From: Anna P Durbin [adurbin1@jhu.edu]
Sent: 9/14/2020 8:04:12 AM
To: Levine, Myron [Mlevine@som.umaryland.edu]
CC: Salim Abdullah [sabdulla@ihi.or.tz]; mimi darko (b)(6) @yahoo.co.uk]; rosanna.lagos@adsl.tie.cl; Stanley Plotkin [stanley.plotkin@vaxconsult.com]; Treanor, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=043d9cf65ad94fa49d37b1522637a0af-HHS-John.Tr]; John Treanor [John_Treanor@URMC.Rochester.edu]; Peter Kremsner [peter.kremsner@uni-tuebingen.de]; Robert Sauerwein [robert.sauerwein@radboudumc.nl]; Vincente Estrada [vicente.estrada@salud.madrid.org]; Yaseen Arabi (b)(6) @yahoo.com]; Punnee Pitisuttithum [punnee.pit@mahidol.ac.th]; vrati@rcb.res.in; 石正丽 [zlshi@wh.iov.cn]; Kanta Subbarao [kanta.subbarao@influenzacentre.org]; Zeb Jamrozik [zeb.jamrozik@monash.edu]; d.king@wellcome.ac.uk; Halvor Sommerfelt [Halvor.Sommerfelt@uib.no]; HENAO RESTREPO, Ana Maria [henaorestrepoa@who.int]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Charlie Weller [C.Weller@wellcome.ac.uk]; Anastazia Older Aguilar (Anastazia.OlderAguilar@gatesfoundation.org) [Anastazia.OlderAguilar@gatesfoundation.org]; cristina.cassetti@nih.gov; Laurie, Ximena (lauriex@who.int) [lauriex@who.int]; Mafunga, Neddy (mafungan@who.int) [mafungan@who.int]; Small, Dottie [Dsmall@som.umaryland.edu]
Subject: Re: UPDATE ON OUR MANUSCRIPT IN PRESS IN CID

Thanks so much Mike - quite an accomplishment with everything going on!
Anna

Anna Durbin, M.D.
Professor, International Health

Johns Hopkins Bloomberg School of Public Health
624 N. Broadway, Room 251
(w) 410-614-4736
www.centerforimmunizationresearch.org

DISCLAIMER: This e-mail is intended only for the individual to whom it is addressed. It may be used only in accordance with applicable laws. If you received this e-mail in error notify the sender and destroy the email.

On Sep 13, 2020, at 1:00 AM, Levine, Myron <Mlevine@som.umaryland.edu> wrote:

External Email - Use Caution

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Warm regards to all,

Mike
<ciaa1290 (1)-GALLEYS with corrections.pdf><Mannheim on behalf of One Day Sooner.pdf>

From: Halvor Sommerfelt [Halvor.Sommerfelt@uib.no]
Sent: 9/13/2020 4:45:58 AM
To: Levine, Myron [Mlevine@som.umaryland.edu]
CC: Abdulla, Salim (sabdulla@ihi.or.tz) [sabdulla@ihi.or.tz]; mimi darko (b)(6) @yahoo.co.uk]; 'rosanna.lagos@adsl.tie.cl' [rosanna.lagos@adsl.tie.cl]; adurbin1@jhu.edu; Stanley Plotkin [stanley.plotkin@vaxconsult.com]; Treanor, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=043d9cf65ad94fa49d37b1522637a0af-HHS-John.Tr]; John_Treanor@URMC.Rochester.edu; Peter Kremsner (peter.kremsner@uni-tuebingen.de) [peter.kremsner@uni-tuebingen.de]; robert.sauerwein@radboudumc.nl; vicente.estrada@salud.madrid.org; (b)(6) @yahoo.com; Punnee Pitisuttithum [punnee.pit@mahidol.ac.th]; vrati@rcb.res.in; 石正丽 [zlshi@wh.iov.cn]; Subbarao, Kanta [kanta.subbarao@influenzacentre.org]; zeb.jamrozik@monash.edu; d.king@wellcome.ac.uk; sabdulla@ihi.or.tz; HENAO RESTREPO, Ana Maria [henaorestrepoa@who.int]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Charlie Weller [C.Weller@wellcome.ac.uk]; D.King@wellcome.ac.uk; Anastazia Older Aguilar (Anastazia.OlderAguilar@gatesfoundation.org) [Anastazia.OlderAguilar@gatesfoundation.org]; 'cristina.cassetti@nih.gov' [cristina.cassetti@nih.gov]; Laurie, Ximena (lauriex@who.int) [lauriex@who.int]; Mafunga, Neddy (mafungan@who.int) [mafungan@who.int]; Small, Dottie [Dsmall@som.umaryland.edu]
Subject: RE: UPDATE ON OUR MANUSCRIPT IN PRESS IN CID

Thank you, Mike, also for all this effort!

