that, well, in the event that you do not file your papers by that time, you will... we will then approach the Court to ask that the matter be heard on an unopposed basis. Then you have to go for chamber book applications as I've set out.

And I've set it fully out in my notes where... what is the actual procedure which you need to follow. So this is not a question that you will have to say at best for the... for the applicant is to say that we have to apply for condonation for two, for the two hours that the matter is... that... but they show no; they show no prejudice. They have not produced an affidavit to say that they have been prejudiced. There's no affidavit before you to say because you only give it not at 12, you give it at 3, therefore I was prejudiced and therefore you need to punished. We have to look at the degrees of what it is. That's assuming the Court accepts that they've made out a point, which we deny, we say that there's no basis.

Let me then turn to the issue of urgency, if I may.

COURT: Before you turn to that issue, counsel, I need to make a ruling regarding those aspects. I need to make a ruling regarding those aspects whether you are properly before the Court. Let me give them an opportunity to reply.

MR TSEGARI: Alright.

COURT: Yes, counsel, do you wish to reply or not, before I make the ruling?

MR SIBANDA ADDRESSES COURT IN REPLY: Thank you, Your Ladyship. Your Ladyship, as regards to the aspect of the exchange of emails. Indeed emails were exchanged and the emails were very, very specific as to say that they were speaking to the filing of papers, service of papers as compared to filing are two separate issues. What was emailed to Mr Viljoen was a document which had not been filed. The actual filing only happens on the 26th after the agreed period that they had requested for and got.

And Your Ladyship, to the suggestion that there must have been a proviso to the effect that if you do not file, therefore it defines logic that having requested for indulgence you get the indulgence and still you want a warning that says if you do not file we will proceed and set the matter as unopposed.

And further, Your Ladyship ...[intervenes]

COURT: What about the aspect of the bar?

MR SIBANDA: I beg your pardon, Your Ladyship?

COURT: What about the aspect of the bar? The notice of bar?

MR SIBANDA: The aspect of the bar, Your Lordship, even if that aspect could be considered as being irregular in the sense that it speaks to actions as against an application, that of itself does not give them the right to come before the Court and say they are not out of time, because the issue, Your Lordship, is that when it comes to condonation, a party has to make an application for condonation, not to just come before court and say my papers have been filed.

COURT: Yes.

MR SIBANDA: In this particular instance, the respondents have not even made an attempt to say they are making an application. They, on the contrary want to create a scenario that necessarily confuses service and filing. Those are two separate issues altogether. They did not file and serve.

COURT: Aren't you really being technical here? And keep in mind that the rules are not there to be used as technical tools, but they are there for the smooth running of matters in order to facilitate matters to be ventilated and it's highly important that matters should be fully ventilated between the parties, right? Again, it seems as if you are not in disagreement pertaining to the aspect that it was served within the time period. Isn't it?

MR SIBANDA: We are in disagreement, Your Ladyship.

COURT: Alright.

MR SIBANDA: The disagreement being that service entails a filed document.

COURT: Remember, there is delivery of pleadings. Delivery entails service and filing. You file at court, you serve at a party, right? So, my question is, was the service within time?

MR SIBANDA: Your Ladyship, I'll still maintain that ...[intervenes]

COURT: No, no just answer the question, counsel or else you're going lose me. Was the service within time?

MR SIBANDA: If service means a filed court process, then no it was not.

COURT: No, no, no.

MR SIBANDA: If service simply means putting your intention across to the other party ...[intervenes]

COURT: No ...[intervenes]

MR SIBANDA: ... then, yes, it could be said that it was being served.

COURT: We can't talk over each other. Delivery entails serving and filing, right. Filing, you file at court. Serve, you serve the other party. Now, my question is, were you served within the time, agreed time?

MR SIBANDA: The papers were emailed on the 25th.

COURT: Yes.

MR SIBANDA: That is conceded.

COURT: Let's go there. Let's go then. So the respondents only failed with the first part of the order, filing.

MR SIBANDA: Yes, that's the aspect that they failed.

COURT: Ja, they're only failing that part, filing.

MR SIBANDA: Yes, M'Lady.

COURT: However, service was done within the timeframe as indicated in the order. Isn't it?

MR SIBANDA: If I'm ...[intervenes]

COURT: Now the question of prejudice?

MR SIBANDA: Your Ladyship, in as far as prejudice is concerned the... on the aspect of prejudice that necessarily occurs is that in as much as the papers were ...[intervenes]

COURT: Were served.

MR SIBANDA: ... served ...[intervenes]

COURT: ... within the agreed time and the agreed from.

MR SIBANDA: ... on the agreed day at 16:39, the applicant necessarily was denied an opportunity to reply on time.

COURT: How so now, if it was served on time? It's only the Court which was denied an opportunity to have insight to the documents within time, isn't it? You were served in accordance with the Court Order.

MR SIBANDA: In the evening, Your Ladyship.

COURT: But the assertion was that there was no time agreed upon.

MR SIBANDA: Absolutely. That is possibly the case, that

there was no time agreed upon.

COURT: Let's move on. Let's move on.

MR SIBANDA: Ja, the time agreed upon was Wednesday at 12 for the heads of argument, but all I'm saying, Your Ladyship, is that the ability to therefore reply having been served in the evening and they've only one day left before court, surely that is prejudicial? But all the same, the most critical aspect in as far as the respondents are concerned, would have to be that they've not made their application. But if the Court ...[intervenes]

COURT: Wouldn't you agree, sorry, sorry... wouldn't you agree that it's very important that the matter should be fully ventilated, particularly if regard is had to the issues which were raised?

MR SIBANDA: Absolutely, absolutely.

COURT: So why should I close the door in the face of the respondents then?

MR SIBANDA: It's not a question of simply closing the door, Your Ladyship. It's a question of them at least accepting where they have also been at fault and them follow the procedure. And be that as it may, the aspects that have also been tabled ...[intervenes]

COURT: Where are you go now?

MR SIBANDA: I beg your... still on their right.

COURT: On this aspect?

MR SIBANDA: Yes, on the same aspect, Your Ladyship. My learned friend raises the issue about the technical nature of the application and talks to the regulations, the NHA regulation. Your Ladyship, with all due respect, this application is not about the applicant seeking to own a pathogen. This is not about the applicant seeking to take possession of a pathogen. So that aspect is misplaced.

COURT: Alright.

MR SIBANDA: So to say the least. And the citing of the first respondent, the President ...[intervenes]

COURT: The President?

MR SIBANDA: ... is necessarily founded upon the fact that he is ...[intervenes]

COURT: I don't think they got an issue with that. They can't dictate to you who you cite.

MR SIBANDA: Indebted to you, Your Ladyship. That is what I was going to ...[intervenes]

COURT: Alright. So you're done?

MR SIBANDA: ... allege further. Ja, and I'm done with them. They are ...[intervenes]

COURT: Ja, then let me make my ruling. I have heard the parties.

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RULING

It appears that the respondents failed to file the answering or opposing papers as ordered by the Order dated 21 April 2021.

It is also evident that it's common cause between the parties that the papers were served within the ordered time. As I said, or indicated to the counsel on behalf of the applicant, orders and rules are not there to be used as technical tools. They are there to facilitate smooth running of matters. It's highly important that matters should be fully ventilated. It's also not encouraged that parties should litigate in an ambush way.

I am not convinced that I should not condone the late filing of the answering affidavits and I am convinced that the respondents are properly before this court.

Consequently, the respondents can proceed and address this court pertaining to urgency.

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MR TSEGARI: M'Lady, as it may please you. May I then on that basis turn to page 9 of my heads of argument? And before I address you, I think the first point *in limine*, assuming that the Court... the first point *in limine*, is still a very strong point *in limine*, because if the Court have regard to what they want, physical, so they must acquire, they must take possession.

So that end, you cannot just simply say that any person

can make a call or request that you ... that a court must come and say and where ... what the applicant is missing the boat, is that there is the trice political principle and separation of powers that constitutionally they do what they're supposed to do within their powers.

COURT: But you agree, counsel, if they fail on urgency ...[intervenes]

MR TSEGARI: Then it's the end of ...[intervenes]

COURT: Yes.

MR TSEGARI: Even so, M'Lady, then that's the end of the matter. But let me turn to that point, that particulars. As I said, as a starting point it is trite that the applicant must and as I said at paragraph 20, the applicant must make out its case in his founding affidavit.

Now with reference to paragraph 1, at page 21, that in the notice of motion paragraph 1, the applicant say that they want this application to be heard as a matter of urgency and that the applicant's failure to comply with the time limits imposed by the rules of this Honourable Court, be condoned in terms of Rule 6(12). And may I just add that you will have to provide reasons and circumstances which render your matter urgent.

Now, I would like the Court to read paragraph 1 together with the allegations or averments which are set out in the applicant's founding affidavit at paragraph 10 to 24. There the

Court will see, they give it a heading and they sought to say that these are the circumstances. On the affidavit this is the circumstances which they say we'll have to meet. They set out as being the basis for the urgency.

Now, for completeness, if the Court turn the page that the respondents have referred specifically to the allegations which are set out in paragraph 10 to 24 where at best, paragraph 10 is argumentative and it's not a factual matter which is before you, where they say:

> "I respectfully submit that this matter cannot wait to be dealt with in the ordinary course."

There is no facts which precede that conclusion. That is a legal conclusion and there is no facts which precedes that. Now if I may, if I turn to page... to paragraph 23 at page 11, there the respondents ...[intervenes]

COURT: [Indistinct]... page 11, not 10?

MR TSEGARI: It's page 10. Paragraph 22 is still part of the heads of argument, page 10. If you turn the page ...[intervenes]

COURT: Where are we now?

MR TSEGARI: At the heads of the argument. The heads of argument, sorry. What I've done, the Court will see is that I've just ... the respondents took the ... those allegations and incorporated it in the heads of argument also to create a better flow of it.

Now, the respondents are amiss to find any facts or circumstances which render the matter urgent on the applicant's own version. Where they say that:

> "This matter is of such urgency that it simply cannot wait for the normal procedure to be completed. I respectfully submit that this application should be heard other than in the normal course.
>
> Now, currently the entire country..."

And there is a reference to:

> "... it's under lockdown 1, which is a serious violation of the citizen's right. To date the Minister of Health has uttered and there are circulating discussions..."

They say, which deals with it. Now, the respondents say that those allegations or legal arguments does not answer the requirements for why the Court should exercise its discretion in favour of the applicant, where the applicant can actually say I have made out a case on papers for the question of urgency.

And then they say there is ... the Court will also see that there is a ...[indistinct] on rollout of vaccines and the vaccine rollout has begun in other countries and that the outcome of the order could very will mean a quick recovery to normal circumstances for the entire nation.

I must just add that there is as much as the applicant seeks to represent the entire nation, there is no confirmatory

affidavits or any other corroboration for his assertions that he's actually here on behalf of other persons. So what we have at best for the applicant is his allegations which he made under disguise that he say he is representing the entire country.

But let me turn to paragraph 23 where the respondent made the following contention. They say that:

> "The respondent contend that the applicant's application falls to be dismissed in that he failed, amongst others, to show that he will not otherwise be afforded redress at the hearing in due course."

The applicant contend that the applicant faintly asserted in paragraph 11...if the Court ... well, there in paragraph 11, this is what the applicant say at best. They say that:

> "This matter is of such urgency that it simply cannot wait for the normal procedures to be complied with."

That is the only faint reference to the question of urgency.

There's no other circumstances or facts which is advanced to demonstrate the existence of this particular urgency. And that point is made at the latter part where the respondents say that:

> "Apart from the letters, statement or no material facts or circumstances are advanced to support."

Now, if you turn the page on the heads of argument at page 12, paragraph 24, that in order to put the applicant's

averments in context I digressed to refer to the reasons why the matter should ... the matter is not urgent, before I deal with the proposition that the urgency was self-created. The main point which the respondents make is to say that the urgency which they referred to here are self-created urgency.

But before I address you later on in the heads of argument, may I just deal with certain observations which is of importance, which is referred to in the cases and I've dealt with that in paragraph 25 and 26. The respondents say that:

> "They contend that the only reasonable inference which could be drawn from the lack of any particularity or facts in the founding affidavit about the substantial redress, stems from the fact that the applicant in essence are seeking final relief."

And this is clear, M'Lady. If the Court will just keep the Court's finger there, we'll see that nowhere in the notice of motion is any reference made to any pending matter.

And that the interim, in as much as they say it's interim urgent interdict, this is in essence a request for final relief.

So they will have to demonstrate a clear right, not a *prima facie* right.

In other words, the granting of an interdict in the manner fawned by the applicant would be dispositive of any matter between the parties. This is so because the applicant is not seeking the relief in paragraph 2 of the notice of motion

pending the resolution of the main or other proceedings. There's no other proceedings. The affidavit or the founding affidavit is silent as to whether or not there are any other proceedings.

In this regard, the respondents referred to *Pikole v President of the RSA*, 2010(1) SA 400 at 403 paragraph H to R. That is on page 11... of page 12 of the heads of argument. Thus, the applicant in paragraph is seeking final relief or relief with final effect. In any event, the applicant is not suggesting that he's seeking through the interdict a freezing of existing rights which are threatened by irreparable harm. That is at paragraph 26, M'Lady.

Now, at paragraph 27, despite or apart from the other defects contained of not complying with the rules in compelling the respondents to come to court on an urgent basis, the respondents contented the urgency which is referred to in this matter, is self-created urgency.

And may I turn the page, M'Lady, at page 13. Now at page 13, the respondents say that:

> "Although it lacks the requisite factors to show urgency, the only allegation in the founding affidavit which contains some vague elements or alleged urgency appears in paragraph 20 of the founding affidavit."

Where they make the following statement. They say:

> "In South Africa there's a vast unemployment and poverty as such, the question of the very cause threatens to drastically increase the already desperate circumstances must at least be thoroughly investigated with utmost haste."

That appears to be the basis for why they say this matter should be heard on an urgent basis.

Now the respondents contend that paragraph 20 of the founding affidavit must be read together with the allegations set out at paragraph 62 of the applicant's ... of the applicant's founding affidavit. There the Court will see that there would be assertion.

> "The applicant has a reasonable suspicion about the existence of Sars-CoVid-2 virus."

That has been dealt with in paragraph 62 of the founding affidavit. Now the respondents say that:

> "That's on the applicant's own version. If the Sars-CoVid-2 virus does not exist, then..."

That's the logic which they say, the Court must accept.

> "... if the virus does not exist, then the other restrictions, namely the lockdown unlawful, irregular and such violates his fundamental rights."

That is the logic of the... of where they're going with this.

> "The respondents contend that the applicant commits an elementary error in that no right is

absolute."

That we know. It's trite and it's appropriate in these circumstances that the rights carried in certain circumstances be limited in terms of Section 36. The Court will recall that their case is in essence that you cannot limit any of those fundamental rights.

Now, if we turn the page, M'Lady, to paragraph 31 of the heads of argument where they say... where the respondents make the point to say that the respondents contended:

> "If the applicant failed to comply with the requirements of the National Health Regulations, then this court may in any event not in law exercise the discretion in favour of the applicants."

That's the first point. So in addition we say that:

> "The granting of the relief sought may thereby enter into the exclusive domain of the executive or the organs of state in circumstances where no case is made out as to whether or not the executive was acting irregular or violate the Constitution."

So may I then now turn to the contention or the argument that the urgency which we deal with here are self-created? That I will deal with more fully in paragraph 33. Now, since the application or the founding affidavit is largely based amongst others on hearsay evidence and matters which appears to be public knowledge, it is common cause that the applicant knew

about the lockdown restrictions, at least from 15 March 2020, on their own version. They knew about it since then. And on their own version they should know that in or during January 2020 the world, on their own application become aware of the so-called Coronavirus. And that the applicant knew or reasonable should have learned that... about the vaccination rollout programs in this country, at least since March 2021.

And in addition... and in the reported cases, the reported cases of infected persons in the country are also within the public domain. The applicants on their own papers say they knew about the existence of that.

COURT: There was a contention which was made that it's not allowed that post-mortems should be done.

MR TSEGARI: The question is, if that is the contention which is made. But the premise of that contention must move from a scientific fact. As a scientist, you will have to follow certain ethical and legal processes before you can do what they ask the Court to do. So, it's quite another thing to say you can't have a post-mortem. That's been the argument, but the... at the end of the day you have to produce facts and circumstances, not legal conclusions or statements unsupported by facts. And that's the... that is the Achilles heel of the applicants that they failed to produce those.

And even if one have regard to what they on their own

papers say, that they say the instances when the President address the citizens of the country about the restrictions is similarly in the public domain. The President most recent even during the beginning of April addressed the citizens of the country. That's in the public domain. And they knew about it since April. They come to this court and they say to the Court, ignore all the processes.

COURT: No, their contention is right. The situation is so fluent, it's continuing. Consequently, they claim the urgency stems from the nature of the relief sought. According to him... to them the urgency is inherent with the nature of the relief sought.

MR TSEGARI: I was lucky enough to hear that analogy which my learned friend was putting forward with regards to the person who was assaulted and with reference to that, that particular person that a crime is committed. And we know that it is not ... it's common knowledge that when a person commit a crime, you follow the CPA and you lodge a complaint, you go to the police, there's a crime. There's a certain procedure which follow. In any democratic country there's certain procedure which is followed. To characterise what is happening or unfolding in the country despite the objective evidence as falling into the same category, is baseless, M'Lady. With great respect, it's baseless. There's no factual information which is put before you.