I think it's great that you are managing to correct the figures for the voting from what is given in https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1290/5898660. The important message is already there; "the AG was split approximately in half....." but, apparently, some people disregard it and quote what a (simple) majority said.

Please do not worry about the slight discrepancy re. the number of appendices. If people wonder, they'll ask and we can explain/send them the three appendices. Thanx, Anna for preparing the synopsis, which will be great help for readers.

Best regards from

Halvor

-----Original Message-----
From: Levine, Myron <Mlevine@som.umaryland.edu>
Sent: Sunday, September 13, 2020 7:00 AM
To: Abdulla, Salim (sabdulla@ihi.or.tz) <sabdulla@ihi.or.tz>; mimi darko (b)(6) @yahoo.co.uk>; 'rosanna.lagos@adsl.tie.cl' <rosanna.lagos@adsl.tie.cl>; adurbin1@jhu.edu; Stanley Plotkin <stanley.plotkin@vaxconsult.com>; Treanor, John (OS/ASPR/BARDA) (CTR) <John.Treanor@hhs.gov>; John_Treanor@URMC.Rochester.edu; Peter Kremsner (peter.kremsner@uni-tuebingen.de) <peter.kremsner@uni-tuebingen.de>; robert.sauerwein@radboudumc.nl; vicente.estrada@salud.madrid.org; (b)(6) @yahoo.com; Punnee Pitisuttithum <punnee.pit@mahidol.ac.th>; vrati@rcb.res.in; 石正丽 <zlshi@wh.iov.cn>; Subbarao, Kanta <kanta.subbarao@influenzacentre.org>; zeb.jamrozik@monash.edu; d.king@wellcome.ac.uk; Halvor Sommerfelt <Halvor.Sommerfelt@uib.no>; sabdulla@ihi.or.tz; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; philip.krause@fda.hhs.gov; Charlie Weller <C.Weller@wellcome.ac.uk>; D.King@wellcome.ac.uk; Anastazia Older Aguilar (Anastazia.OlderAguilar@gatesfoundation.org) <Anastazia.OlderAguilar@gatesfoundation.org>; 'cristina.cassetti@nih.gov' <cristina.cassetti@nih.gov>
Cc: Laurie, Ximena (lauriex@who.int) <lauriex@who.int>; Mafunga, Neddy (mafungan@who.int) <mafungan@who.int>; Small, Dottie <Dsmall@som.umaryland.edu>
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From: 石正丽 [zlshi@wh.iov.cn]
Sent: 9/13/2020 4:26:07 AM
To: Levine, Myron [Mlevine@som.umaryland.edu]
CC: Abdulla, Salim (sabdulla@ihi.or.tz) [sabdulla@ihi.or.tz]; mimi darko (b)(6) @yahoo.co.uk]; 'rosanna.lagos@adsl.tie.cl' [rosanna.lagos@adsl.tie.cl]; adurbin1@jhu.edu; Stanley Plotkin [stanley.plotkin@vaxconsult.com]; Treanor, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=043d9cf65ad94fa49d37b1522637a0af-HHS-John.Tr]; John_Treanor@URMC.Rochester.edu; Peter Kremsner (peter.kremsner@uni-tuebingen.de) [peter.kremsner@uni-tuebingen.de]; robert.sauerwein@radboudumc.nl; vicente.estrada@salud.madrid.org; (b)(6) @yahoo.com; Punnee Pitisuttithum [punnee.pit@mahidol.ac.th]; vrati@rcb.res.in; Subbarao, Kanta [kanta.subbarao@influenzacentre.org]; zeb.jamrozik@monash.edu; d.king@wellcome.ac.uk; ' Halvor Sommerfelt' [Halvor.Sommerfelt@uib.no]; HENAO RESTREPO, Ana Maria [henaorestrepoa@who.int]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Charlie Weller [C.Weller@wellcome.ac.uk]; Anastazia Older Aguilar (Anastazia.OlderAguilar@gatesfoundation.org) [Anastazia.OlderAguilar@gatesfoundation.org]; 'cristina.cassetti@nih.gov' [cristina.cassetti@nih.gov]; Laurie, Ximena (lauriex@who.int) [lauriex@who.int]; Mafunga, Neddy (mafungan@who.int) [mafungan@who.int]; Small, Dottie [Dsmall@som.umaryland.edu]
Subject: Re: FW: UPDATE ON OUR MANUSCRIPT IN PRESS IN CID

Thanks, well done.

"'Levine, Myron'" <Mlevine@som.umaryland.edu>写道：
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>
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From: Subbarao, Kanta [kanta.subbarao@influenzacentre.org]
Sent: 9/13/2020 1:23:04 AM
To: Levine, Myron [Mlevine@som.umaryland.edu]; Abdulla, Salim (sabdulla@ihi.or.tz) [sabdulla@ihi.or.tz]; mimi darko (b)(6) @yahoo.co.uk]; 'rosanna.lagos@adsl.tie.cl' [rosanna.lagos@adsl.tie.cl]; adurbin1@jhu.edu; Stanley Plotkin [stanley.plotkin@vaxconsult.com]; Treanor, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=043d9cf65ad94fa49d37b1522637a0af-HHS-John.Tr]; John_Treanor@URMC.Rochester.edu; Peter Kremsner (peter.kremsner@uni-tuebingen.de) [peter.kremsner@uni-tuebingen.de]; robert.sauerwein@radboudumc.nl; vicente.estrada@salud.madrid.org; (b)(6) @yahoo.com; Punnee Pitisuttithum [punnee.pit@mahidol.ac.th]; vrati@rcb.res.in; 石正丽 [zlshi@wh.iov.cn]; zeb.jamrozik@monash.edu; d.king@wellcome.ac.uk; ' Halvor Sommerfelt' [Halvor.Sommerfelt@uib.no]; sabdulla@ihi.or.tz; HENAO RESTREPO, Ana Maria [henaorestrepoa@who.int]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Charlie Weller [C.Weller@wellcome.ac.uk]; D.King@wellcome.ac.uk [d.king@wellcome.ac.uk]; Anastazia Older Aguilar (Anastazia.OlderAguilar@gatesfoundation.org) [Anastazia.OlderAguilar@gatesfoundation.org]; 'cristina.cassetti@nih.gov' [cristina.cassetti@nih.gov]
CC: Laurie, Ximena (lauriex@who.int) [lauriex@who.int]; Mafunga, Neddy (mafungan@who.int) [mafungan@who.int]; Small, Dottie [Dsmall@som.umaryland.edu]
Subject: Re: UPDATE ON OUR MANUSCRIPT IN PRESS IN CID

Thank you Mike and others who helped get this massive effort completed.

Best wishes,
Kanta

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WARNING: This message originated from outside the Northern/Melbourne/Western Health e-mail network. The sender cannot be validated. Caution is advised. Contact IT Services for more information.

From: Krause, Philip [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=00C6330FEA0042FDB5571C3FDEF792ED-KRAUSE]
Sent: 9/22/2020 5:13:09 PM
To: rbaric@email.unc.edu
Subject: brief chat

Hi Ralph, I left a message on your assistant's voicemail—would you have a moment to chat? You can reach me on my cellphone: (b)(6) Thanks! Phil

From: William Dowling [william.dowling@cepi.net]
Sent: 11/24/2020 7:27:49 AM
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Subject: Agenda for WHO working group on COVID-19 assays

Hello all

Here is the agenda for tomorrow's meeting of the WHO working group on COVID-19 assays:

1. David Eyre form Oxford University will talk about the paper "Antibodies to SARS-CoV-2 are associated with protection against reinfection " doi: https://doi.org/10.1101/2020.11.18.20234369
2. Updates:
a. Simon Funnell - update on the working group on SARS-COV-2 propagation
b. Mark page- update on the work towards an International Standard
c. Any other updates from the group
3. Discussion on future topics

Best regards
Bill

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Sensitivity: CEPI Internal

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Subject: Verizon is killing my family using 5G cellular radiation. Your family is next.

Verizon is installing 5G antennas on light poles next to my house to kill my family by causing cancer. Your family comes next.

Studies have repeatedly shown that cell phone radiation is unsafe and causes cancer. Big Telecom is corrupting the science to lie and kill for profit.

Google appropriately displays an ad showing a cancer-stricken child at St.Jude hospital, above an article on cell phone antennas on light/telephone poles.

https://time.com/5069317/california-mobile-phone-radiation/

https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/EHIB/CDPH%20Document%20Library/Cell-Phone-Guidance.pdf

Report of final results regarding brain and heart tumors in Sprague-Dawley rats exposed from prenatal life until natural death to mobile phone radio frequency field representative of a 1.8 GHz GSM base station environmental emission.
https://www.ncbi.nlm.nih.gov/pubmed/29530389

CONCLUSIONS:
The RI findings on far field exposure to RFR are consistent with and reinforce the results of the NTP study on near field exposure, as both reported an increase in the incidence of tumors of the brain and heart in RFR-exposed Sprague-Dawley rats. These tumors are of the same histotype of those observed in some epidemiological studies on cell phone users. These experimental studies provide sufficient evidence to call for the re-evaluation of IARC conclusions regarding the carcinogenic potential of RFR in humans.