But the more fundamental problem is this, the Court will know it is trite, if a party depose to an affidavit, that party must have personal knowledge of the facts which he depose to. Now let me again just step aside for a minute and just go to ... it forms part of the question of urgency and their claim that this is, if the Court will have regard to paragraph 2 of the founding affidavit. There the applicant say:

> "It's an adult male, Ricardo, who holds an MA International Politics obtained at the University of Leister in the UK. He specialise in post-cold war order, international security, intelligence and security and US foreign policy."

Right? That is the sum total of what is the deponent say the scope and nature of his knowledge are. Right? Now, if in certain circumstances, hearsay evidence may be permitted in urgent applications, we're dealing here with a matter where a person who is not otherwise qualified or as an expert on the field, give evidence on matters where he bears no personal knowledge about.

So the Court will have to take that into account when the Court have to assess whether or not the relief which the applicant seeks are properly before you. That he can properly obtain the relief which he seek.

Now, because most of the... Court will see if you have reference to even RM1, RM2, RM3, RM4, all those letters in

particular RM4, relates to a statement on the virus isolation in their papers. That raise the question as to whether the Court can actually have proper regard to when that paper is written by a scientist and the person is not a scientist, either microbiology or any of those other fields, that the Court can say that I have regard to the probative value of what he's saying because the evidence is in the affidavit. You will have to make out your case in your affidavit.

The respondents say that:

> "Despite all the above information at the disposal at the time of the applicant, it now wishes to leapfrog the court procedure and insist that he must be heard on an urgent basis whilst no discernable case is made out in the founding affidavit for urgency. More importantly..."

And this is where the applicant is actually contradicting his own case. The court will recall that you can only come, assuming that they have a case for interim interdict, which is not, that they can only ask for relief if you have no alternative remedy. That is the whole basis of it. May I then turn to paragraph 35 on page 15 of my heads? It say that:

> "More importantly, the applicant rushes to court despite the fact that he on his own case, has an alternative remedy."

This is evident from paragraph 132 of his affidavit where he

make the following statement. He say that:

> "The applicant has a right to access to information in terms of Section 32 of the Constitution and that he is essentially..."

This is what he is essentially requesting here. This is what he say. The applicant is saying what is essence he's requesting the Court is the access to information, on his own version. That the Court will find at his own paragraph 132. If I may just take the Court there? It's at page 32, M'Lady of the founding affidavit.

COURT: Hmm.

MR TSEGARI: This is what the applicant say:

> "The applicant has a right to access to information in terms of Section 32 of the Constitution."

And he say the following, he say that:

> "And that is what he is essentially requesting here."

Now on his own case ...[intervenes]

COURT: Isn't he making reference to the relief sought that ...[intervenes]

MR TSEGARI: Yes.

COURT: ... he's asking for the information ...[intervenes]

MR TSEGARI: Yes.

COURT: ... show me. Show me that there is a virus?

MR TSEGARI: Ja. That's the information. But the Court will see in the context of his own case where he dealt with *prima*

facie right and those list there. He want that information to be shown, on his own case, ja. So he can't say without having invoked his right to access to information in this year. We know that he previously have done so and he attach the papers that he ... the last time that he had done so was in... it was in May 2020 and in June. The Court will find that... they are unnumbered, but they will follow immediately after RM15.

COURT: Is your bundle not paginated?

MR TSEGARI: No, the file is not paginated, M'Lady. The file is not paginated.

COURT: The Court has page 174, RM13. RM14, 179.

MR TSEGARI: There's certain aspects ...[intervenes]

COURT: 183.

MR TSEGARI: There's 187. 189 appears to be one of it and then ...[intervenes]

COURT: Are you referring to this document?

MR TSEGARI: Ja, that document. There... the point... the short point that I would like to make, M'Lady, is that there the Court can see in May 2020 he has requested information, right? On 6 May there was another request for the information. And then on 18 June 2020, there was a response and another response appears also at what appears to be a numbered page 197, 198. It bears the same date namely 18 June 2020.

COURT: Indeed. 195.

MR TSEGARI: Ja. And even at page 202. Again, this information relates to information which appears to be done in 2020. The short point is this, if you had access, if you've previously invoked that right to access information and you now come to court and say you don't have an alternative remedy, why didn't you invoke this right? You could have done so in 2021 to ask for the information which you're now requesting.

COURT: Can't they say that process was not fruitful, hence they are now approaching the Court?

MR TSEGARI: But they were asking different things, M'Lady.

COURT: Alright.

MR TSEGARI: At the time they were asking for different things. This appears to be... and M'Lady will see that the... at the time, the information which was, for example, requested at the time by the applicant was in his capacity as the National Coordinator. At the foot of 191. So this time around, this application appears to be he'd done it on his own basis. So nothing have stopped the applicant, the point being simply this, is that nothing stopped the applicant to have requested the same information which he say, this is actually what he want. This is the alternative remedy. Again, on that basis, his ... his application cannot be regarded as urgent. Because he have already at his own case demonstrated the existence of an alternative remedy.

In any event, M'Lady, when you deal with a matter such as this, which raise important legal questions and policy issues, the best place to deal with this particular matter is the unopposed ... is on the semi-urgent roll, where you allocate the matter and at best, because of the importance of this matter, or the issues which seems to be raised here, at best there's supposed to be at least two judges or more, or a full court. I think the issues is of such a nature that at least you're supposed to have a full court.

And I've referred in the note to the practice directive as to how you're supposed to deal with matters such as this, where you need to ... first of all you need to comply with the practice directive to paginate and index the file and then the matter needs to be referred to the semi ... at least the semi-urgent roll where it can be dealt with on that basis that the issues must be properly ventilated.

And even in this case where it is apparent that there will be a dispute of fact. So you cannot really deal with the matter on that basis alone. May I then return to say that at paragraph 36 where the respondents say that:

> "The applicant put up no grounds or facts why he omitted to invoke his rights to access information."

He doesn't say anything there. The respondents contended that:

> "It is in any event not suggested by the applicant in

his affidavit that he during March or April 2021 submitted a request for information and his request was declined."

There's no evidence before you that his request was declined.

"Accordingly, the respondents contend that on his own version that the applicant has an alternative remedy which he should have invoked before he come to court. In the circumstances, the respondents contend that the applicant's failure to do so should be regarded as an abuse of the court process."

And this is so because, not only is the ... is he requesting relief with far reaching consequences for how the executive and the organs of state should positively comply with their constitutional obligations by protecting the population and the health resources of the country, but the [indistinct] of his relief, is that it might very well place the lives of millions of persons at risk in the event that the Court say I will grant paragraph 2, the physical, isolated, purified SARS virus.

Nowhere in his papers does he say the reasons for why he is requesting it. Be that as it may, I'll ... that being the issue of the mails.

"So accordingly, the handover of the physical virus to him as requested pose serious dangers for the effective protection of the population. In the

> premise, the respondents contend that the applicant's application falls to be dismissed on this ground also. However, should the Court nevertheless be amenable to, which is denied, to consider his application for whatever reason, the respondents contend that this application should be dismissed on the grounds set out below."

And that being the third point *in limine*, which I will not, since that would be with the merits, M'Lady.

COURT: You're going to stop there?

MR TSEGARI: Ja.

COURT: Yes.

MR TSEGARI: The Court say I must address you on the question of urgency.

COURT: Urgency, yes.

MR TSEGARI: So just to sum up, M'Lady. The first point is that you will have to make out your case in your founding affidavit. And two, you'll have to show or demonstrate that you have no alternative remedy. We have established that there's an alternative remedy.

Three, you'll have to show the irreparable harm to your rights, but you'll have to show in your case. In this case, they're not asking the Court for an interim interdict. They're asking the Court for final ... a final relief or relief of a final effect.

If the Court were to grant that, it means its dispositive of the entire matter. Then it clearly cannot be done if one have regard to the issues raised on the papers before you. So, we submit that there's no circumstances set out or facts which supports the view that the Court can exercise its discretion in favour of the applicant to say that the matter must be regarded as urgent.

Accordingly, we submit that on the basis of urgency alone and given the fact that we know all these matters, it is not enough to say that we are dealing with a continuous issue, therefore the urgency is on that basis self-evident, as I understand my learned friend to say. But then you will have to say that across the world, for example, that you will ... because that is a very wide point to make and that in itself is not sufficient to justify the granting of urgent relief. Because when you start speaking about the existence or the continuous threat it pose to the nation, you then have to deal with the issues relating to the science behind it. And you will have to corroborate your point of saying that I have found other persons who support my position to say it's not only the applicant, but there's other persons also who have deposed to affidavits supporting that particular point.

So the question of a continuous danger and that's the reason and I think the Court must weigh it up against the following, the whole point of restrictions is really to attempt to

flatten the curve of the infection.

COURT: Sorry to interject, counsel. The converse of it from the applicant's side is that it's actually the respondents who are endangering the population.

MR TSEGARI: That's the converse what they say. But again, if they make that point which appears to be a legal one; if they make that point, that cannot be done on an urgent basis. That requires a court to ventilate all of the issues. The Court cannot on the basis only of urgency say that I will deal with it on an urgent basis and for that reason. This is unlike a situation where you have a father or estranged persons. The father take the child without the consent of the mother and you now come to court and say to the Court you're upper guardian of the child, I need your assistance to come and help me to stop the husband to take the child away from me.

This is something which is much more complex than it appears. It is not something which only raise what the applicant seeks the Court to understand that, you know, it's simply you request the respondents, here is the virus. The virus exist, you can just hand it over.

COURT: They say there's no virus.

MR TSEGARI: On their case there's no virus.

COURT: There's no virus.

MR TSEGARI: Despite the fact that on their own case they say there's infection of persons of in excess of 1.4 million.

And on their own case they say in the paragraphs which I have cited; on their own case they say that this is the amount of persons which have died as a result of, as they put it. They make that point in the, if I may just ... oh, ja. If one, if the Court will have regard to what is also before you, which is the founding affidavit at paragraph 51 read together to say at paragraph 57 of their founding affidavit.

COURT: 51 and 57?

MR TSEGARI: No, no, it ... at page 15, it's at paragraph 51 of the founding affidavit. There the Court will see one will have to take this as to be their position with regards to the public knowledge. They say that:

> "During January 2020 the world become aware of the so-called Coronavirus."

I've referred to that again. At the writing, they take the point further, they say:

> "At the writing of this affidavit, the reported South African scientifical information of so-called virus are as follows..."

They referred to:

> "1.4 cases has been reported and... "

And then they attach RM6. Right. And then at paragraph 53, they make again references to the amount of persons who is infected by the virus and the recovery rate. It is 1.4 infected, 1.2 is the recovery rate. So ... and then they say in paragraph

54:

> "There are currently 150 800 people in South Africa had the so-called virus of which namely 546 are in serious or critical condition."

So on their own case, even if they say it doesn't exist, but they admit, this is the consequences of what is happening.

COURT: Are they really admitting or merely citing statistics which are there?

MR TSEGARI: But that's a case we can make, M'Lady.

COURT: Alright.

MR TSEGARI: That's the case I make. You cannot come to court and say, well, I can distance myself from my founding affidavit. You come to court and say I try to explain to the Court what is my position and then you use information like that, right? And you say in your own affidavit, you say that:

> "The facts deposed to in this affidavit falls within my personal knowledge."

And you ... and they say in their notice of motion that the application of ... or the affidavit of Ricardo will be used in support of this application. So, you can't, like they were doing, M'Lady, they try to cherry-pick the matters which they feel it's comfortable for them to use and they say the Court must ignore the others.

The Court must have regard to the entire affidavit as it is in order that the Court can have a full picture of what they

actually try to ask the Court to do. So, it's of no consequence that they say that there's a continuous virus. We ... nobody knows how long the virus will be in existence. Nobody knows. No one even knows and the world can do it, they have remedial steps like vaccines to try to curb it. But nobody knows really how to deal with it. It's not something unique only to South Africa. It's something which is across the world.

COURT: I mean assertions – an assertion was made that the President has announced that we are going towards a third wave.

MR TSEGARI: That's the assertion, M'Lady. But now we see, and if I may at this point and that is my ... that point is made or that allegation is made in paragraph 13 of the affidavit, right.

And may I just put it on record that the respondents has also filed an application to strike out some of the hearsay evidence or argumentative matter which is contained in this affidavit. But that's... that being an application which is not now going to be dealt with. We dealt with, if we have regard for example to paragraph 13 where they say that:

> "Currently the entire state is under lockdown level 1, which is a very serious violation of the citizen's fundamental rights. To date the Minister of Health has uttered and there are circulating discussions that lockdown measures will be

tightened which begs these measures to be scrutinised."

And if the Court will have regard to what they try to rely on for that, they refer to RM1. RM1 appears to be newspaper or internet articles which they pull from the internet and they attach them in support of that allegation. And we, in our striking out application, which the Court will also have regard, is that we ask that that information because they amount to hearsay. There's no corroboration or no confirmatory affidavit from the authors of these... of this particular articles to say that they support what the applicants have to say.

So on that score, M'Lady, one cannot simply say, you know, sort of there are circulating discussions. And if there is certain circulating discussions, it needs to be backed up by facts and circumstances, not mere say so or what is in the public domain. There's a lot of things in the public domain. But one needs to distinguish between what is factually correct and what is ... some assertions which are circulating in the public domain. And that is something which the applicant has failed to do in his own case.

Because I did not have the benefit of hearing the other part of the question of urgency, I would like the Court to just remind me of the other aspects which I need to address because I haven't had that opportunity, apart from the ones which the Court now raised here.

COURT: No, I think you've traversed everything, counsel. I think you traversed everything. You canvassed everything.

MR TSEGARI: Thank you, M'Lady. So, in conclusion, the respondents would just like to request that this application ought to be dismissed because ...[intervenes]

COURT: Dismissed? Let's say the Court is inclined ... if the Court is inclined to find that there is no urgency ...[intervenes]

MR TSEGARI: Yes?

COURT: ... you are requesting that the Court should dismiss the application?

MR TSEGARI: Ja. If there's no urgency, the application must be dismissed.

COURT: Not to be removed from the roll?

MR TSEGARI: The alternative is to remove it from the roll, M'Lady. If the Court say that there's no... then they must remove it from the roll and follow ...[intervenes]

COURT: Then it should go to the normal course.

MR TSEGARI: ... and follow the proper procedure. And more so, M'Lady, I cannot impress it more than in this division, the Court makes it very clear, there's a reason why there's practice directives. There's a reason why there's rules. This case of the applicant is in flagrant violation of all the rules and the practice directives. The applicant, at best, should have at least anticipate that there's opposition, that the best possible way to deal with the matter is to either approach for request

for earlier allocation of the matter or to ask that the matter be placed on the semi-urgent roll so that the issues must be properly ventilated. This was not done.

They have not bring such a request to the Court to say this is what... this is the most appropriate way of dealing with the matter. What they want to do, is the Court to say well, let's leapfrog the procedures and then say to the Court that you must now hear us now, here and now and what makes it problematic, M'Lady, is that they are seeking final relief which request that we have to look at the probabilities and we can't deal with probabilities on the papers. If there's no other, further questions, M'Lady, that's the ...[intervenes]

COURT: And costs? Costs?

MR TSEGARI: The cost, M'Lady, is, the cost we are compelled to come to court on an urgent basis. The cost must follow the event.

COURT: Isn't this public interest?

MR TSEGARI: M'Lady, in as much as you have a discretion to decide, it's a question of public interest, what is important in this matter is that the persons who deposed to the affidavit are required to deal with more pressing issues and the ... we're dealing with scarce resources where we have to pull those people out of the work which are pressing in this ... in the rising of the infection rate.

COURT: Ja, but would it not be in a constitutional

democracy?

MR TSEGARI: I accept that, M'Lady. I accept that. But we say that if you do bring proceedings to court, you must at least make sure that those proceedings are properly before the Court.

COURT: But it's a situation of a citizen versus the executive?

MR TSEGARI: A citizen who was properly represented and from the look of things the citizen has an army of representatives. So this citizen is not a person who stand alone. And he doesn't bring this in his... as a person who is doing his own matter. He has got an army of person who assist. So it's not ... this matter is similar from a situation where you have a concerned citizen who say I will litigate on my own and I'll bring this matter to court and that the Court can deal with it and in that regard we're not saying that the Court should close the door on people who raise issues, they can, after all we live in a democratic society where you have to tolerate freedom of expression and different views. People can do that.

All that we say in doing so, your right must be exercised in such a way that you attach reasonableness as to how it will impact on the other person. And that's the balance which we need to ... we're not always right, but that's balance and that's the reason why the practice directives and the rules seeks to strike a balance between this. So if the Court is not amenable

to dismiss the application outright, which we would ask, then it's within the Court's discretion to struck it from the roll.

And we would still urge the Court to consider a cost issue, but it remains within your discretion to say each party will carry its own cost, but that's a decision which the Court will have to make. M'Lady, if there is no any other matter, that is the submissions on behalf of the respondents.

COURT: No. Thank you, no counsel.

MR VILJOEN: M'Lady ...[intervenes]

COURT: I will allow one counsel to address, not two.

MR VILJOEN: Thank you, M'Lady. It's actually a very simple matter, M'Lady. Whenever we address there's circumstances of the virus. We say the so-called virus. M'Lady, there is factual evidence of urgency and harm here. RM6 is an attachment of the Government Gazette where the lockdown has been announced, M'Lady. Now, what can be more urgent than a lockdown that locks down the entire nation, it locks down the economical activities, it locks down the freedom of choice whether they can wear a mask ...[intervenes]

COURT: But that was in the past, isn't it?