National Institute of Environmental Health Sciences (NIEHS)/National Toxicology Program (NTP)

High Exposure to Radio Frequency Radiation Associated With Cancer in Male Rats

https://www.niehs.nih.gov/news/newsroom/releases/2018/november1/index.cfm

"We believe that the link between radio frequency radiation and tumors in male rats is real, and the external experts agreed," said Bucher.

The carcinogenic potential of non-ionizing radiations: The cases of S-50 Hz MF and 1.8 GHz GSM radio frequency radiation.

https://www.ncbi.nlm.nih.gov/pubmed/30801980

Association between vestibular schwannomas and mobile phone use

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3907669/

FCC's fake science meets reality

WHO

https://www.iarc.fr/wp-content/uploads/2018/07/pr208_E.pdf

"The WHO/International Agency for Research on Cancer (IARC) has classified radiofrequency electromagnetic fields as possibly carcinogenic to humans (Group 2B),based on an increased risk for glioma, a malignant type of brain cancer, associated with wireless phone use."

FCC

The following FCC site says:

https://www.fcc.gov/engineering-technology/electromagnetic-compatibility-division/radio-frequency-safety/faq/rf-safety#Q5

"It is generally agreed that further research is needed to determine the generality of such effects and their possible relevance, if any, to human health."

"research is continuing"

"The FDA, which has primary jurisdiction for investigating mobile phone safety, has stated that it cannot rule out the possibility of risk, but if such a risk exists, "it is probably small." "

That's called speculation, not science, from the same corrupted FDA.

"Further, it has stated that, while there is no proof that cellular telephones can be harmful, concerned individuals can take various precautionary actions, including limiting conversations on hand-held cellular telephones and

making greater use of telephones with hands-free kits where there is a greater separation distance between the user and the radiating antenna."

"no proof that cellular telephones can be harmful"? That is **UNACCEPTABLE NONSENSE**. We want proof that cellular telephones/antennas **ARE HARMLESS** before **ANY DEPLOYMENT**.

Taking that advise from the FDA we demand that such "small cell" antennas NOT be installed, so we can get a greater separation distance between the user and the radiating antenna**.**

"The Government Accountability Office (GAO) prepared a report of its investigation into safety concerns related to mobile phones.
The report concluded that further research is needed to confirm whether mobile phones are completely safe for the user."

The **SAFETY SCIENCE SIMPLY DOES NOT EXIST**. Without the science, you CANNOT create a safety specification. So the current "specifications" are ridiculous, arbitrary, PROVEN TO BE DANGEROUS and ABSOLUTELY UNACCEPTABLE.

The corrupted, incompetent FCC should STOP LYING about RF safety. We have to demand that all such cell installations be IMMEDIATELY BANNED AND TORN DOWN until the UNCORRUPTED SCIENCE is completed.

Reality

After several childhood cancer cases at one school, parents question radiation from cell tower

https://www.cbsnews.com/news/cell-tower-shut-down-some-california-parents-link-to-several-cases-of-childhood-cancer/

Firefighters suffer neurological disorders

https://www.iaff.org/om/cell-tower-radiation-health-effects/

How much abuse can the human body take? Pesticide-laden food, rocket fuel in drinking water, polluted air, dirty, contaminated vaccines, carcinogen-laden pharmaceuticals, power line radiation and now 5G on top of 2/3/4G radiation.

FAA/Boeing lied. 346 died due to the 737 MAX. FDA/Pharma lie. Vaccines maim and kill millions. FCC/Telecom lie. Cellular radiation maims and kills millions.

Corruption kills. COVID or not.

Covid-19: politicisation, "corruption," and suppression of science
https://www.bmj.com/content/371/bmj.m4425

Thanks,

Vinu

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Subject: Re: CEPI Covid-19 update

Dear Richard

Thanks for this update and congratulations on the new BMGF grant and the ongoing great work.
It's good to see that we are thinking of investing in the second generation candidates. Could Melanie let the SAC know if we can be of assistance in reviewing these products or in any other aspect of the work.

Stay well everyone and best regards
Helen

From: CEPI SAC <CEPISAC@cepi.net>
Date: Wednesday, 18 November 2020 at 11:26
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<mark.polhemus@cepi.net>, Carolyn Clark <carolyn.clark@cepi.net>
Subject: CEPI Covid-19 update

Dear all,

Please find the weekly update on COVID/COVAX below. As ever, updated portfolio and finance slides, are on Boardvantage

Best regards,
Richard

18th November 2020

Portfolio

- CEPI will receive a grant of up to $20M from the Bill & Melinda Gates Foundation to expand its portfolio of COVID-19 vaccines to include candidates that are differentiated from those already in advanced development. With the expectation that COVID-19 will be circulating in the population for years to come, the grant will accelerate the development of the next generation of vaccines ('Wave 2 vaccines') that could address gaps in the current global vaccine development landscape.
- To ensure vaccines are available in the near future that are easier to deliver and address the specific needs of a diverse range of populations and settings, CEPI has announced a new call for proposals for Vaccine platform technologies for rapid response against SARS-CoV-2. The call looks to identify second generation vaccine candidates against COVID-19 which are distinct from current COVID-19 vaccines in scientific, technical or manufacturing approaches, and additionally strive for platforms with potential for use against other emerging infectious diseases. The call remains open until 19th November.
- CEPI welcomes the announcements from Pfizer/BioNTech and from Moderna of the positive interim data from Phase III trials of the leading COVID-19 mRNA vaccine candidates. These are hugely positive and encouraging interim results and are testament to the ingenuity and skill of the scientific community in advancing vaccine candidates against COVID-19. We believe these interim results also increase the probability of success of other COVID-19 candidate vaccines which use a similar approach [pre-fusion spike as their immunogen], including all but one of the vaccines in the CEPI portfolio.

COVAX/ACT

- Namibia on Monday announced that it would join COVAX, becoming the 187th participant to commit to the effort.
- The COVAX: Pillar and Structure document, containing the terms of reference and membership of all groups in COVAX, was published in alignment with efforts to increase transparency.
- The COVAX Technical Review Group (TRG) welcomed the CSO representative to a meeting for the first time on Tuesday 10th November and the onboarding of CSO representatives to the SWAT teams has also been initiated.
- The 17th Covax Coordiantion Meeting (CCM) next week will focus on the COVAX position and strategy towards mRNA candidates, partner engagement, AMC country engagement, integrated communication strategy, indemnification/liability progress update
- UNICEF and PAHO launched a joint COVID-19 vaccine tender on behalf of COVAX facility on 11th November. The tender will be open for 6 weeks with the aim to provide 2 billion doses of vaccine to the COVAX Facility to ensure equitable and accelerated access to quality assured vaccine for the 186 economies participating as of today. UNICEF will hold a pre-bid meeting on Nov 18th to answer questions and provide clarifications to manufacturers.
- WHO held an ad-hoc Consultation on COVID-19 Vaccine Clinical Evaluation on 6th November on the right methodological approaches to be used to generate evidence and recommendations for deployment of an unlicensed vaccine.
- Last week the WHO published a working position on labelling COVID-19 vaccines and a working position on bar codes, QR codes and vaccine vial monitors. Unifying labelling requirements for vaccines that will be supplied through the COVAX Facility further supports the goal of broad and equitiable allocation and distribution.
- COVAX Development and Manufacturing workstream:
  - On 19th November, the Clinical Development and Operations SWAT will hold the first workshop of the COVID-19 Vaccine Correlates of Protection working group
  - The Regulatory Advisory Group will hold their 4th meeting on 19th November to discuss regulatory harmonization on topics related to accelerated COVID-19 vaccine development
  - On 9th December the Manufacturing SWAT will bring together developers and experts for a workshop on 'Best practices for determining and updating storage temperate and vaccine shelf life'

CEPI news

- Gaming developers Ndemic Creations last week launched their new game, *Plague Inc: The Cure*. Designed with input from experts at CEPI, WHO and other organisations, the new game is an expansion of the global hit *Plague. Inc* - which has 160 million gamers worldwide. Players are invited to develop and deploy tools like vaccines, testing kits, and public health campaigns to control the spread of an infectious disease. The CEPI Team have also created a new webpage for players to find out more about real-world outbreak response efforts. Now available to download on the App Store and Google Play.

- CEPI also this week took part in Prime Minister of Norway Erna Solberg's #TakeTheBall social media campaign, aimed at raising awareness of the Sustainable Development Goals. Through the art of juggling, our CEO, Richard Hatchett, shared his video on Twitter. You can also take part in the initiative, through recording yourself with the hashtag **#TakeTheBall.**

Upcoming
18th November, 17th COVAX coordination meeting (CMM)
19th November, 1st COVAX AMC Engagement Group meeting
19th November, ACT-A principals meeting

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Sensitivity: CEPI Internal

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Subject:	Canceled until December 3rd: WHO COVID-19 Animal Models Meetings

Dear all,

This is just to let you know that this week and next week's WHO COVID-19 Animal Models Group calls have been canceled. We will resume our weekly calls on December 3rd.