MR VILJOEN: It's happening right now, M'Lady. You don't have a freedom of choice whether you're going to wear a mask or not. And, M'Lady, we're talking about vaccination passport. So, the respondents are saying we're not going to force you do to it, but we'll exclude you from the entire community if you

don't do it. M'Lady ...[intervenes]

COURT: Has that been said?

(AFFIRMATIVE REACTION FROM WHOLE COURT ROOM)

MR VILJOEN: Yes, M'Lady.

COURT: Is it?

MR VILJOEN: And it's happening in circumstances already. M'Lady, and then there's also the circumstances of people whose apparently dying from taking the vaccine.

(AFFIRMATIVE REACTION FROM WHOLE COURT ROOM)

COURT: People, please try and restrain yourselves.

MR VILJOEN: M'Lady, there can't be any more urgency than violating an entire nation's right to freedom of movement, their right to earn a living, their right to decide at what time they'll drive at night. And that has been submitted in the Government Gazette. That's a factual fact that their fundamental rights and the economic ...[intervenes]

COURT: [Indistinct] before, counsel, sorry to disturb. What's the point of a Government then?

MR VILJOEN: Exactly, M'Lady. This is being, and this is our point. The point of Government is do ... make rational decisions, not on assumptions, M'Lady. So all we... we're not asking the Court to make any decision. We have a right; Section 25 of the Constitution give us the right to freedom of information. This is amended by the Promotion of Access to Information Act, Section 12 that says – and Section 11,

M'Lady.

So the applicant has followed these process, M'Lady. He's been ignored. How many times must you be ignored before you can say okay, he's been ignored three times at least, M'Lady. So, he has exhausted all other revenues. He's been desperate from the beginning, M'Lady. So, one can't say this is self-inflicted. And secondly, the ... I can't think of anything more urgent than this current lockdown on our economic and on the freedom of movement of people and the freedom of movement.

M'Lady, and we're talking about a third wave. The Court can take judicial notice of that. M'Lady, that means that we're going to go up to a level 2 or level 3 where people's prevented from going to the beach ...[intervenes]

COURT: But you're speculating.

MR VILJOEN: No, M'Lady. It's a fact. We're on level 1 now. What's to say that we'll go into level 2 tomorrow? We don't know, M'Lady. And this is all based on the assumption and the respondents is saying the virus is existing. We say; all we're asking is show us. We're not asking give it to us, we'll go around the corner and play with it, M'Lady. We're asking ... our wording is very specific, produce it in circumstances that you're happy with, M'Lady, to the applicant. Meaning the applicant will come with his people and they'll confirm whether the virus actually exist or not, M'Lady.

And then from there further actions can follow. That's all we're asking is the Court to make an order that our right to access to information be respected and that the Government show us what they allege is existing, M'Lady. There's nothing ... we're not asking them to go through financial burdens or to ... the Court to make any prejudicial orders against them. We're just simply asking them to produce us what they're claiming that they have, M'Lady.

And under the circumstances that they prefer. We're not asking to take the virus and go with it, M'Lady. Definitely not and that's not our application.

COURT: Thank you, counsel.

MR VILJOEN: Thank you, M'Lady.

MR SIBANDA: Your Ladyship ...[intervenes]

COURT: What I'm going ... I said I was only one.

MR SIBANDA: May I just request that one important point, Your Ladyship on the issue of costs.

COURT: Oh yes.

MR SIBANDA: Please hear me on the cost, Your Ladyship. My learned friend makes a very important point about the applicant engaging the services of several lawyers. Indeed, that is correct. The reason why applicant had to take that particular route is because when he tried it on his own, he failed because he just didn't know what he was doing procedurally, which then explains the 8th of March when he

tried to push his case through to the Court. And my learned friend fails to basically address the aspect as well that there are lawyers who do work *pro bono* and there are lawyers who will do public interest cases because they believe in the necessity to protect the interest of the citizens of the country. So I'd love Your Ladyship in applying her mind to the issue of costs to be cognisant ...[intervenes]

COURT: I always apply my mind to everything, counsel.

MR SIBANDA: Particularly we're talking about costs at this particular stage, Your Ladyship, to be cognisant of the fact that the applicant has got a *pro bono* team of lawyers in that, Your Ladyship.

COURT: Thank you. What I'm proposing to do, I'm only going to give ruling pertaining to the aspect of urgency. Right? Reasons, unfortunately will have to follow as I am on urgent duties.

RULING

COURT ADJOURNS [16:04]

TRANSCRIBER'S CERTIFICATE

I, the undersigned, hereby certify that **so far as it is audible to me**, the aforegoing is a true and correct transcript of the proceedings recorded by means of a digital recorder in the matter between:

R MAARMAN // THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA & 3 OTHERS

CASE NUMBER	: 5852/2021
RECORDED AT	: CAPE TOWN
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PROBLEMS EXPERIENCED WITH RECORDING

1. **Recording was transcribed *verbatim* and therefore grammar not corrected.**
2. **Where no clear annotations are furnished, names are transcribed phonetically.**
3. **Court stenographer's annotation totally incomplete.**
4. **Advocate Sibanda sometimes speaks unclear.**
5. **Presiding Judge sometimes speaks soft and unclear.**
6. **Advocate Tsegari tends to speak unclear at times by swallowing words and/or lowering his voice at the end of sentences causing indistinct words and/or phrases.**

DATE COMPLETED: 2021.06.14

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_____
HERMIE JOUBERT

inlexso
INNOVATIVE LEGAL SOLUTIONS

IN THE HIGH COURT OF SOUTH AFRICA

(WESTERN CAPE DIVISION, CAPE TOWN)

CASE NO.: 5852/2021

DATE: 2021.05.27

In the matter between

RICARDO MAARMAN Applicant

and

THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA First Respondent

THE MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS Second Respondent

PROFESSOR SALIM ABDOOL KARIM obo the GOVERNMENTAL COVID ADVISORY COMMITTEE Third Respondent

THE DEPARTMENT OF HEALTH Fourth Respondent

RULING

NZIWENI, AJ:

My ruling is as follows:

The applicant has not made a case for urgency.

Consequently the matter is struck off the roll. The applicant has got another course which the applicant, if he wishes, can take. That is my ruling.

Pertaining to costs, each party will pay its own costs.

10

NZIWENI, AJ

JUDGE OF THE HIGH COURT

AL MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

DÑA. MARÍA CONCEPCIÓN CUEVAS MONTOTO, mayor de edad, con DNI 10872968-V, en nombre y representación de la asociación **LIBERUM**, con NIF G-04958344, con domicilio en la calle José Ramón Zaragoza, 12, 1º A, 33550, de Cangas de Onís, Asturias; Tfno: 639 284 548, en su calidad de presidenta, conforme al acta fundacional y NIF que se aportan, comparezco ante esta Administración y **DIGO:**

Que, por medio del presente escrito, en base a los **Arts.12 y siguientes de la Ley 19/2013, de 9 de diciembre, de transparencia, acceso a la información pública y buen gobierno**, nos dirigimos a este Ministerio y al resto de órganos que del mismo dependan, así como a las personas o entidades que trabajen para el mismo, y con el motivo de conocer el estado actual de la gestión de la pandemia originada por el COVID-19, interesamos lo siguiente

PRIMERO.- Que, por parte de esta Administración o de sus órganos dependientes, o bien, de la personas o entidades que trabajen para ésta, se proceda a contestarnos a las preguntas siguientes:

AISLAMIENTO DEL VIRUS SARS-COV-2

1.- ¿Tienen ustedes pruebas o alguna publicación científica que demuestre que el virus SARS CoV 2 ha sido correctamente aislado de una muestra tomada de un paciente enfermo por Covid-19, la cual no haya sido mezclada con otra fuente de material genético como pueden ser las células Vero?

Por favor, téngase en cuenta que cuando hablamos de "aislar", nos referimos al sentido estricto de la palabra (separar algo del resto). No preguntamos por registros en los que por "aislar" se refieran a:
El cultivo de algo.
El resultado de la amplificación mediante PCR.
La secuenciación de algo.

2.- ¿En que tipo de células se ha cultivado este virus SARS CoV 2?

3.- Se ha conseguido cultivar el virus SARS CoV 2 en células normales no tumorales del aparato respiratorio humano?

4.- ¿Existe una micrografía electrónica del virus SARS CoV 2 puro y completamente caracterizado o secuenciado?

5.- Si hay pruebas de la existencia del SARS CoV 2, ¿Está en su posesión el test de anticuerpos que cumple los postulados de Koch? Y, a su vez, ¿tiene un falso positivo por debajo del 30% que puede confirmar el haber sido infectado por el SARS Cov 2?

6.- ¿Se han cumplido los postulados de Koch para ofrecer la completa seguridad que efectivamente se trata del patógeno que causa la enfermedad?

7.- ¿Cuál es el título del trabajo, o el artículo, o paper científico del principal experto, revisado por pares, en el que se ilustra el mencionado virus, siendo su información genética descrita en su totalidad?

SARS-COV-2 Y COVID-19

¿Cuál es el título del trabajo, o del artículo, o paper científico del principal experto, revisado por pares, que ofrece una prueba inequívoca de que el virus SARS CoV 2 es la única causa de la enfermedad conocida como COVID-19?

TEST RT-PCR

Desde el mismo momento en que fue declarada la pandemia, ha sido utilizada la prueba PCR como el método diagnóstico por excelencia, contabilizándose como casos Covid todos aquellos que dieron positivo a dicha prueba, independientemente de la clínica, cuando los mismos fabricantes advierten de las limitaciones de las mismas. La propia OMS se ha visto obligada a alertar, en un comunicado del 13 de enero de 2021, a los usuarios para que consulten el manual de uso para interpretar los resultados de las PCR. Según el citado texto, los usuarios de productos para el diagnóstico in vitro deben leer atentamente el manual de uso a fin de determinar si es necesario ajustar manualmente el umbral de positividad de la PCR, siendo preciso actuar con precaución a la hora de interpretar un resultado positivo débil, dado que el ciclo umbral establecido para detectar el virus es inversamente proporcional a la carga vírica del paciente. También advierte que la prevalencia de la enfermedad modifica el valor predictivo de los resultados de las pruebas (cuanto más baja es la prevalencia, mayor es el riesgo de obtener un falso resultado positivo o negativo) por lo que la probabilidad de que una persona con un resultado positivo esté realmente infectada por ese virus se reduce a medida que baja la prevalencia,

independientemente de la supuesta especificidad de la prueba. Añade además que son instrumentos que simplemente ayudan a establecer el diagnóstico; por consiguiente, se deben interpretar sus resultados teniendo en cuenta el momento de muestreo, el tipo de muestra obtenida, las características del ensayo, las observaciones clínicas, los antecedentes del paciente, la infección confirmada en cualquiera de sus contactos y la información epidemiológica. Además, advierte de la necesidad de consignar el valor de Ct en el informe que remita al profesional de salud solicitante.
Teniendo en cuenta todo esto,

1. ¿Se ha procedido en todo momento conforme a estas indicaciones de la OMS?

2. ¿Pueden certificar que los cebadores que se están utilizando son exclusivos para el virus Sars-CoV-2 y que no pueden estar detectando cualquier otro coronavirus, virus influenza, sincitial ... o incluso material genético del propio paciente?

3. ¿Se están realizando de manera habitual cultivos virales de las personas con RT PCR positivos en España?

4. ¿Se dispone de cultivos virales con partículas viables de alguno de los pacientes RT PCR positivos en España?

AEROSOLES

¿Pueden facilitarnos algún paper científico en el cual se demuestre que haya sido aislado un virus Sars-Cov-2 viable en los aerosoles de un paciente enfermo y que se demuestre que ese virus que se ha aislado sea infectivo?

Por favor, téngase en cuenta que cuando hablamos de "aislar", nos referimos al sentido estricto de la palabra (separar algo del resto). No preguntamos por registros en los que por "aislar" se refieran a:
El cultivo de algo.
El resultado de la amplificación mediante PCR.
La secuenciación de algo.

MASCARILLAS

¿Podrían dar a la luz pública los estudios que se han realizado sobre el uso de las mascarillas, tanto respecto de su protección ante el virus, como de posibles problemas a corto, medio y largo plazo que se pudieran derivar de su uso?

VACUNA

La propia OMS ha reconocido que no tiene ninguna muestra del virus aislado y diversos gobiernos incluyendo Irlanda y Australia entre otros, han reconocido que el virus nunca ha sido secuenciado de una forma correcta. La revisión de todos los artículos publicados demuestra que se utilizaron extractos no purificados de secreciones "supuestamente provenientes de enfermos de Covid" y mediante el uso de cebadores inespecíficos fabricaron una estructura viral hipotética cuyos espacios intermedios fueron rellenados por un algoritmo informático con datos de genes procedentes de una base de datos internacional que en absoluto demuestra la existencia de ningún nuevo virus. Finalmente, al estudiar las pruebas de confirmación se comprueba que no se realizaron correctamente los protocolos de Koch y las imágenes supuestamente interpretadas como virus fuera de las células no son más que exosomas secundarios al daño tisular causado por los propios experimentos.

1.- ¿Como pueden hacer una vacuna específica del Covid si no se ha aislado correctamente y no se conoce la secuencia genética del mismo?

2- ¿Han comprobado mediante cribados por franjas de edad la tasa de anticuerpos específicos desarrollados tras la vacunación completa y un mes después, para ver si los inoculados desarrollan respuesta inmune?

3- ¿Existe algún estudio o fundamento científico que haya provocado la decisión de no optar por alcanzar la inmunidad de rebaño de manera natural en lugar de asumir el riesgo de alcanzar esa misma inmunidad por la vía artificial mediante la inoculación de un tratamiento experimental (vacuna)?

4- ¿Existe algún estudio científico independiente de lo declarado por las compañías productoras de las vacunas y revisado por pares, que indique que el riesgo de contraer la enfermedad Covid19 y de morir por causa de ella, es superior al riesgo de padecer efectos adversos moderados o graves por causa de la inoculación de los productos experimentales que están siendo inoculados a la población?

5- ¿Está siendo llevada a cabo la fase experimental a medio y largo plazo en la población general, sin el debido consentimiento informado? ¿Es cierto que se ha cambiado la legislación para permitir la experimentación sin el preceptivo consentimiento informado? (Ley 41/202, de 14 de noviembre, básica reguladora de la autonomía de paciente y de derechos y obligaciones en materia de información y documentación clínica. Artículo 3).

DATOS EPIDEMIOLÓGICOS

1. ¿Por qué no se hacen estudios de SEROPREVALENCIA (cribados de test de anticuerpos) que es el único dato con valor epidemiológico en caso de epidemia?

2. ¿Por qué se utiliza la incidencia acumulada absoluta para valorar la evolución de la pandemia, cuando es un dato carente de rigor y sin valor epidemiológico?

3. ¿Cuál es la razón para,

a) seguir calculando el índice acumulado después de 14 días, en vez de utilizar los 10 días de acuerdo con las nuevas directrices de la OMS sobre el contagio de 7 a 10 días?
b) no uniformizar los datos con respecto a un valor referenciado en los positivos por PCR con el fin de hacer un seguimiento más razonable de la evolución de los infectados?
c) no aplicar un factor corrector respecto a los asintomáticos que no desarrollan la enfermedad.

SEGUNDO.- Que, por parte de esta Administración o de sus órganos dependientes, o bien, de la personas o entidades que trabajen para ésta, se proceda a facilitarnos la documentación siguiente:

1. Todos los registros en posesión, custodia o control del Ministerio de Sanidad, Administración dependientes o entidades colaboradoras, concernientes a cada una de las preguntas formuladas con anterioridad.

2. Información suficiente sobre cada registro de forma que pueda identificar y acceder a cada registro con precisión (por ejemplo, título, autores, …) fecha de publicación, así como, la forma en la que el público pueda acceder a los mismos.

Por lo expuesto,

SOLICITO que, se tenga por presentado este escrito, se admita, se tengan por formuladas las preguntas y peticiones de documentación indicadas anteriormente a este Ministerio y al resto de órganos que del mismo dependan, así como a las personas o entidades que trabajen para el mismo, se nos conceda el acceso a la información solicitada, procediéndose a dar respuesta a las referidas preguntas indicadas en el cuerpo de este escrito, así como aportándonos la información solicitada.

En Madrid, a 26 de abril de 2021.

Fdo. María Concepción Cuevas Montoto

Presidenta de LIBERUM

TO THE MINISTRY OF HEALTH, CONSUMPTION AND

SOCIAL WELFARE

MRS. MARÍA CONCEPCIÓN CUEVAS MONTOTO, of legal age, with DNI 10872968-V, on behalf of the **LIBERUM** association, with NIF G-04958344, with address at calle José Ramón Zaragoza, 12, 1º A, 33550, Cangas de Onís , Asturias; Phone: 639 284 548, in her capacity as president, in accordance with the founding act and NIF that are provided, I appear before this Administration and **I SAY**:

That, by means of this document, based on Articles 12 and following of the Law 19/2013, of December 9, on transparency, access to public information and good governance, we address this Ministry and the rest of the bodies that depend on it, as well as the people or entities that work for it, and in order to know the current status of the management of the pandemic caused by COVID-19, we are interested in the following

FIRST: Legal provisions to demand public information from the Ministry of Health and depending bodies on the following subjects:

ISOLATION OF THE SARS-COV-2 VIRUS

1.- Do you have evidence or any scientific publication that demonstrates that SARS CoV 2 virus has been correctly isolated from a sample taken from a Covid-19 patient, which has not been mixed with another source of genetic material such as Vero cells?
Please note that when we talk about "isolate", we are referring to the strict sense of the word (to separate something from the rest). We do not ask for records where by "isolate" it is meant:
The cultivation of something.
The result of PCR amplification.
The sequencing of something.

2.- In what type of cells has this SARS CoV 2 virus been cultured?

3.- Has SARS CoV 2 been successfully cultured in normal non-tumor cells of the human respiratory system?

4.- Is there an electron micrograph of the pure and fully characterized or sequenced SARS CoV 2 virus?

5.- If there is evidence of SARS CoV 2, is in your possession the antibody test that meet the Koch's postulates? Does it have a false positive rate positive below 30% that can confirm having been infected by SARS Cov 2?

6.- Have Koch's postulates been fulfilled to offer complete certainty that the pathogen is indeed the one that causes the disease?

7.- What is the title of the work, or the article or peer-reviewed scientific paper in which the mentioned virus is illustrated, being its genetic information fully described?

SARS-COV-2 AND COVID-19

What is the title of the peer-reviewed work, or scientific article or paper that provides unequivocal proof that SARS CoV 2 is the sole cause of the disease known as COVID-19?

RT-PCR TEST

From the very moment the pandemic was declared, the PCR test has been used as the diagnostic method par excellence. Covid cases have been counted as all those that tested positive to this test, independently of the clinical manifestations, although the manufacturers themselves warn of the limitations of such tests. The WHO itself has been obliged to warn, in a communiqué dated January 13, 2021, to users to consult the user's manual to interpret the results of the tests. According to the text, users of in vitro diagnostic products should carefully read the user's manual to determine whether it is necessary to manually adjust the PCR positivity threshold, and caution should be exercised when interpreting a weak positive result, since the threshold cycle set to detect the virus is inversely proportional to the viral load of the patient. It also warns that the prevalence of the disease modifies the predictive value of test results. (the lower the prevalence, the higher the risk of obtaining a false positive or negative result), so that the probability that a person with a positive test result is actually infected with the virus decreases as prevalence decreases, regardless of the supposed specificity of the test. It further adds that the PCR tests are instruments that simply help to establish the diagnosis; therefore, their results must be interpreted taking into account the time of sampling, the type of sampling, the type of sample obtained, the characteristics of the test, the clinical observations, the patient's clinical observations, patient history, confirmed infection in any contacts, and epidemiological information. In addition, it warns the need to include the Ct value in the report sent to the requesting health professional.

Keeping this in mind:

1. Have these WHO guidelines been followed at all times?

2. Can you certify that the primers being used are unique to the Sars-CoV-2 virus and cannot be detecting any any other coronavirus, influenza, syncytial coronavirus or even genetic material from the patient's own genetic material?

3. Are viral cultures of people with positive RT-PCR in Spain being routinely performed?

4. Are viral cultures with viable particles available from any of the RT PCR-positive patients in Spain?

AEROSOLS

Can you provide us with any scientific paper in which it has been demonstrated that a viable Sars-Cov-2 virus has been isolated in the aerosol of a sick patient and that that the virus that has been isolated is infective?

Please note that when we speak of "isolate", we are referring to the (to separate something from the rest). We do not ask for records where by "isolate" we mean:
The cultivation of something.
The result of PCR amplification.
The sequencing of something.

MASKS

Could you please make public the studies that have been carried out on the use of masks, both with respect to their protection against the virus and to possible problems in the short, medium and long term that may arise from their use?

VACCINE

The WHO itself has acknowledged that it does not have any sample of the isolated virus, and several governments including Ireland and Australia among others, have acknowledged that the virus has never been properly sequenced. A review of all published articles shows that unpurified extracts of secretions "supposedly from Covid patients" were used and by using non-specific primers, they fabricated a hypothetical viral structure. The gaps in between were filled in by a computer algorithm with gene data from an international database that in no way proves the existence of any new virus. Finally, after a study of the confirmatory tests, it was found that the Koch's protocols were not performed correctly and the images supposedly interpreted as viruses outside the cells are but exosomes secondary to tissue damage caused by the experiments themselves.

1.- How can they make a specific Covid vaccine if it has not been isolated correctly and its genetic sequence is not known?
2- Have you checked by screening by age groups the rate of specific antibodies developed after the complete vaccination and one month later, to see if those inoculated develop an immune response?
3- Is there any study or scientific basis for the decision not to opt for achieving herd immunity in a natural way instead of taking the risk of achieving the same immunity artificially by inoculation of an experimental treatment (vaccine)?
4- Is there any scientific study independent of what has been declared by the companies producing the vaccines and peer-reviewed, which indicates that the risk of contracting the Covid19 disease and dying from it is higher than the risk of suffering adverse the risk of suffering moderate or severe adverse effects from inoculation with the experimental products?

5- Is the experimental phase being carried out in the medium and long term in the general population without the proper informed consent, and is it true that the legislation has been changed to allow experimentation without the mandatory informed consent? (Law 41/202, of November 14, 2002, regulating patient autonomy and of rights and obligations regarding clinical information and documentation. Article 3)?

EPIDEMIOLOGICAL DATA

1. Why are SEROPREVALENCE studies (antibody test screening) not performed? They are the only data with epidemiological value in the event of an epidemic.

2. Why is the absolute cumulative incidence used to evaluate the evolution of the pandemic, when this datum lacks rigor and has no epidemiological value?

3. What is the reason for:

a) continuing calculating the cumulative index after 14 days, instead of using the 10 days in accordance with the new WHO guidelines on 7 to 10 days of infection?
b) not standardizing the data with respect to a value referenced in the PCR positives in order to make a more reasonable follow-up of the evolution of those infected?
c) not applying a correction factor for asymptomatic patients who do not develop the disease?

SECOND.- That, on the part of this Administration or of its dependent bodies, or of the persons or entities working for it, to provide us with the following documentation:

1. All the records in possession, custody or control of the Ministry Health, dependent Administration or collaborating entities, concerning each of the questions formulated above.

2. Sufficient information on each record so that you can accurately identify and access each record with precision (e.g., title, authors, date of publication), as well as, the way in which the public can access them.

For the exposed,

I REQUEST that, if this writing is considered to be presented, it is admitted, that the questions and requests for documentation indicated above be considered to this Ministry and to the rest of the bodies that depend on it, as well as to the people or entities that work for it. , we are granted access to the requested information, proceeding to respond to the aforementioned questions indicated in the body of this letter, as well as providing us with the requested information.

In Madrid, April 26, 2021

Signed. Maria Concepcion Cuevas Montoto

President of LIBERUM

MINISTERIO DE SANIDAD

SECRETARIA DE ESTADO DE SANIDAD

DIRECCIÓN GENERAL DE SALUD PÚBLICA

Nº EXPEDIENTE: 001-059144
FECHA DE LA SOLICITUD: 22 de julio de 2021
FECHA DEL DOCUMENTO: 8 de septiembre de 2021

NOMBRE: [redacted]BOUZA
NIF: [redacted]
CORREO ELECTRÓNICO:

[redacted]
ESPAÑA

Con fecha 22 de julio de 2021, tuvo entrada en la Unidad de Información de Transparencia del Ministerio de Sanidad, su solicitud de acceso a la información pública al amparo de la Ley 19/2013, de 9 de diciembre, de Transparencia, Acceso a la información pública y Buen gobierno, solicitud que quedó registrada con el número 001-059144.

Con fecha 10 de agosto de 2021, esta solicitud se recibió en la Dirección General de Salud Pública, fecha a partir de la cual comienza a contar el plazo de un mes previsto en el artículo 20.1 de la Ley 19/2013 de 9 de diciembre, para su resolución. Con fecha 12 de agosto de 2021 se le notificó, escrito de ampliación de plazo por los motivos expuesto en el mismo precepto legal.

Una vez analizada su solicitud, esta Dirección General resuelve, conceder su derecho de acceso a la información. Le indicamos que los datos de los que dispone el Ministerio de Sanidad en relación a la pandemia por SARS-CoV-2 la puede encontrar en los siguientes enlaces:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/home.htm

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos.htm

En ellos puede acceder a distintos documentos de información científico técnica, procedimientos y medidas para la prevención y el control de la infección, preparación y respuesta a la pandemia, recomendaciones para el manejo clínico de casos, actuaciones en el contexto de la respuesta a la COVID-19 por ámbitos, colectivos y grupos, y aspectos de comunicación.

Específicamente, en relación a los ciclos de una PCR y los test de antígenos, puede consultar la información en el siguiente documento:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/COVID19_Estrategia_vigilancia_y_control_e_indicadores.pdf

Las vacunas frente a COVID-19 se administran en España en estos momentos según la Estrategia de vacunación frente a COVID-19 en España [aprobada por el Consejo Interterritorial del Sistema Nacional de Salud], y son gratuitas para la ciudadanía. En este sentido no requieren receta médica. Puede consultar la Estrategia y sus actualizaciones, así como un resumen de las características de las vacunas y de su ficha técnica en el siguiente enlace:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/vacunaCovid19.htm

La eficacia de las vacunas se mide en términos ideales de laboratorio, y posteriormente se mide en la población real, una vez que las vacunas se han administrado. Puede encontrar información en el siguiente enlace:

CORREO ELECTRÓNICO

D I R E C C I Ó N
PASEO DEL PRADO 18-20 28014 MADRID
TELÉFONO:
FAX:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/20210820_INMUNIDAD_y_VACUNAS.pdf

También puede consultar estudios sobre este aspecto en la bibliografía de las Actualizaciones de la Estrategia, en especial de la 8.

https://www.mscbs.gob.es/profesionales/saludPublica/prevPromocion/vacunaciones/covid19/docs/COVID-19_Actualizacion8_EstrategiaVacunacion.pdf

Las reacciones a las vacunas se estudian a través de la farmacovigilancia. Puede consultar el tema en el siguiente enlace:

https://www.aemps.gob.es/la-aemps/ultima-informacion-de-la-aemps-acerca-del-covid%e2%80%9119/vacunas-contra-la-covid%e2%80%9119/farmacovigilancia-de-vacunas/informes-periodicos-de-farmacovigilancia-de-vacunas-covid-19/

Sobre secuenciación genómica del virus puede consultar el siguiente enlace:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/Integracion_de_la_secuenciacion_genomica-en_la_vigilancia_del_SARS-CoV-2.pdf

El Ministerio de Sanidad no dispone de cultivo de SARS-CoV-2 para ensayos, y no tiene un registro de los laboratorios con capacidad de cultivo y aislamiento para ensayos.

En relación a las pruebas diagnósticas de SARS-COV-2, y en general, con los temas relacionados con la pandemia por SARS-Cov-2, el Ministerio de Sanidad trabaja con los documentos antes mencionados, que se van actualizando según la necesidad epidemiológica, para posibilitar la toma de decisiones en relación a la gestión de la pandemia, y la difusión de información a terceros que puedan utilizarla en sus entornos específicos. En este sentido, los temas más conceptuales y de definiciones quedan más en los entornos académicos y docentes, jugando el Ministerio de Sanidad un papel más secundario y no obrando dichos temas en su poder.

Finalmente, la evaluación de los pacientes en relación a su estado de salud, sea COVID-19 u otra enfermedad o patología, es competencia de los profesionales sanitarios de referencia. Los test, por si solos no suelen ser suficientes para determinar enfermedad, requiriéndose una evaluación experta de la persona a la que se le ha realizado el test. De cualquier manera, la definición de caso la puede encontrar en el siguiente enlace:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/COVID19_Estrategia_vigilancia_y_control_e_indicadores.pdf

Contra la presente resolución, que pone fin a la vía administrativa, podrá interponerse recurso contencioso-administrativo ante el órgano judicial competente [Ley 39/2015, de 1 de octubre, del procedimiento administrativo común de las administraciones públicas, y Ley 29/1998, de 13 de julio, reguladora de la jurisdicción contencioso-administrativa], en el plazo de dos meses o, previa y potestativamente, reclamación ante el Consejo de Transparencia y Buen Gobierno en el plazo de un mes; en ambos casos, el plazo se contará desde el día siguiente al de la notificación de la presente resolución.

LA DIRECTORA GENERAL DE SALUD PÚBLICA

Pilar Aparicio Azcárraga.

Con fecha 22 de julio de 2021, tuvo entrada en la Unidad de Información de Transparencia del Ministerio de Sanidad, su solicitud de acceso a la información pública al amparo de la Ley 19/2013, de 9 de diciembre, de Transparencia, Acceso a la información pública y Buen gobierno, solicitud que quedó registrada con el número 001-059144.

Con fecha 10 de agosto de 2021, esta solicitud se recibió en la Dirección General de Salud Pública, fecha a partir de la cual comienza a contar el plazo de un mes previsto en el artículo 20.1 de la Ley 19/2013 de 9 de diciembre, para su resolución. Con fecha 12 de agosto de 2021 se le notificó, escrito de ampliación de plazo por los motivos expuesto en el mismo precepto legal.

Una vez analizada su solicitud, esta Dirección General resuelve, conceder su derecho de acceso a la información. Le indicamos que los datos de los que dispone el Ministerio de Sanidad en relación a la pandemia por SARS-CoV-2 la puede encontrar en los siguientes enlaces:

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https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos.htm

En ellos puede acceder a distintos documentos de información científico técnica, procedimientos y medidas para la prevención y el control de la infección, preparación y respuesta a la pandemia, recomendaciones para el manejo clínico de casos, actuaciones en el contexto de la respuesta a la COVID-19 por ámbitos, colectivos y grupos, y aspectos de comunicación.

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https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/COVID19_Estrategia_vigilancia_y_control_e_indicadores.pdf

Las vacunas frente a COVID-19 se administran en España en estos momentos según la Estrategia de vacunación frente a COVID-19 en España [aprobada por el Consejo Interterritorial del Sistema Nacional de Salud], y son gratuitas para la ciudadanía. En este sentido no requieren receta médica. Puede consultar la Estrategia y sus actualizaciones, así como un resumen de las características de las vacunas y de su ficha técnica en el siguiente enlace:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/vacunaCovid19.htm

La eficacia de las vacunas se mide en términos ideales de laboratorio, y posteriormente se mide en la población real, una vez que las vacunas se han administrado. Puede encontrar información en el siguiente enlace:

CORREO ELECTRÓNICO

D I R E C C I Ó N
PASEO DEL PRADO 18-20 28014 MADRID
TELÉFONO:
FAX:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/20210820_INMUNIDAD_y_VACUNAS.pdf

También puede consultar estudios sobre este aspecto en la bibliografía de las Actualizaciones de la Estrategia, en especial de la 8.

https://www.mscbs.gob.es/profesionales/saludPublica/prevPromocion/vacunaciones/covid19/docs/COVID-19_Actualizacion8_EstrategiaVacunacion.pdf

Las reacciones a las vacunas se estudian a través de la farmacovigilancia. Puede consultar el tema en el siguiente enlace:

https://www.aemps.gob.es/la-aemps/ultima-informacion-de-la-aemps-acerca-del-covid%e2%80%9119/vacunas-contra-la-covid%e2%80%9119/farmacovigilancia-de-vacunas/informes-periodicos-de-farmacovigilancia-de-vacunas-covid-19/

Sobre secuenciación genómica del virus puede consultar el siguiente enlace:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/Integracion_de_la_secuenciacion_genomica-en_la_vigilancia_del_SARS-CoV-2.pdf

El Ministerio de Sanidad no dispone de cultivo de SARS-CoV-2 para ensayos, y no tiene un registro de los laboratorios con capacidad de cultivo y aislamiento para ensayos.

En relación a las pruebas diagnósticas de SARS-COV-2, y en general, con los temas relacionados con la pandemia por SARS-Cov-2, el Ministerio de Sanidad trabaja con los documentos antes mencionados, que se van actualizando según la necesidad epidemiológica, para posibilitar la toma de decisiones en relación a la gestión de la pandemia, y la difusión de información a terceros que puedan utilizarla en sus entornos específicos. En este sentido, los temas más conceptuales y de definiciones quedan más en los entornos académicos y docentes, jugando el Ministerio de Sanidad un papel más secundario y no obrando dichos temas en su poder.

Finalmente, la evaluación de los pacientes en relación a su estado de salud, sea COVID-19 u otra enfermedad o patología, es competencia de los profesionales sanitarios de referencia. Los test, por si solos no suelen ser suficientes para determinar enfermedad, requiriéndose una evaluación experta de la persona a la que se le ha realizado el test. De cualquier manera, la definición de caso la puede encontrar en el siguiente enlace:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/COVID19_Estrategia_vigilancia_y_control_e_indicadores.pdf

Contra la presente resolución, que pone fin a la vía administrativa, podrá interponerse recurso contencioso-administrativo ante el órgano judicial competente [Ley 39/2015, de 1 de octubre, del procedimiento administrativo común de las administraciones públicas, y Ley 29/1998, de 13 de julio, reguladora de la jurisdicción contencioso-administrativa], en el plazo de dos meses o, previa y potestativamente, reclamación ante el Consejo de Transparencia y Buen Gobierno en el plazo de un mes; en ambos casos, el plazo se contará desde el día siguiente al de la notificación de la presente resolución.

LA DIRECTORA GENERAL DE SALUD PÚBLICA

Pilar Aparicio Azcárraga.