Stay safe everyone and thank you for your support

Best regards

César, Simon and Bill

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Subject: RE: CEPI Covid-19 update

Just to say that I applaud this update and hope that we will continue to receive others from time to time.
Stanley

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Cc: Melanie Saville <melanie.saville@cepi.net>; Joseph Simmonds-Issler <jsi@cepi.net>; Mark Polhemus <mark.polhemus@cepi.net>; Carolyn Clark <carolyn.clark@cepi.net>
Subject: CEPI Covid-19 update

Dear all,

Please find the weekly update on COVID/COVAX below. As ever, updated portfolio and finance slides, are on Boardvantage

Best regards,
Richard

18th November 2020

Portfolio

- CEPI will receive a grant of up to $20M from the Bill & Melinda Gates Foundation to expand its portfolio of COVID-19 vaccines to include candidates that are differentiated from those already in advanced development. With the expectation that COVID-19 will be circulating in the population for years to come, the grant will accelerate the development of the next generation of vaccines ('Wave 2 vaccines') that could address gaps in the current global vaccine development landscape.
- To ensure vaccines are available in the near future that are easier to deliver and address the specific needs of a diverse range of populations and settings, CEPI has announced a new call for proposals for Vaccine platform technologies for rapid response against SARS-CoV-2. The call looks to identify second generation vaccine candidates against COVID-19 which are distinct from current COVID-19 vaccines in scientific, technical or manufacturing approaches, and additionally strive for platforms with potential for use against other emerging infectious diseases. The call remains open until 19th November.
- CEPI welcomes the announcements from Pfizer/BioNTech and from Moderna of the positive interim data from Phase III trials of the leading COVID-19 mRNA vaccine candidates. These are hugely positive and encouraging interim results and are testament to the ingenuity and skill of the scientific community in advancing vaccine candidates against COVID-19. We believe these interim results also increase the probability of success of other COVID-19 candidate vaccines which use a similar approach [pre-fusion spike as their immunogen], including all but one of the vaccines in the CEPI portfolio.

COVAX/ACT

- Namibia on Monday announced that it would join COVAX, becoming the 187th participant to commit to the effort.
- The COVAX: Pillar and Structure document, containing the terms of reference and membership of all groups in COVAX, was published in alignment with efforts to increase transparency.
- The COVAX Technical Review Group (TRG) welcomed the CSO representative to a meeting for the first time on Tuesday 10th November and the onboarding of CSO representatives to the SWAT teams has also been initiated.
- The 17th Covax Coordiantion Meeting (CCM) next week will focus on the COVAX position and strategy towards mRNA candidates, partner engagement, AMC country engagement, integrated communication strategy, indemnification/liability progress update
- UNICEF and PAHO launched a joint COVID-19 vaccine tender on behalf of COVAX facility on 11th November. The tender will be open for 6 weeks with the aim to provide 2 billion doses of vaccine to the COVAX Facility to ensure equitable and accelerated access to quality assured vaccine for the 186 economies participating as of today. UNICEF will hold a pre-bid meeting on Nov 18th to answer questions and provide clarifications to manufacturers.
- WHO held an ad-hoc Consultation on COVID-19 Vaccine Clinical Evaluation on 6th November on the right methodological approaches to be used to generate evidence and recommendations for deployment of an unlicensed vaccine.
- Last week the WHO published a working position on labelling COVID-19 vaccines and a working position on bar codes, QR codes and vaccine vial monitors. Unifying labelling requirements for vaccines that will be supplied through the COVAX Facility further supports the goal of broad and equitiable allocation and distribution.
- COVAX Development and Manufacturing workstream:
  - On 19th November, the Clinical Development and Operations SWAT will hold the first workshop of the COVID-19 Vaccine Correlates of Protection working group
  - The Regulatory Advisory Group will hold their 4th meeting on 19th November to discuss regulatory harmonization on topics related to accelerated COVID-19 vaccine development
  - On 9th December the Manufacturing SWAT will bring together developers and experts for a workshop on 'Best practices for determining and updating storage temperate and vaccine shelf life'

CEPI news

- Gaming developers Ndemic Creations last week launched their new game, *Plague Inc: The Cure*. Designed with input from experts at CEPI, WHO and other organisations, the new game is an expansion of the global hit *Plague. Inc* - which has 160 million gamers worldwide. Players are invited to develop and deploy tools like vaccines, testing kits, and public health campaigns to control the spread of an infectious disease. The CEPI Team have also created a new webpage for players to find out more about real-world outbreak response efforts. Now available to download on the App Store and Google Play.
- CEPI also this week took part in Prime Minister of Norway Erna Solberg's #TakeTheBall social media campaign, aimed at raising awareness of the Sustainable Development Goals. Through the art of juggling, our CEO, Richard Hatchett, shared his video on Twitter. You can also take part in the initiative, through recording yourself with the hashtag **#TakeTheBall.**

Upcoming

18th November, 17th COVAX coordination meeting (CMM)
19th November, 1st COVAX AMC Engagement Group meeting
19th November, ACT-A principals meeting

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Subject: CEPI update on COVID-19: Pfizer, and SARC-CoV-2 in mink

Dear SAC,
I hope this email finds you well.
Underneath is an email with relevant updates from Richard.

Best wishes
Stig

Dear all

We just wanted to send a quick note following the news regarding mink mutation over the weekend, and regarding Pfizer this morning. The end of the note includes some confidential information about an upcoming announcement – please do not share or forward.

We will provide any additional information on these topics in the next weekly update.

Best regards,
Richard

Pfizer

- Today Pfizer announced interim data from their phase 3 clinical trial indicate over 90% efficacy of their COVID-19 vaccine
- This was based on 94 confirmed cases from 43,538 enrolled participants
- No safety concerns raised to date and they will wait minimum safety follow up requirements have been met for Emergency Use Authorization (EUA) before submitting for EUA
- The trial will continue to enroll until the 164 case final analysis for efficacy is conducted
- This is a positive result for vaccines based on the spike protein. The 8 candidates in the CEPI portfolio in clinical trials are based on the spike which is encouraging and merits their further investment

- CEPI released a statement – https://cepi.net/news_cepi/cepi-statement-in-response-to-announcement-from-pfizer-biontech-positive-interim-data-from-phase-iii-trial-of-covid-19-vaccine-candidate/
- This has begun to be picked up, including the key point that it is our belief that these interim results increase the probability of other COVID-19 candidates which use pre-fusion spike as their immunogen being successful – which includes all vaccines CEPI has funded
- Our view remains it is critical that the world has multiple vaccines, and the potential success shows the importance of the work CEPI is doing and that we are fully funded
- If Board members would like any talking points regarding CEPI's position, please contact Tom Mooney (copied)

Epidemiological situation: SARS-CoV-2 in mink

- Outbreaks of SARS-CoV-2 in mink were first reported in the Netherlands from 23 April in large mink farms (SARS-CoV-2 infection in farmed minks, the Netherlands, April and May 2020, Euro Surveill. 2020 Jun 11; 25(23): 2001005.) Large culls have taken place in last months. In the Netherlands, Erasmus MC have been investigating human cases and Wageningen are investigating animal cases.
- Danish authorities announced this week the decision to cull all farmed mink in Denmark (>17m animals), because of an association with mutated SARS-CoV-2 that has also been detected in the human population (Links: Statement by Danish authorities/SSI and WHO Disease Outbreak News):
  - Since June 2020, human cases of SARS-CoV-2 associated with infected mink have been documented in Denmark. The Danish public health authorities have reported the detection of a new mink-associated SARS-COV-2 variant termed "cluster 5" in 12 persons. SSI (Danish national institute of public health) has identified seven unique mink mutations in the SARS-CoV2 Spike protein of the variants circulating in minks and humans. SSI tested a variant with four simultaneous changes in the Spike protein (amino acid changes: H69del/V70del, Y453F, I692V, M1229I, collectively termed "cluster 5"), which were identified in minks and 12 humans. SSI isolated this virus from a human patient. Virus neutralization cross reactivity is being investigated. SSI have stated that preliminary findings indicate some resistance to neutralisation with convalescent sera, but the findings have not yet been published in full and likely need further validation.
  -
  - Initial observations suggest the clinical presentation, severity and transmission among those infected are similar to the other circulating SARS-CoV-2 viruses.
  - Human cases: age range 8-94 years old; 11 of 12 cases were detected in North Jutland. One case was detected during an outbreak investigation at a nursing home outside of North Jutland.
  - Given restricted access to mink farms (for humans), it is not entirely clear whether transmission has occurred via mink workers or via other species that can circulate in the farms (e.g. stray cats, rodents, other).
  - Movement restriction and enhanced IPC measures have been implemented in part of Denmark to limit spread of the new variant.
- SARS-CoV-2 has now been detected in Swedish mink farms (population 600 000). Sequencing of animal isolates is underway. No plans to cull since most of the animals due for abattoir in coming weeks anyway.

GISAID Preliminary analysis on mink-associated variant found in humans:

- Y453F (310x human 39x mink): host receptor and antibody binding mutation, found in Dutch minks
- H69del V70del (1,706x human): 6 nucleotide (2 amino acid) deletion structurally viable, removes part of a surface loop (changes spike surface)
- D614G (common): Genetic backbone in most current viruses, affects spike complex stability
- I692V (11x human): Surface mutation not seen before, little or no effect expected
- M1229I (220x human) In unstructured C-terminus, little or no effect expected
- Summary: the mutations can affect host receptor and antibody binding.