AUTO-TRANSLATION

MINISTERY
OF HEALTH

SECRETARY OF STATE
OF HEALTH

GENERAL DIRECTORATE
OF PUBLIC HEALTH

PROCEEDINGS: 001-059144
DATE OF APPLICATION: July 22, 2021
DATE OF DOCUMENT: September 8, 2021

NUMBER….
NIF: ….
EMAIL: ….

On July 22, 2021, the Transparency Information Unit of the Ministry of Health received a request for access to public information under Law 19/2013, of December 9, on Transparency, Access to public information and Good governance, a request that was registered under number 001-059144.

On August 10, 2021, this request was received at the General Directorate of Public Health, date from which the one-month period provided for in article 20.1 of Law 19/2013 of December 9 begins to run, for resolution. On August 12, 2021, you were notified of a written extension of the term for the reasons set forth in the same legal provision.

Once your request has been analyzed, this General Directorate resolves to grant your right of access to information. We indicate that the data available to the Ministry of Health in relation to the SARS-CoV-2 pandemic can be found at the following links:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/home.htm

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos.htm

In them you can access different documents of technical scientific information, procedures and measures for the prevention and control of infection, preparation and response to the pandemic, recommendations for clinical case management, actions in the context of the response to COVID -19 by areas, collectives and groups, and communication aspects.

Specifically, in relation to the cycles of a PCR and antigen tests, you can consult the information in the following document:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/COVID19_Estrategia_vigilancia_y_control_e_indicadores.pdf

Vaccines against COVID-19 are administered in Spain at the moment according to the Vaccination Strategy against COVID-19 in Spain [approved by the Interterritorial Council of the National Health System], and are free for citizens. In this sense, they do not require a prescription. You can consult the Strategy and its updates, as well as a summary of the characteristics of the vaccines and their technical data sheet at the following link:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/vacunaCovid19.htm

The efficacy of vaccines is measured in ideal laboratory terms, and is subsequently measured in the actual population, once the vaccines have been administered. You can find information at the following link:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/20210820_INMUNIDAD_y_VACUNAS.pdf

You can also consult studies on this aspect in the bibliography of the Strategy Updates, especially 8.

https://www.mscbs.gob.es/profesionales/saludPublica/prevPromocion/vacunaciones/covid19/docs/COVID-19_Actualizacion8_EstrategiaVacunacion.pdf

Reactions to vaccines are studied through pharmacovigilance. You can check the topic at the following link:

https://www.aemps.gob.es/la-aemps/ultima-informacion-de-la-aemps-acerca-del-covid%e2%80%9119/vacunas-contra-la-covid%e2%80%9119/farmacovigilancia-de-vacunas/informes-periodicos-de-farmacovigilancia-de-vacunas-covid-19/

On genomic sequencing of the virus you can consult the following link:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/Integracion_de_la_secuenciacion_genomica-en_la_vigilancia_del_SARS-CoV-2.pdf

The Ministry of Health does not have a SARS-CoV-2 culture for testing, and it does not have a registry of laboratories with culture and isolation capacity for testing.

In relation to the SARS-COV-2 diagnostic tests, and in general, with issues related to the SARS-Cov-2 pandemic, the Ministry of Health works with the aforementioned documents, which are updated according to epidemiological need, to enable decision-making in relation to the management of the pandemic, and the dissemination of information to third parties that can use it in their specific environments. In this sense, the most conceptual and definitional issues remain more in academic and teaching environments, with the Ministry of Health playing a more secondary role and not acting on these issues in its power.

Finally, the evaluation of patients in relation to their state of health, be it COVID-19 or another disease or pathology, is the responsibility of the reference health professionals. The tests, by themselves, are not usually sufficient to determine disease, requiring an expert evaluation of the person who has been tested. Either way, the case definition can be found at the following link:

https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/COVID19_Estrategia_vigilancia_y_control_e_indicadores.pdf

Against this resolution, which puts an end to administrative proceedings, a contentious-administrative appeal may be filed before the competent judicial body [Law 39/2015, of October 1, on the common administrative procedure of public administrations, and Law 29/1998, of July 13, regulating the contentious-administrative jurisdiction], within a period of two months or, previously and optionally, a claim before the Council of Transparency and Good Governance within a period of one month; in both cases, the term will be counted from the day following the notification of this resolution.

THE GENERAL DIRECTOR OF PUBLIC HEALTH

Pilar Aparicio Azcárraga.

Registro Electrónico General de la AGE

administracion.gob.es
punto de acceso general

JUSTIFICANTE DE PRESENTACIÓN

Número de registro: 2021012163107
Oficina: O00000318 - REGISTRO ELECTRÓNICO
Fecha y hora de 10/02/2021 17:56:15
Tipo de registro: Entrada

Interesados

Interesado		Representante
Nombre:	KEPA MIRENA ORMAZABAL SANCHEZ	Nombre:
NIF:		
e-mail:	[redacted]	

Información del registro

Resumen: Derecho de acceso

Asunto: Solicitud Acceso Transparencia

Expone:

Solicita: [Ámbito] : UIT Sanidad (8)
[Información que solicita] : Todos los registros bibliográficos científicos en conocimiento del Ministerio de Sanidad y de los organismo dependientes de él en los que se describa el aislamiento del virus SARS-Cov2 directamente de muestras tomadas de pacientes diagnosticados de covid-19, vivos o muertos. La solicitud no se refiere a registros bibliográficos científicos basados en muestras que hayan sido mezcladas con otras fuentes de material genético, como, por ejemplo, células de riñón de simio o células de hígado canceroso. Nótese que se usa el término "aislamiento" en el sentido que le da el Diccionario la Real Academia Española de "dejar algo solo y separado de otras cosas" o "separar un elemento o un cuerpo de una combinación o del medio en que se halla, generalmente para identificarlo o analizarlo".

Por tanto, no estoy solicitando información sobre registros bibliográficos científicos sobre cultivos celulares, ni resultados de amplificación de material genético (ya sea por técnica PCR u otras) ni secuenciaciones de material genético.
[Notificaciones y recepción de la información] : Deseo ser notificado a través del Portal de la Transparencia
[Asunto] : aislamiento virus sars-cov2
[Notificacion Sede] : Por Sede

General Electronic Registry of the Age
inistracion.gob.es
general access point

PROOF OF PRESENTATION

Registration number:	2021012163107
Office:	000000318 - ELECTRONIC REGISTRATION
Date and time:	02/10/2021 17:56:15
Type of registration:	Entry

Interested

Interest

Name:	KEPA Ml RENA ORMAZABAL SANCHEZ
NIF:	(blank)
e-mail:	[redacted]
Representative:	(blank)

Registry information

Summary:	Right of Access
Affair:	Transparency Access Request

Exposes: (blank)

[Scope]: ITU HEALTH (8)

[Information requested]:

All scientific bibliographic records known to the Ministry of Health and its dependent organizations in which the isolation of the SARS-Cov2 virus is described directly from samples taken from patients diagnosed with covid-19, alive or dead. The application does not refer to scientific bibliographic records based on samples that have been mixed with other sources of genetic material, such as, for example, simian kidney cells or cancer liver cells. Note that the term "isolation" is used in the sense given by the Real Academia Espanola Dictionary of "leaving something alone and separated from other things" or "separating an element or a body from a combination or from the medium in which it is found, generally to identify or analyze it. "

Therefore, I am not requesting information on scientific bibliographic records on cell cultures, nor results of amplification of genetic material (either by PCR or other techniques) nor sequencing of genetic material.

[Notifications and receipt of information]: I wish to be notified through the Transparency Portal

[Subject]: sars-cov2 virus isolation

[Headquarters Notification]: By Headquarters

Con fecha 10 de febrero de 2021 tuvo entrada en la Unidad de Información de Transparencia del Ministerio de Sanidad, solicitud de acceso a la información pública al amparo de la Ley 19/2013, de 9 de diciembre, de transparencia, acceso a la información pública y buen gobierno, presentada por D./Dña. Kepa Mirena Ormazábal Sánchez, solicitud que quedó registrada con el número **001-053660**.

Con fecha 15 de febrero de 2021 esta solicitud se recibió en la Dirección General de Salud Pública, fecha a partir de la cual empieza a contar el plazo de un mes previsto en el artículo 20.1 de la Ley 19/2013, de 9 de diciembre, para su resolución.

Una vez analizada la solicitud, esta Dirección General resuelve conceder el acceso a la información a que se refiere la solicitud deducida por D./Dña. Kepa Mirena Ormazábal Sánchez.

La bibliografía científica que maneja el Ministerio de Sanidad la puede encontrar en los distintos documentos técnicos para profesionales publicados en la página web de este Ministerio [a la que puede acceder a través del siguiente enlace: https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos.htm] y, en concreto, en el apartado titulado *Documentos de preparación y respuesta al brote.*

Contra la presente resolución, que pone fin a la vía administrativa, podrá interponerse recurso contencioso-administrativo ante el la Sala de lo Contencioso-Administrativo del Tribunal Superior de Justicia de Madrid [Ley 39/2015, de 1 de octubre, del procedimiento administrativo común de las administraciones públicas, y Ley 29/1998, de 13 de julio, reguladora de la jurisdicción contencioso-administrativa], en el plazo de dos meses o, previa y potestativamente, reclamación ante el Consejo de Transparencia y Buen Gobierno en el plazo de un mes; en ambos casos, el plazo se contará desde el día siguiente al de la notificación de la presente resolución.

LA DIRECTORA GENERAL DE SALUD PÚBLICA
(firmado electrónicamente)

Pilar Aparicio Azcárraga

MINISTRY OF HEALTH

SECRETARIAT OF STATE OF HEALTH
GENERAL DIRECTORATE OF PUBLIC HEALTH
Transparency portal
Government of Spain

On February 10, 2021, it entered the Transparency Information Unit from the Ministry of Health, request for access to public information under the Law 19/2013, of December 9, on transparency, access to public information and good government, presented by D./Dña. Kepa Mirena Ormazábal Sánchez, request that remained registered under number 001-053660.

On February 15, 2021, this request was received at the General Directorate of Health Public, date from which the period of one month foreseen in the article begins to count. 20.1 of Law 19/2013, of December 9, for its resolution.

Once the request has been analyzed, this General irectorate resolves to grant access to the information referred to in the request deduced by Mr./Dña. Kepa Mirena Ormazábal Sanchez.

The scientific bibliography managed by the Ministry of Health can be found in the different technical documents for professionals published on the website of this Ministry (which you can access through the following link: https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos.htm] and, specifically, in the section entitled Preparation and response documents to the outbreak.

Against this resolution, which puts an end to administrative proceedings, an appeal may be lodged contentious-administrative before the Contentious-Administrative Chamber of the Court Superior of Justice of Madrid [Law 39/2015, of October 1, on the procedure common administrative law of public administrations, and Law 29/1998, of July 13, regulator of contentious-administrative jurisdiction], within two months or, prior and Optionally, claim before the Council of Transparency and Good Governance within the term of one month; In both cases, the period will be counted from the day following the notification of the present resolution.

THE GENERAL DIRECTOR OF PUBLIC HEALTH
(electronically signed)
Pilar Aparicio Azcárraga

REFID: KIB0123839 - VB: Sv: Tillgång till dokumentation gällande isolering och rening av SARS-COV-2

From: kib@ki.se <kib@ki.se>
To: John Blaid [redacted]
Cc: KI Registrator <registrator@ki.se>, KI Communicationsoffice <communicationsoffice@ki.se>
Date: 2021-10-18 11:45

Hej John!

Registrator och kommunikationsavdelningen på Karolinska Institutet har nu svarat att de inte har tillgång till dessa uppgifter.

För närvarande har universitetsbiblioteket inte möjlighet att utföra sökuppdrag åt externa kunder. Ett förslag är att göra en sökning i den fritt tillgängliga databasen PubMed. Om du har möjlighet att besöka oss kan du använda även andra databaser.
https://kib.ki.se/om-kib/kontakt-oppettider

I PubMed finns MeSH-termen SARS-CoV-2/isolation and purification, som f n ger 5251 referenser.
https://pubmed.ncbi.nlm.nih.gov/?term=%22SARS-CoV-2%2Fisolation+and+purification%22&sort=relevance

Vill du se vilka som arbetar med frågan på Karolinska Institutet eller Karolinska Universitetssjukhuset kan du lägga till Karolinska. Då blir det just nu 29 artiklar, Du hittar kontaktuppgifter till varje.
https://pubmed.ncbi.nlm.nih.gov/?term=%28%22SARS-CoV-2%2Fisolation+and+purification%22%29+AND+%28karolinska%29&size=50

Med vänlig hälsning

Johnny Carlsson
1:e bibliotekarie

Universitetsbiblioteket | Karolinska Institutet

https://kib.ki.se

Från: KI Communicationsoffice (communicationsoffice@ki.se)

Skickat: 2021-10-14 16:34:33

Ämne: VB: Sv: Tillgång till dokumentation gällande isolering och rening av SARS-COV-2

Meddelande:

Hej!
Detta meddelande har kommit till Karolinska Institutets e-postbrevlåda. Vi är tacksamma för hjälp med handläggning av frågan.
Med vänlig hälsning/Best regards
Anki Israelsson
Kommunikationsavdelningen/Communications and Public Relations Office Karolinska Institutet | ki.se
Karolinska Institutet – a medical university

Från: John Blaid [redacted] **Skickat:** den 13 oktober 2021 08:42 **Till:** KI Registrator <registrator@ki.se> **Ämne:** Re: Sv: Tillgång till dokumentation gällande isolering och rening av SARS-COV-2

Hej,

Det var 1 månad sen jag begärde dokumentation av er och jag har inte fått något svar än.
Med vänlig hälsning
John Blaid

From: KI Registrator <registrator@ki.se> **To:** 'John Blaid' [redacted] **Sent:** 2021-09-15 9:28 **Subject:** Sv: Tillgång till dokumentation gällande isolering och rening av SARS-COV-2

> Hej!
>
> Karolinska Institutet har mottagit din begäran och påbörjat handläggningen.
>
> Vänlig hälsning
> Frida
>
> **Frida Majling** | Registrator
> Juridiska avdelningen | Karolinska Institutet
> Nobels väg 5 | 171 77 Stockholm
> 08-524 865 95 | Vxl 08-524 800 00
> registrator@ki.se | ki.se
>
> _____
> Karolinska Institutet – ett medicinskt universitet

Från: John Blaid [redacted] **Skickat:** den 14 september 2021 20:43 **Till:** KI Registrator <registrator@ki.se> **Ämne:** Tillgång till dokumentation gällande isolering och rening av SARS-COV-2

> Hej,
>
> Har försök skicka detta email 2021-08-27 till er men vet inte om det kom fram då jag inte har fått något svar av er än så jag försöker igen.
>
> Detta är en formell begäran om tillgång till dokumentation
>
> **Beskrivning av begärd dokumentation:**
>
> Alla studier och/eller rapporter som Karolinska Institutet innehar, förvarar eller kontrollerar som beskriver **rening** (dvs. genom

filtrering och ultracentrifugering) av alla **"COVID-19-virus** " (även kallat "SARS-COV-2" inklusive eventuella påstådda "varianter", dvs "B.1.1.7", "B.1.351", "P.1") direkt från ett prov från en sjuk människa, där patientprovet **inte** först kombinerades med någon annan källa av **genetiskt** material (dvs apnjurceller aka Vero -celler; fetalt bovint serum).

Observera att jag **inte** begär studier/rapporter där forskare misslyckades med att **rena** det misstänkta "viruset" (separera det påstådda "viruset" från allt annat i patientprovet) och istället:

- odlade ett orenat prov eller annat orenat ämne, och/eller
- utförde ett amplifieringstest (dvs ett PCR -test) på det totala RNA från ett patientprov eller från en cellodling, eller på genetiskt material från orenat ämne, och/eller
- tillverkade ett genom baserat på PCR-detekterade sekvenser i det totala RNA från ett patientprov eller från en cellodling eller från någon orenad substans, och/eller
- producerade elektronmikroskopibilder av orenade saker i en cellkultur.

Förtydligande av begäran

För ytterligare klarhet, observera att jag redan är medveten om att i enlighet med virusteorin att ett ”virus” kräver värdceller för att replikera så jag begär **inte** dokument som beskriver **replikering** av ett ”virus” utan värdceller.

Dessutom begär jag **inte** privat patientinformation eller dokument som beskriver ett misstänkt "virus" som flyter i ett vakuum; Jag begär helt enkelt dokument som beskriver dess **rening** (**separering** från allt annat i patientprovet, enligt standardlaboratorium för rening av andra mycket små saker).
Observera att min begäran innefattar alla studier/rapporter som matchar ovanstående beskrivning, till exempel (men inte begränsat till) alla publicerade peer-reviewed studier som är **författade av någon, var som helst.**
Om något studie och/eller rapport matchar ovanstående beskrivning av begärd dokumentation och för närvarande är tillgänglig i det offentliga rummet, vänligen ange tillräckligt med information om varje dokument så att jag kan identifiera och komma åt var och en med säkerhet (dvs. titel, författare, datum, journal, där allmänheten kan komma åt den). Ange webbadresser där det är möjligt.
Dokument : Jag vill inte att ha något PDF -dokument skickat till mig via e-post.

Med vänlig hälsning John Blaid

Begäran om allmän handling John Blaid 2021-08-20

From: Info Folkhälsomyndigheten <info@folkhalsomyndigheten.se>
To: [redacted]
Date: 2021-08-24 9:33

Hej!
Nej, några sådana handlingar finns inte.

Med vänlig hälsning,
Registrator

Folkhälsomyndigheten
171 82 Solna

Folkhälsomyndigheten
Box 505
831 26 Östersund

Webbplats: http://www.folkhalsomyndigheten.se

Från: John Blaid[redacted]
Skickat: den 23 augusti 2021 15:54
Till: Info Folkhälsomyndigheten <info@folkhalsomyndigheten.se>
Ämne: Re: Svar - Begäran om allmän handling John Blaid 2021-08-20

Hej,

Så ni har inga allmänna handlingar eller potentiella allmänna handlingar men har ni några studier/rapporter som uppfyller min förfrågan nedan som **inte** är tillgänglig för allmänheten?

Med vänlig hälsning
John Blaid

From: Info Folkhälsomyndigheten <info@folkhalsomyndigheten.se>
To: [redacted]
Sent: 2021-08-23 8:13
Subject: Svar - Begäran om allmän handling John Blaid 2021-08-20

> Hej
>
> Det som efterfrågas finns inte sammanställt på myndigheten, vi har därför inga allmänna handlingar eller potentiella allmänna handlingar i frågan att lämna ut.
>
> Med vänlig hälsning,
> Registrator
>
> Folkhälsomyndigheten
> 171 82 Solna
>
> Folkhälsomyndigheten
> Box 505

831 26 Östersund

Webbplats: http://www.folkhalsomyndigheten.se

Från: John Blaid[redacted]
Skickat: den 20 augusti 2021 10:17
Till: Kundtjänst Mikrobiologen <kundtjanst.mikrobiologen@folkhalsomyndigheten.se>
Ämne: Tillgång till dokumentation gällande isolering och rening av “SARS-COV-2”

Detta är en formell begäran om tillgång till allmän dokumentation

Beskrivning av begärd dokumentation:
Alla studier och/eller rapporter som Folkhälsomyndigheten innehar, förvarar eller kontrollerar som beskriver **rening** (dvs. genom filtrering och ultracentrifugering) av alla **"COVID-19-virus** " (även kallat "SARS-COV-2" inklusive eventuella påstådda "varianter", dvs "B.1.1.7", "B.1.351", "P.1") direkt från ett prov från en sjuk människa, där patientprovet inte först kombinerades med någon annan källa av **genetiskt** material (dvs apnjurceller aka Vero -celler; fetalt bovint serum).
Observera att jag **inte** begär studier/rapporter där forskare misslyckades med att **rena** det misstänkta "viruset" (separera det påstådda "viruset" från allt annat i patientprovet) och istället:

- odlade ett orenat prov eller annat orenat ämne, och/eller
- utförde ett amplifieringstest (dvs ett PCR -test) på det totala RNA från ett patientprov eller från en cellodling, eller på genetiskt material från orenat ämne, och/eller
- tillverkade ett genom baserat på PCR-detekterade sekvenser i det totala RNA från ett patientprov eller från en cellodling eller från någon orenad substans, och/eller
- producerade elektronmikroskopibilder av orenade saker i en cellkultur.

Förtydligande av begäran
För ytterligare klarhet, observera att jag redan är medveten om att i enlighet med virusteorin att ett ”virus” kräver värdceller för att replikera så jag begär **inte** dokument som beskriver **replikering** av ett ”virus” utan värdceller.
Dessutom begär jag **inte** privat patientinformation eller dokument som beskriver ett misstänkt "virus" som flyter i ett vakuum; Jag begär helt enkelt dokument som beskriver dess **rening** (**separering** från allt annat i patientprovet, enligt standardlaboratorium för rening av andra mycket små saker).

Observera att min begäran innefattar alla studier/rapporter som matchar ovanstående beskrivning, till exempel (men inte begränsat till) alla publicerade peer-reviewed studier som är **författade av någon, var som helst.**

Om något studie och/eller rapport matchar ovanstående beskrivning av begärd dokumentation och för närvarande är tillgänglig i det offentliga rummet, vänligen ange tillräckligt med information om varje dokument så att jag kan identifiera och komma åt var och en med säkerhet (dvs. titel, författare, datum, journal, där allmänheten kan komma åt den). Ange webbadresser där det är möjligt.

Format :
Pdf -dokument skickade till mig via e -post; Jag önskar inte att något ska skickas till mig.

Med vänlig hälsning

John Blaid

Covid-19 virus isolation Romanian National Institute of Public Health

[redacted] Mon, Jan 31, 2022 at 11:36 AM
Reply-To: [redacted]
To: cmssyc@gmail.com
Cc: crgeditor@yahoo.com

Dear Mrs. Massey,

We recently sent a freedom of information inquiry to the Romanian Ministry of Health in order to show us what evidence they possess, documented in research papers, regarding the isolation and purification of the SARS-COV-2 (Covid-19) virus. Our request was based on the detailed inquiry model provided by you at the end of this web page:

https://www.globalresearch.ca/foi-reveal-health-science-institutions-around-world-have-no-record-sars-cov-2-isolation-purification-anywhere-ever/5751969

We thus specified several criteria for excluding all research papers claiming virus isolation but employing in the process vero monkey kidney cells, bovine fetal serum, etc. Basically, we requested only research papers who claim isolation and purification of a substance which consists of the SARS-COV-2 virus (or any variants) obtained from a sample belonging to a diseased human being and host cells (of human origin).

The attached swift reply from the Romanian National Institute of Public Health, also countersigned by the Romanian Center for Disease Control, does not appear to have taken seriously our detailed criteria. They provided the following research papers, currently available online:

https://www.nejm.org/doi/full/10.1056/nejmoa2001017

https://www.cdc.gov/coronavirus/2019-ncov/lab/grows-virus-cell-culture.html

https://www.nature.com/articles/s41586-020-2012-7

https://pubmed.ncbi.nlm.nih.gov/32979576/

https://www.nature.com/articles/s41586-020-2665-2

None of these papers appear to satisfy our isolation criteria, so the Romanian health authorities served us a nothingburger instead of aknowledging they have no records of proper virus isolation. Please confirm on your end if our insights are correct and eventually update your article on GlobalResearch.ca with this new info.

Thank you and we admire your work and dedication regarding this subject.

Yours truly,

Teodor George

------- Original Message -------
Subject: ref adresa info dovezi stiintifice covid
Date: 2022-01-28 12:06
From: "Comunicare" <comunicare@insp.gov.ro>

To: <[redacted]>
Cc: <presa2@ms.ro>, <relatii.publice@ms.ro>

Buna ziua,

Primiti atasat raspunsul adresei dumneavoastra inregistrata la INSP cu nr 1469/27.01.2022.

Cu stima,

Compartiment Comunicare

---

2 attachments

ref adresa dl George Teodor.pdf
463K

Cerere legea 544 din 2000.pdf
138K

Cerere de informații de interes public

Denumirea autorității sau instituției publice: Ministerul Sănătății

Sediul/Adresa: Str. Cristian Popişteanu, nr. 1-3, sector 1, cod 010024, Bucureşti

Data: 18 ianuarie 2022

Stimate Domnule Ministru Rafila,

Prin prezenta formulez o cerere conform Legii nr. 544/2001 privind liberul acces la informațiile de interes public, cu modificările și completările ulterioare. Doresc să primesc o copie a următoarelor documente:

Toate studiile de cercetare transpuse în articole ştiinţifice aflate în posesia ministerului şi a instituţiilor subordonate (Institutul Naţional de Sănătate Publică, CNSCBT, etc.) care demonstrează izolarea şi purificarea "virusului Covid-19" (numit şi "SARS-COV-2" - incluzînd oricare variantă sau tulpină). **Pentru clarificări, a se vedea instrucţiunile alăturate.**

Doresc ca informațiile solicitate să îmi fie furnizate:

Pe e-mail, la adresa [redacted]	X
Pe e-mail în format editabil PDF la adresa [redacted]	X
Pe format de hârtie, la adresa.....	

.....

Sunt dispus să plătesc costurile aferente serviciilor de copiere a documentelor solicitate (dacă se solicită copii în format scris).

Vă mulțumesc pentru solicitudine,

.....
semnătura petentului (opțional)

Numele și prenumele petentului: [redacted]

Adresa la care se solicită primirea răspunsului/e-mail: [redacted]

Telefon: [redacted]

Detaliere cerere referitoare la studiile privind izolarea si purificarea virusului Sars-CoV-2

Stimate Domnule Ministru Rafila,

Descrierea cererii:

Toate studiile de cercetare transpuse în articole ştiinţifice aflate în posesia ministerului şi a instituţiilor subordonate (Institutul Naţional de Sănătate Publică, CNSCBT, etc.) care demonstrează izolarea şi purificarea "virusului Covid-19" (numit şi "SARS-COV-2" - incluzînd oricare variantă sau tulpină), obţinut dintr-o mostră de material biologic de la un om bolnav. Această mostră de material biologic prelevată de la un om bolnav nu trebuie să fi fost în nici un caz denaturată prin amestecare cu material genetic străin provenind de la alte specii de vieţuitoare (de ex. celule vero obţinute de la primate, ser fetal bovin etc.).

Mai precizăm că nu cerem studii sau articole unde cercetătorii nu au izbutit să izoleze virusul SARS-COV-2, ci au reuşit doar :

- Cultivarea in vitro a ceva, şi/sau
- Realizarea unui test de amplificare (ex. RT-PCR), şi/sau
- Fabricarea unui genom din aşa zise secvenţieri ale unor substanţe eterogene (nepurificate), şi/sau
- Producerea unor imagini la microscopul electronic ale unor amestecuri eterogene (nepurificate);

Sîntem la curent cu faptul că, potrivit teoriilor referitoare la virusuri, aceştia necesită celule gazdă pentru a se înmulţi; în acest sens, nu cerem studii sau articole ştiinţifice care descriu înmulţirea unui virus fără celule gazdă. Mai mult, nu cerem documentaţie care descrie o strictă îndeplinire a Postulatelor lui Koch, sau lucrări care descriu un potenţial virus ce ar pluti în vid, sau informaţii confidenţiale referitoare la sănătate ale unor pacienţi.

Solicităm numai lucrări de specialitate care descriu un proces de purificare, adică separarea unui virus de restul substanţelor conţinute într-o mostră provenind de la un pacient bolnav, după practicile standard de laborator în ce priveşte purificarea substanţelor la nivel microscopic.

Pe cale de consecinţă, cererea noastră are ca obiect oricare lucrare ştiinţifică care nu este descalificată în raport cu criteriile de mai sus, publicată de oricine, oriunde în lume.

În cazul în care documentele solicitate se pot regăsi în spaţiul public, vă rugăm să ne furnizaţi informaţii îndestulătoare în vederea identificării acestora (titluri, autori, dată, publicaţie şi URL-uri, acolo unde este cazul).

Mulţumesc.

Cu stimă,

[redacted]

AUTO-TRANSLATION

Request for information of public interest

Name of public authority or institution: Ministry of Health

Headquarters / Address: Str. Cristian Popişteanu, no. 1-3, sector 1, code 010024, Bucharest

Date: January 18, 2022

Dear Minister Rafila,

I hereby formulate a request according to Law no. 544/2001 regarding the free access to information of public interest, with subsequent amendments and completions. I would like to receive a copy of the following documents:

All research studies transposed into scientific articles in possession ministry and subordinate institutions (National Institute of Public Health, CNSCBT, etc.) which demonstrates the isolation and purification of the "Covid-19 virus" (called and "SARS-VOC-2" - including any variant or strain). **For clarification, see the instructions below.**

I would like the requested information to be provided to me:

By e-mail to [redacted] X

E-mail in editable PDF format to [redacted] X

On paper, at Address..... .....

I am willing to pay for the copying services requested (if written copies are requested).

Thank you for your request, ...

petitioner's signature (optional)

Name and surname of the petitioner: Georgexxxxxx Teodor

Address to which the reply is requested / e-mail: info@fortistradxxxxxxers.com

Phone: 031630xxxx1065

Detailed application for studies on the isolation and purification of Sars- virus CoV-2

Dear Minister Rafila,

Application description:

All research studies transposed into scientific articles in the possession of the ministry and of subordinate institutions (National Institute of Public Health, CNSCBT, etc.) which demonstrates the isolation and purification of the “Covid-19 virus” (also called “SARS-VOC-2” - including any variant or strain), obtained from a sample of biological material from a sick man. This sample of biological material taken from a sick person does not it must in no case have been distorted by mixing with foreign genetic material from other living species (eg primate cells obtained from primates, ser fetal bovine etc.).

We also point out that we do not ask for studies or articles where researchers have not been able to isolate SARS-VOC-2 virus, but only succeeded in:

- In vitro culture of something, and / or

- Performing an amplification test (eg RT-PCR), and / or
- Manufacture of a genome from so-called sequencers of heterogeneous substances (unpurified), and / or
- Production of electron microscopic images of heterogeneous mixtures (unpurified);

We are aware that, according to theories about viruses, they require host cells to multiply; In this regard, we do not require scientific studies or articles which describe the proliferation of a virus without host cells. Moreover, we do not require documentation describing a strict fulfillment of Koch's Postulates, or works describing a potential virus that would float in a vacuum, or confidential health information of the some patients.

We only request specialized works that describe a purification process, ie separation of a virus from the rest of the substances contained in a sample from a sick patient, according to standard laboratory practices for purification substances at the microscopic level.

Consequently, our request concerns any scientific paper that does not is disqualified from the above criteria, published by anyone, anywhere in the world.

If the required documents can be found in the public space, please provide sufficient information to identify them (titles, authors, date, publication and URLs, where applicable).
Thanks.
Regards,
[redacted]

MINISTERUL SĂNĂTĂȚII
INSTITUTUL NAȚIONAL DE SĂNĂTATE PUBLICĂ
NATIONAL INSTITUTE OF PUBLIC HEALTH

Str. Dr. Leonte nr. 1-3, 050463, București, ROMÂNIA
Tel: (401) 021 318 36 20, director (401) 021 318 36 19, fax (401) 021 312 34 26
e-mail: directie.generala@insp.gov.ro

CĂTRE
[redacted]
E-mail [redacted]

Spre informare,
Ministerul Sănătății
Direcția Relații cu Presa, Afaceri Europene și Relații Internaționale

Ca urmare a adresei dumneavoastră, înregistrată la INSP cu nr 1469/27.01.2022, vă transmitem, mai jos, link-urile pe care le puteți accesa în vederea obținerii informațiilor solicitate respectiv, dovezile științifice privind izolarea virusului în cultură.

Stelzer-Braid S, Walker GJ, Aggarwal A, Isaacs SR, Yeang M, Naing Z, Ospina Stella A, Turville SG, Rawlinson WD. Virus isolation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) for diagnostic and research purposes. Pathology. 2020 Dec;52(7):760-763. doi: 10.1016/j.pathol.2020.09.012. Epub 2020 Oct 8. PMID: 33131800; PMCID: PMC7543926.

Francis R, Le Bideau M, Jardot P, Grimaldier C, Raoult D, Bou Khalil JY, La Scola B. High-speed large-scale automated isolation of SARS-CoV-2 from clinical samples using miniaturized co-culture coupled to high-content screening. Clin Microbiol Infect. 2021 Jan;27(1):128.e1-128.e7. doi: 10.1016/j.cmi.2020.09.018. Epub 2020 Sep 23. PMID: 32979576; PMCID: PMC7510445.

https://www.cdc.gov/coronavirus/2019-ncov/lab/grows-virus-cell-culture.html

https://www.nejm.org/doi/full/10.1056/nejmoa2001017

Zhou, P., Yang, XL., Wang, XG. et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin. Nature 579, 270–273 (2020). https://doi.org/10.1038/s41586-020-2012-7

Harcourt J, Tamin A, Lu X, Kamili S, Sakthivel SK, Murray J, et al. Severe Acute Respiratory Syndrome Coronavirus 2 from Patient with Coronavirus Disease, United States. Emerg Infect Dis. 2020;26(6):1266-1273. https://doi.org/10.3201/eid2606.200516

Ke, Z., Oton, J., Qu, K. et al. Structures and distributions of SARS-CoV-2 spike proteins on intact virions. Nature 588, 498–502 (2020). https://doi.org/10.1038/s41586-020-2665-2.

Stelzer-Braid S, Walker GJ, Aggarwal A, et al. Virus isolation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) for diagnostic and research purposes. Pathology. 2020;52(7):760-763. doi:10.1016/j.pathol.2020.09.012.

Cu stimă,

Director General,
Dr. Simona Pârvu

Director CNSCBT,
Dr. Anca Sîrbu

Medic şef secţie SCBT,
Dr. Lavinia Zota

Compartiment Comunicare,
Veronica Zoicaş

正　本

檔　　號：
保存年限：

發文日期：中華民國111年1月17日
發文字號：疾管檢驗字第1110030890號
主旨：署長信箱民眾意見-信件編號:202201090000006-Thank you for responding to my request 20220102000

[redacted]

Thank you for your email dated January 9, 2022. Our reply to your inquiry is as follows:

We did not purify SARS-CoV2 viruses from original specimens or virus culture.In Taiwan CDC the SARS-CoV2 is detected by using real-time RT-PCR.

If you have further questions regarding COVID-19, you can visit Taiwan CDC's website at http://www.cdc.gov.tw.

Best regards,

Taiwan Centers for Disease Control

[redacted]

副本：cdcwwwod@cdc.gov.tw

裝

訂

線

[redacted]

感謝您 2022 年 1 月 9 日的來信，以下是我們的回復：

我們沒有從原始標本或培養的病毒中純化SARS-CoV2病毒，而是使用real-time RT-PCR進行 SARS-CoV2 檢測。

如您需要其他 COVID-19 相關訊息，歡迎至本署全球資訊網首頁之「嚴重特殊傳染性肺炎（COVID-19）」防疫專區（http://www.cdc.gov.tw 首頁 > 傳染病與防疫專題 > 傳染病介紹 > 第五類法定傳染病嚴重特殊傳染性肺炎）查閱。

衛生福利部疾病管制署 敬復

DIRECTORATE FOR COVID PUBLIC HEALTH
COVID : COVID Ready Society

Scottish Government
Riaghaltas na h-Alba
gov.scot

Mr [redacted]
[redacted]

Our Reference: 202200277454

15 February 2022

Dear Mr [redacted]

REQUEST UNDER THE FREEDOM OF INFORMATION (SCOTLAND) ACT 2002 (FOISA)

Thank you for your request dated 01 February 2022 under the Freedom of Information (Scotland) Act 2002 (FOISA).

Your request

You asked for:

'All records in possession, custody or control of Scottish Government describing the isolation of a SARS-COV-2 virus, directly from a sample taken from a diseased patient, where the patient sample was not first combined with any source of genetic material (i.e. monkey kidney cells aka 'vero cells', liver cancer cells).
Please note I am using 'isolation' in the every-day sense of the word; the act of separating a thing(s) from everything else. I am not requesting records where 'isolation of SARS-COV-2' refers instead to:

- *the culturing of something, or*
- *the performance of an amplification test (i.e. a PCR test), or*
- *the sequencing of something.*

To clarify, I am requesting all such records that are in possession, custody or control of Scottish Government (i.e. downloaded to a computer, printed, in hard copy etc).
Please note my request is not limited to records that were authored by the Scottish Government or that pertain to work done by the Scottish Government. My request includes any sort of record, (i.e. but not limited to any published peer-reviewed study that the Scottish Government has downloaded or printed).
If any records match the above description of requested records and are currently available to the

public elsewhere, please provide enough information about each record so that I may identify and access each record with certainty (i.e. title, author(s), date, journal, where the public may access).'

Response to your request

This is a formal notice under **Section 17(1)** of FOISA that the Scottish Government does not have the information you have requested.

Throughout the epidemic, having a clear route for synthesising scientific evidence and presenting that to Government is important. To do this, scientific advice is provided by the Scottish Government COVID-19 Advisory Group. In addition, the Scottish Government is informed by SAGE, and its sub groups of which further details can be found on the UK Government website.

To assist you with your query, multiple scientific papers that are publicly accessible, have documented that they were able to isolate SARS-CoV-2, the causative agent of Covid-19. The hyperlink provided will direct you to some of the papers that detail the isolation of the virus.

Your right to request a review

If you are unhappy with this response to your FOI request, you may ask us to carry out an internal review of the response, by writing to Richard Foggo, Covid-19 Directorate, St Andrews House, Edinburgh, EH1 3DG or by emailing Richard.Foggo@gov.scot.

Your review request should explain why you are dissatisfied with this response, and should be made within 40 working days from the date when you received this letter. We will complete the review in accordance with FOISA as soon as possible, and not later than 20 working days from the day following the date we receive your review request.

If you are not satisfied with the result of the review, you then have the right to appeal to the Scottish Information Commissioner. More detailed information on your appeal rights is available on the Commissioner's website here.

Yours sincerely

Jason Carroll
Covid Ready Society

Subject **Re: Fwd: FOI -Switzerland- Purified SARS-CoV-2: no record**
From [redacted]
To <christinem@fluoridefreepeel.ca>
Date 2022-02-23 11:15 AM

roundcube

- CH-BAG-(FOPH)-Request-and-answer_geschw.pdf (~263 KB)
- CH-IVI-1-Request_geschw.pdf (~218 KB)
- CH-IVI-2-Answer-Bgö Gesuch NN_geschw.pdf (~299 KB)
- CH-Labor-Spiez-(FOCP)-Request-and-answer_geschw.pdf (~280 KB)
- CH-Virusisolation-FOPH-IVI-FOCP.pdf (~607 KB)

Hi Christine,

at last I am sending you the promised answer to my FOIA-requests. Actually I have three answers of official Swiss offices. At the IVI there works Prof. Volker Thiel who seems to be a big shot at the SARS-CoV-2-front. He built the "virus" on his platform to build things out of RNA/DNA.

Is it okay that I redacted the e-mails myself? Or do you need the unredacted ones?
The answer from IVI has two parts.
The file "CH-Virusisolation-FOPH-IVI-FOCP.pdf" contains all the answers.
At the end of each document, on a separate page, I've added a translation to English. I did not translate my request, it is essentially your sample, translated as precisely as possible.

I have another answer from the canton of Zurich, but they essentially tell me, that they just have to execute what the federal government is ordering. In Switzerland, health is a matter of the cantons, the states, not a federal matter. Only because the federal government announced a "special situation", they can govern the cantons. And the canton Zurich told me, that they cannot question what the federal government is telling them to do.

Thanks again for your work and hosting all these answers.

Cheers,
[redacted]

Betreff: Ihr Gesuch vom 17. Oktober 2021 - Einsicht in Akten - gereinigtes Virus - Antwort
Von: <lorenz.overhage@bag.admin.ch>
Datum: 23.11.2021, 11:34
An: [redacted]@gmx.ch>

Sehr geehrter Herr [redacted]
zurückkommend auf Ihr Zugangsgesuch vom 17. Oktober 2021 nach Öffentlichkeitsgesetz (BGÖ; SR 152.3) darf ich Ihnen mitteilen, dass beim BAG keine Dokumente zum gewünschten Inhalt vorhanden sind.

Wir betrachten Ihr Gesuch als erledigt und weisen Sie darauf hin, dass Sie gestützt auf Art. 13 BGÖ die Möglichkeit haben, unsere Antwort durch die Schlichtungsstelle überprüfen zu lassen, indem Sie innerhalb von 20 Tagen nach Empfang dieser Mitteilung schriftlich einen Schlichtungsantrag stellen (Eidgenössischer Datenschutz- und Öffentlichkeitsbeauftragter EDÖB, Feldeggweg 1, 3003 Bern, www.edoeb.admin.ch).

Lorenz Overhage
MLaw

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit BAG
Abteilung Recht

Schwarzenburgstrasse 157,
CH-3003 Bern
Tel. +41 58 469 08 63
lorenz.overhage@bag.admin.ch
www.bag.admin.ch

Von: Overhage Lorenz BAG
Gesendet: Freitag, 5. November 2021 17:23
An: [redacted]@gmx.ch>
Betreff: WG: Ihr Gesuch vom 17. Oktober 2021 - Einsicht in Akten - gereinigtes Virus - Fristverlängerung

Sehr geehrter Herr [redacted]

Wir beziehen uns auf Ihr Zugangsgesuch vom 17. Oktober 2021 nach Öffentlichkeitsgesetz (BGÖ; SR 152.3).

Das BAG ist seit Monaten mit der Bewältigung der Coronakrise ausserordentlich hoch belastet. Es ist uns daher nicht möglich, Ihr Gesuch innerhalb der gesetzlichen Fristen zu beantworten. Uns fehlen dazu bis auf Weiteres schlicht die notwendigen Ressourcen. Die krisenbedingten Aufgaben, die Umsetzung der damit zusammenhängenden Massnahmen und die intensiven Abklärungen im Rahmen der aktuellen Lage haben gegenwärtig absoluten Vorrang und dürfen nicht durch andere Aufgaben beeinträchtigt werden.

Das BGÖ sieht die Möglichkeit vor, die Bearbeitung aufzuschieben, wenn die Behörde das Gesuch mit den verfügbaren Ressourcen nicht zu behandeln vermag. Das ist in der jetzigen Krisensituation der Fall. Daher schieben wir die Beantwortung Ihres Gesuches gestützt auf Art. 10 Abs. 4 Bst. c BGÖ und Art. 10 Öffentlichkeitsverordnung (VBGÖ; SR 152.31) bis zum **26. 11. 2021** auf. Angesichts der momentanen Situation erscheint uns diese Frist notwendig und angemessen. Trotz dieser grundsätzlichen Aufschiebung werden wir Ihnen selbstverständlich je nach Arbeitsanfall und Bearbeitungsaufwand nach Möglichkeit bereits vor Mitte Juli 2021 die gewünschten Dokumente zukommen lassen.

Wir hoffen auf Ihr Verständnis für die besondere Situation. Selbstverständlich steht es Ihnen frei, unsere Haltung durch die Schlichtungsstelle überprüfen zu lassen und gestützt auf Art. 13 BGÖ innerhalb von 20 Tagen nach Erhalt dieser Mitteilung schriftlich einen Schlichtungsantrag zu stellen (Eidgenössischer Datenschutz- und Öffentlichkeitsbeauftragter EDÖB, Feldeggweg 1, 3003 Bern; www.edoeb.admin.ch).

Mit bestem Dank für Ihr Verständnis und freundlichen Grüssen

Lorenz Overhage
MLaw

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit BAG
Abteilung Recht

Schwarzenburgstrasse 157,
CH-3003 Bern
Tel. +41 58 469 08 63
lorenz.overhage@bag.admin.ch
www.bag.admin.ch

Von: Liechti Federica BAG
Gesendet: Mittwoch, 20. Oktober 2021 11:38
An: [redacted]@gmx.ch>
Betreff: Ihr Gesuch vom 17. Oktober 2021 - Einsicht in Akten - gereinigtes Virus - Eingangsbestätigung

Sehr geehrter Herr [redacted]
Wir bestätigen Ihnen den Eingang Ihres untenstehenden Zugangsgesuches.
Wir bearbeiten es so rasch wie möglich. Sollte sich abzeichnen, dass wir die gesetzliche Antwortfrist nicht einhalten können, werden wir Sie rechtzeitig informieren.
Freundliche Grüsse

Federica Liechti
lic.iur.

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit BAG
Abteilung Recht, Rechtsbereich 3

Schwarzenburgstrasse 157
CH-3003 Bern
Tel. +41 58 462 94 94
mailto:federica.liechti@bag.admin.ch
http://www.bag.admin.ch/

-----Ursprüngliche Nachricht-----
Von: [redacted]@gmx.ch>
Gesendet: Sonntag, 17. Oktober 2021 23:16
An: _BAG-GEVER <gever@bag.admin.ch>
Betreff: Gesuch um Einsicht in Akten - gereinigtes Virus - Bundesamts für Gesundheit

Sehr geehrter Herr Overhage
Sehr geehrte Damen und Herren

Folgender Einleitungs-Satz in einem Paper zur mathematischen Modellierung der Übertragungs-Modi von Influenzaviren hat mich veranlasst, mich mit Viren etwas genauer zu beschäftigen:
"Influenza is a long-standing public health concern, but its transmission remains poorly understood."
Dieses Paper wurde 2018 veröffentlicht: Xiao et al., 2018, Probable transmission routes of

the influenza virus in a nosocomial outbreak, https://doi.org/10.1017/S0950268818001012. Wenn die Übertragung von Influenza-Viren, welche seit über hundert Jahren bekannt zu sein scheinen, unklar ist, wie ist es dann möglich, dass wir über SARS-CoV-2 in den knapp zwei Jahren seiner Bekanntheit dermassen viel mit Sicherheit wissen, dass wir gravierendste Eingriffe in das Leben der Menschen mit diesem Wissen rechtfertigen können? Ist dieses Wissen wirklich gesichert? Die Politik hat sich entschieden, auf Grund des Wissens über ein Virus etliche einschneidende Massnahmen zu ergreifen, die Gesellschaft in ihren Grundfesten zu gefährden und dutzende von Milliarden Franken auszugeben, a-fonds-perdu. Deshalb ist anzunehmen und gleichsam zu fordern, dass die Existenz dieses Virus ohne Zweifel bewiesen wurde und entsprechende Studien, die seine Existenz und seine Pathogenität zweifelsfrei belegen, vorhanden sind.

Das Bundesgesetz über das Öffentlichkeitsprinzip der Verwaltung (BGÖ) hat zum Grundsatz, die Transparenz in der Bundesverwaltung zu fördern.
In diesem Sinne bitte ich Sie, mir gestützt auf BGÖ und Öffentlichkeitsverordnung (VBGÖ) Einsicht in das Folgende zu gewähren:

Beschreibung der angeforderten Dokumente:

Alle Studien und/oder Berichte, die sich im Besitz, in der Obhut oder unter der Kontrolle des Bundesamts für Gesundheit (BAG) befinden und in denen die Reinigung/Purifikation des sog. Virus "SARS-CoV-2" (auch bekannt als "COVID-19-Virus" oder in der Sprache der Gesundheitsdirektion des Kantons Zürich als "SARS-CoV-19" benannt, einschließlich aller angeblichen "Varianten") direkt aus einer aus einem erkrankten Menschen entnommenen Probe beschrieben wird, wobei die Patientenprobe vor der Reinigung/Purifikation zuvor nicht mit einer anderen Quelle genetischen Materials (z. B. Nierenzellen von Affen, auch bekannt als Vero-Zellen, fötales Rinderserum) vermischt wurde.

Klarstellung der Anfrage:

Bitte beachten Sie, dass ich keine Studien/Berichte anfordere, bei denen die Forscher es unterlassen haben, das vermutete "Virus" zu reinigen, d.
h. von allem anderen abzutrennen, und stattdessen:

- etwas kultiviert haben, und/oder
- einen Amplifikationstest (z.B. PCR) durchgeführt haben, und/oder
- ein Genom aus Sequenzen fabriziert haben, die in einer unreinen Substanz entdeckt wurden, und/oder
- elektronenmikroskopische Bilder von nicht gereinigten Dingen erstellt haben.

Mir ist bekannt, dass ein "Virus" nach der geltenden Virentheorie Wirtszellen benötigt, um sich zu vermehren, und ich fordere keine Unterlagen an, die die Vermehrung eines "Virus" ohne Wirtszellen beschreiben. Ich fordere auch keine Unterlagen an, die die strikte Erfüllung der Koch'schen Postulate beschreiben, oder Unterlagen, die ein mutmassliches "Virus" beschreiben, das in einem Vakuum schwimmt, oder private Patienteninformationen.

Ich fordere lediglich Unterlagen an, in denen die Reinigung beschrieben wird, d. h. die Abtrennung des angeblichen Virus von allem anderen in der Patientenprobe, wie es in der Laborpraxis Standard ist für die Reinigung von anderen sehr kleinen Dingen.

Bitte beachten Sie, dass meine Anfrage jede Studie und jeden Bericht einschließt, welche der obigen Beschreibung entsprechen, egal von wem und wo sie verfasst wurden.

Wenn Dokumente, die der obigen Beschreibung der angeforderten Dokumente entsprechen, derzeit öffentlich zugänglich sind, bitte ich um die Angabe von ausreichender Information, damit ich sie mit Sicherheit identifizieren und abrufen kann (d. h. Titel, Autoren, Datum, Name der Zeitschrift, DOI). Sie können auch URLs angeben.

Angesichts der Wichtigkeit der Anfrage sollten die Dokumente, die verlangt werden, bereits vorhanden sein und somit schnell produzierbar sein.

Bitte senden Sie mir die Unterlagen in elektronischer Form zu.

Ich bitte Sie, von der Erhebung einer Gebühr abzusehen, so wie dies die Gebührenverordnung in Fällen von «überwiegendem öffentlichem Interesse» vorsieht. Bei einem besonderen Informationsinteresse der Öffentlichkeit ist auch laut der Empfehlung der Generalsekretärenkonferenz vom 22.
November 2013 ein Gebührenverzicht angezeigt.

Schliesslich bitte ich Sie, mir den Eingang meines Gesuchs kurz schriftlich zu bestätigen.

Mit freundlichen Grüssen
[redacted]

Translation:

Dear Mr.,
In response to your request for access dated 17 October 2021 in accordance with the Federal Act on the Freedom of Information (FoIA; SR 152.3), I would like to inform you that the FOPH does not have any documents with the requested content.

We consider your request to be settled and would like to point out that, based on Art. 13 FoIA, you have the possibility of having our answer reviewed by the conciliation body by submitting a request for conciliation in writing within 20 days of receipt of this communication. ...

Lorenz Overhage
MLaw

Betreff: WG: Gesuch um Einsicht in Akten - gereinigtes Virus - IVI
Von: <barbara.wieland@ivi.admin.ch>
Datum: 19.01.2022, 09:13
An: [redacted]@gmx.ch>

Sehr geehrter Herr [redacted]

Besten Dank für Ihr Interesse an unserer Arbeit.
Wir haben ihr Gesuch betreffend Einsicht in Akten zu gereinigtem Virus geprüft, unsere Antwort finden Sie im Anhang.

Mit freundlichen Grüssen

Barbara Wieland, Dr. med. vet., PhD
Institutsleiterin IVI

Eidgenössisches Departement des Innern EDI
Institut für Virologie und Immunologie IVI
In Kooperation mit der Vetsuisse-Fakultät der Universität Bern

CH-3147 Mittelhäusern, Schweiz
Tel: +41 58 469 9230
barbara.wieland@ivi.admin.ch
www.ivi.admin.ch

-----Ursprüngliche Nachricht-----
Von: [redacted]@gmx.ch>
Gesendet: Montag, 17. Januar 2022 12:16
An: _IVI-Info <info@ivi.admin.ch>
Betreff: Gesuch um Einsicht in Akten - gereinigtes Virus - IVI

Sehr geehrte Damen und Herren

Das Bundesgesetz über das Öffentlichkeitsprinzip der Verwaltung (BGÖ) hat zum Grundsatz, die Transparenz in der Bundesverwaltung zu fördern.
In diesem Sinne bitte ich Sie, mir gestützt auf BGÖ und Öffentlichkeitsverordnung (VBGÖ) Einsicht in das Folgende zu gewähren:

Beschreibung der angeforderten Dokumente:

Alle Studien und/oder Berichte, die sich im Besitz, in der Obhut oder unter der Kontrolle des Instituts für Virologie und Immunologie (IVI) befinden und in denen die Reinigung/Purifikation des sog. Virus "SARS-CoV-2" (auch bekannt als "COVID-19-Virus" oder in der Sprache der Gesundheitsdirektion des Kantons Zürich als "SARS-CoV-19" benannt, einschließlich aller angeblichen "Varianten") direkt aus einer aus einem erkrankten Menschen entnommenen Probe beschrieben wird, wobei die Patientenprobe vor der Reinigung/Purifikation zuvor nicht mit einer anderen Quelle genetischen Materials (z. B. Nierenzellen von Affen, auch bekannt als Vero-Zellen, fötales Rinderserum) vermischt wurde.

Klarstellung der Anfrage:

Bitte beachten Sie, dass ich keine Studien/Berichte anfordere, bei denen die Forscher es unterlassen haben, das vermutete "Virus" zu reinigen, d.
h. von allem anderen abzutrennen, und stattdessen:

- etwas kultiviert haben, und/oder
- einen Amplifikationstest (z.B. PCR) durchgeführt haben, und/oder
- ein Genom aus Sequenzen fabriziert haben, die in einer unreinen Substanz entdeckt wurden, und/oder
- elektronenmikroskopische Bilder von nicht gereinigten Dingen erstellt haben.

Mir ist bekannt, dass ein "Virus" nach der geltenden Virentheorie Wirtszellen benötigt, um sich zu vermehren, und ich fordere keine Unterlagen an, die die Vermehrung eines "Virus" ohne Wirtszellen beschreiben. Ich fordere auch keine Unterlagen an, die die strikte Erfüllung der Koch'schen Postulate beschreiben, oder Unterlagen, die ein mutmassliches "Virus" beschreiben, das in einem Vakuum schwimmt, oder private Patienteninformationen.

Ich fordere lediglich Unterlagen an, in denen die Reinigung beschrieben wird, d. h. die Abtrennung des angeblichen Virus von allem anderen in der Patientenprobe, wie es in der Laborpraxis Standard ist für die Reinigung von anderen sehr kleinen Dingen.

Bitte beachten Sie, dass meine Anfrage jede Studie und jeden Bericht einschließt, welche der obigen Beschreibung entsprechen, egal von wem und wo sie verfasst wurden.

Wenn Dokumente, die der obigen Beschreibung der angeforderten Dokumente entsprechen, derzeit öffentlich zugänglich sind, bitte ich um die Angabe von ausreichender Information, damit ich sie mit Sicherheit identifizieren und abrufen kann (d. h. Titel, Autoren, Datum, Name der Zeitschrift, DOI). Sie können auch URLs angeben.

Angesichts der Wichtigkeit des Erfragten sollten die Dokumente, die verlangt werden, bereits vorhanden und somit schnell produzierbar sein.

Bitte senden Sie mir die Unterlagen in elektronischer Form zu.

Ich bitte Sie, von der Erhebung einer Gebühr abzusehen, so wie dies die Gebührenverordnung in Fällen von «überwiegendem öffentlichem Interesse» vorsieht. Bei einem besonderen Informationsinteresse der Öffentlichkeit ist auch laut der Empfehlung der Generalsekretärenkonferenz vom 22. November 2013 ein Gebührenverzicht angezeigt.

Schliesslich bitte ich Sie, mir den Eingang meines Gesuchs kurz schriftlich zu bestätigen.

Mit freundlichen Grüssen
[redacted]

Anhänge:

Bgö Gesuch [redacted].pdf 235 KB

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössisches Departement des Innern EDI
Institut für Virologie und Immunologie IVI

CH-3147 Mittelhäusern, IVI

Herr [redacted]
Email: [redacted]@gmx.ch

Sachbearbeiter/in: Barbara Wieland
Mittelhäusern, 19. Januar 2022

Zugangsgesuch nach dem Bundesgesetz über das Öffentlichkeitsprinzip der Verwaltung (BGÖ; SR 152.3)

Sehr geehrter Herr [redacted]

Sie haben am 17. Januar 2022 ein Zugangsgesuch nach dem Bundesgesetz über das Öffentlichkeitsprinzip der Verwaltung (BGÖ; SR 152.3) eingereicht. Darin fordern Sie den Zugang zu alle Studien und/oder Berichten, in denen die Reinigung/Purifikation des sog. Virus SARS-CoV-2/ SARS-CoV-19 (oder andere Varianten) direkt aus einer aus einem erkrankten Menschen entnommenen Probe beschrieben wird, wobei die Patientenprobe vor der Reinigung/Purifikation zuvor nicht mit einer anderen Quelle genetischen Materials vermischt wurde.

Da unser Institut für Virologie und Immunologie (IVI) nicht für die Diagnose von SARS-Cov-2 zuständig ist, erhalten wir keine Proben von Patienten. Wir haben deshalb in unserem Institut selber kein SARS-Cov-2 Virus aus Patientenproben isoliert. Für die Forschung, die am IVI durchgeführt wird, erhalten wir jeweils Viren, die von anderen Laboratorien isoliert wurden. Wir verfügen demnach nicht über die von Ihnen gewünschten Dokumente oder Berichte, d.h. es liegt kein amtliches Dokument nach Art. 5 BGÖ vor, welches wir Ihnen zugänglich machen können.

Freundliche Grüsse

B Wieland

Barbara Wieland, Dr. med. vet, PhD
Institutsleiterin

Institut für Virologie und Immunologie IVI
Barbara Wieland
Sensemattstrasse 293, 3147 Mittelhäusern
Tel. +41 58 46 99 211, Fax +41 58 46 99 222
barbara.wieland@ivi.admin.ch
www.ivi.admin.ch

In Kooperation mit
der Vetsuisse Fakultät Bern
UNIVERSITÄT BERN

Translation:

Request for access pursuant to the Federal Act on the Principle of Public Access to Administrative Documents (FPA; SR 152.3)

Dear Mr.

On 17 January 2022, you submitted an access request in accordance with the Federal Act on Freedom of Information in the Administration (Freedom of Information Act, FoIA; SR 152.3). In it, you request access to all studies and/or reports describing the purification/purification of the so-called SARS-CoV-2/ SARS-CoV-19 virus (or other variants) directly from a sample taken from a diseased human, where the patient sample has not been previously mixed with any other source of genetic material prior to purification/purification.

Since our Institute of Virology and Immunology (IVI) is not responsible for the diagnosis of SARS-Cov-2, we do not receive samples from patients. Therefore, we have not isolated SARS-Cov-2 virus from patient samples ourselves at our institute. For research conducted at the IVI, we receive viruses isolated by other laboratories. We therefore do not have the documents or reports you requested, i.e. there is no official document according to Art. 5 FoIA which we can make available to you.
Kind regards

Barbara Wieland, Dr. med. vet, PhD
Head of Institute

Betreff: AW: WG: BGÖ-Gesuch um Einsicht in Akten - gereinigtes Virus - Labor Spiez
Von: <eliane.brogini@babs.admin.ch>
Datum: 28.01.2022, 14:57
An: [redacted]@gmx.ch>
Kopie (CC): <labor-spiez@babs.admin.ch>, <claudia.geiger@babs.admin.ch>

Sehr geehrter Herr [redacted]

Vielen Dank für Ihre Anfrage und für Ihr Interesse an den Aufgaben und Tätigkeiten des Labor Spiez.

Das Bundesamt für Bevölkerungsschutz hat keine amtlichen Dokumente erstellt, die den von Ihnen beschriebenen Anforderungen (Ziffer 2) entsprechen.

In der wissenschaftlichen Fachliteratur gibt es hingegen inzwischen eine Vielzahl von Publikationen, in denen die Isolierung von SARS-Cov-2-Viren beschrieben worden ist. Nur als Beispiel finden Sie in der Anlage eine Publikation aus Nature, einer der weltweit angesehensten Zeitschriften für Naturwissenschaften (Wölfel, R., Corman, V.M., Guggemos, W. et al. Virological assessment of hospitalized patients with COVID-2019. Nature 581, 465–469 (2020).

Wir weisen Sie darauf hin, dass Sie nach Artikel 13 BGÖ die Möglichkeit haben, innerhalb von 20 Tagen nach Erhalt dieser Mitteilung schriftlich einen Schlichtungsantrag an die Schlichtungsbehörde zu stellen (Eidgenössischer Datenschutz- und Öffentlichkeitsbeauftragter EDÖB, Feldeggweg 1, 3003 Bern; www.edoeb.admin.ch) und unsere oben dargelegte Haltung überprüfen zu lassen.

Für allfällige Fragen stehen wir gerne zur Verfügung.

Freundliche Grüsse,
Eliane Brogini

-----Ursprüngliche Nachricht-----
Von: [redacted]@gmx.ch>
Gesendet: Dienstag, 25. Januar 2022 10:18
An: Brogini Eliane BABS <eliane.brogini@babs.admin.ch>
Betreff: Re: WG: Gesuch um Einsicht in Akten - gereinigtes Virus - Labor Spiez

Sehr geehrte Frau Brogini

Vielen herzlichen Dank für Ihre schnelle Antwort.

Das ist sehr schade. Bitte erlauben Sie mir deshalb, mein Gesuch nach BGÖ um folgende zwei Anfragen zu ergänzen:

1. Bitte senden Sie mir andere als "amtliche Dokumente", über welche Sie verfügen und die den im Gesuch vom 21. Januar 2022 beschriebenen Anforderungen entsprechen.

2. Bitte senden Sir mir Dokumente, über welche Sie verfügen, welche die Existenz des SARS-CoV-2 belegen. Diese Dokumente müssen, um nachvollziehbar sein zu können, eine genaue Beschreibung der Methoden zur Gewinnung und Darstellung des SARS-CoV-2 beinhalten.

Ich danke Ihnen vielmals für Ihre Bemühungen.

Mit freundlichen Grüssen
[redacted]

Am 25.01.2022 um 08:45 schrieb eliane.brogini@babs.admin.ch:

> Sehr geehrter Herr [redacted]
>
> Besten Dank für Ihr Gesuch um Einsicht in Akten gemäss Bundesgesetz über das Öffentlichkeitsprinzip der Verwaltung.
> Wir verfügen über keine amtlichen Dokumente, die den von Ihnen beschriebenen Anforderungen entsprechen.
>
> Freundliche Grüsse,
> Eliane Brogini
>
> ---
> -
>
> Eliane Brogini, lic. iur., LL.M.
> Juristin / Stv. Chefin Recht
>
> Eidgenössisches Departement für Verteidigung, Bevölkerungsschutz und
> Sport VBS Bundesamt für Bevölkerungsschutz BABS
>
> Guisanplatz 1B, 3003 Bern
> Tel +41 58 465 03 86
> Fax +41 58 462 59 89
> Mailto:eliane.brogini@babs.admin.ch
> www.bevoelkerungsschutz.ch
>
> Hinweis zur Vertraulichkeit:
>
> Diese Nachricht und ihr eventuell angehängte Dateien sind nur für den Adressaten bestimmt. Sie kann vertrauliche oder

gesetzlich geschützte Daten oder Informationen beinhalten. Falls Sie diese Nachricht irrtümlich erreicht hat, bitten wir Sie höflich, diese unter Ausschluss jeglicher Reproduktion zu löschen und die absendende Person zu benachrichtigen. Danke für Ihre Hilfe.

This message and any attached files are for the sole use of the recipient named above. It may contain confidential or legally protected data or information. If you have received this message in error, please delete it without making any copies whatsoever and notify the sender. Thank you for your assistance.

-----Ursprüngliche Nachricht-----
Von: [redacted]@gmx.ch>
Gesendet: Freitag, 21. Januar 2022 16:02
An: _BABS-Labor Spiez <labor-spiez@babs.admin.ch>
Betreff: Gesuch um Einsicht in Akten - gereinigtes Virus - Labor Spiez

Sehr geehrte Damen und Herren

Das Bundesgesetz über das Öffentlichkeitsprinzip der Verwaltung (BGÖ) hat zum Grundsatz, die Transparenz in der Bundesverwaltung zu fördern.
In diesem Sinne bitte ich Sie, mir gestützt auf BGÖ und Öffentlichkeitsverordnung (VBGÖ) Einsicht in das Folgende zu gewähren:

Beschreibung der angeforderten Dokumente:

Alle Studien und/oder Berichte, die sich im Besitz, in der Obhut oder unter der Kontrolle des Instituts für Virologie und Immunologie (IVI) befinden und in denen die Reinigung/Purifikation des sog. Virus "SARS-CoV-2" (auch bekannt als "COVID-19-Virus" oder in der Sprache der Kantonsärztin des Kantons Zürich als "SARS-CoV-19" benannt, einschliesslich aller angeblichen "Varianten") direkt aus einer aus einem erkrankten Menschen entnommenen Probe beschrieben wird, wobei die Patientenprobe vor der Reinigung/Purifikation zuvor nicht mit einer anderen Quelle genetischen Materials (z. B. Nierenzellen von Affen, auch bekannt als Vero-Zellen, fötales Rinderserum) vermischt wurde.

Klarstellung der Anfrage:

Bitte beachten Sie, dass ich keine Studien/Berichte anfordere, bei denen die Forscher es unterlassen haben, das vermutete "Virus" zu reinigen, d.
h. von allem anderen abzutrennen, und stattdessen:

- etwas kultiviert haben, und/oder
- einen Amplifikationstest (z.B. PCR) durchgeführt haben, und/oder
- ein Genom aus Sequenzen fabriziert haben, die in einer unreinen Substanz entdeckt wurden, und/oder
- elektronenmikroskopische Bilder von nicht gereinigten Dingen erstellt haben.

Mir ist bekannt, dass ein "Virus" nach der geltenden Virentheorie Wirtszellen benötigt, um sich zu vermehren, und ich fordere keine Unterlagen an, die die Vermehrung eines "Virus" ohne Wirtszellen beschreiben. Ich fordere auch keine Unterlagen an, die die strikte Erfüllung der Koch'schen Postulate beschreiben, oder Unterlagen, die ein mutmassliches "Virus" beschreiben, das in einem Vakuum schwimmt, oder private Patienteninformationen.

Ich fordere lediglich Unterlagen an, in denen die Reinigung beschrieben wird, d. h. die Abtrennung des angeblichen Virus von allem anderen in der Patientenprobe, wie es in der Laborpraxis Standard ist für die Reinigung von anderen sehr kleinen Dingen.

Bitte beachten Sie, dass meine Anfrage jede Studie und jeden Bericht einschliesst, welche der obigen Beschreibung entsprechen, egal von wem und wo sie verfasst wurden.

Wenn Dokumente, die der obigen Beschreibung der angeforderten Dokumente entsprechen, derzeit öffentlich zugänglich sind, bitte ich um die Angabe von ausreichender Information, damit ich sie mit Sicherheit identifizieren und abrufen kann (d. h. Titel, Autoren, Datum, Name der Zeitschrift, DOI). Sie können auch URLs angeben.

Angesichts der Wichtigkeit des Erfragten sollten die Dokumente, die verlangt werden, bereits vorhanden und somit schnell produzierbar sein.

Bitte senden Sie mir die Unterlagen in elektronischer Form zu.

Ich bitte Sie, von der Erhebung einer Gebühr abzusehen, so wie dies die Gebührenverordnung in Fällen von «überwiegendem öffentlichem Interesse» vorsieht. Bei einem besonderen Informationsinteresse der Öffentlichkeit ist auch laut der Empfehlung der Generalsekretärenkonferenz vom 22.
November 2013 ein Gebührenverzicht angezeigt.

Schliesslich bitte ich Sie, mir den Eingang meines Gesuchs kurz schriftlich zu bestätigen.

Mit freundlichen Grüssen
[redacted]

Anhänge:

COVID-2019.pdf 3.0 MB

Translation:

First answer on 01/25/2022:

Dear Mr.
Thank you for your request to inspect files in accordance with the Federal Act
on Freedom of Information in the Administration.
We do not have any official documents that meet the requirements you have described.
Kind regards,
Eliane Brogini

Specification on 01/25/2022:

Dear Mrs. Brogini
Thank you very much for your quick reply.
This is a great pity. Therefore, please allow me to add the following two requests to my FoIA-request:
1. Please send me other than "official documents" that you have and that meet the requirements described in the request of January 21st 2022.
2. Please send me documents that prove the existence of SARS-CoV-2. These documents must, in order to be comprehensible, include a detailed description of the methods used to obtain and to present the SARS-CoV-2.
Thank you very much for your efforts.
Kind regards

Second answer on 01/28/2022:

Dear Mr.
Thank you for your inquiry and for your interest in the tasks and activities of Spiez Laboratory.
The Federal Office for Civil Protection has not produced any official documents that meet the requirements you have described (point 2).
In the scientific literature, on the other hand, there are now a large number of publications in which the isolation of SARS Cov-2 viruses has been described. Just as an example, please find enclosed a publication from Nature, one of the world's most respected journals for natural sciences (Wölfel, R., Corman, V.M., Guggemos, W. et al. Virological assessment of hospitalized patients with COVID-2019. Nature 581, 465-469 (2020).
...
Please do not hesitate to contact us if you have any questions.
Kind regards,
Eliane Brogini