Confidential: soon to be released announcements regarding CEPI and Gisaid and Public Health England partnership – NOT TO BE FORWARDED OR SHARED

- CEPI has partnered with GISAID to build their capacity for hosting, curating and sharing sequences of circulating SARS CoV-2, and to analyse and report on spike diversity and emerging variants. The project will also support their overall capacity for responding to emerging infectious diseases.

In addition CEPI will also partner with PHE and NIBSC to evaluate biological relevance of newly emerging strains, to obtain early information on likely impact on vaccine candidates and cross neutralization of new strains, as well as to evaluate possible changes in pathogenesis in animal models.

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Subject: 1st CEPI SAC MEETING 2021 AGENDA
Attachments: Agenda_SAC_Jan-2021 Final.pdf

Dear SAC members,

We hope you are well.

Please find attached the agenda for the upcoming meeting on **26 – 01 – 2021, 3 – 7 pm CEST**.

Expect to receive meeting pre-reads in the next few days.

Lastly, CEPI will soon be opening the member renewal process for the 2021 SAC. We will inform you immediately via email once this process is launched.

We look forward to a productive meeting.

Best regards

CEPI

CEPI New vaccines for a safer world

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SAC meeting January 2021

Date	Time	Location
26 January 2021	14:00 – 18:00 (GMT)	TC/Video

Time	Agenda item	Description	Presenter(s)
14:00 - 14:10		Welcome and introduction	Helen Rees Richard Hatchett
14:10 – 14:30 (20 min)	#1	The path to CEPI 2.0: framing our 2021 strategy against a changing landscape	Frederik Kristensen Melanie Saville
14:30-16:00 (1 hr 30 min)	#2	COVID-19: learnings from Wave 1 and CEPI's immediate response to emerging variants	Nick Jackson Celine Gurry Matthew Downham Jakob Cramer Adam Hacker
16:00-16:15 (15 min)		Break	
16:15-17:45 (1 hr 30 min)	#3	From COVID-19 to Disease X: defining CEPI's response roadmap • Application and improvement of mRNA/LNP technologies • Advancing broadly protective beta-CoV vaccines • Preparing for Disease X • New working groups to address key scientific/technical challenges	Nick Jackson Melanie Saville
17:45-17:55 (10 min)	#4	2021 SAC: Application process and questions	Melanie Saville
17:55-18:00 (5 min)		Concluding remarks to outgoing SAC membership	Helen Rees Melanie Saville Richard Hatchett

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Subject: RE: WHO COVID-19 Animal Models Group Call

Dear All,

Please find below the agenda for this week's WHO COVID-19 Animal Models group call.

Best,
Lauren – César, Simon, and Bill

Agenda WHO COVID-19 Animal Models group call Thursday January 21 3PM CET (Geneva time)

1. Troy Sutton (PSU) - *Transmission and protection against re-infection in the ferret model with the SARS-CoV-2 USA-WA1/2020 isolate*
2. Neeltje van Doremalen (NIAID) - *Intranasal ChAdOx1 nCoV-19/AZD1222 vaccination reduces shedding of SARS-CoV-2 D614G in rhesus macaques and hamsters*
3. Mitchell Palmer (USDA) & Diego Diel (Cornell) - *Susceptibility of white-tailed deer (Odocoileus virginianus) to SARS-CoV-2*

-----Original Appointment-----
From: SCHWARTZ, Lauren
Sent: Sunday, January 17, 2021 5:21 PM
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Subject: WHO COVID-19 Animal Models Group Call

When: Thursday, January 21, 2021 6:00 AM-7:30 AM (UTC-08:00) Pacific Time (US & Canada).

Where: https://who.zoom.us/ (b)(6)

Agenda to follow.

Join Zoom Meeting
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149.137.40.110 (Singapore)
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Subject: FW: CEPI COVID-19 update

Dear SAC,
Please find an update on CEPI/COVAX COVID-19 activities. We look forward to the SAC meeting on 26th January.
Kind regards
Melanie

Portfolio

- At the end of 2020, CEPI announced a partnership with Biological E Limited (BioE), an India-based company, to advance development of a COVID-19 subunit vaccine candidate. CEPI will initially contribute to scaling up manufacturing of the vaccine and will explore additional funding with the goal of potentially enabling the production of 100 million doses in 2021.

- On 28th December Novavax initiated a Ph3 pivotal trial of their protein nanoparticle vaccine in the US and Mexico. The trial aims to enroll 30,000 volunteers. Novavax completed enrollment for a Phase3 trial in the UK at the end of November, enrolling 15,203 volunteers. First vaccine efficacy results are anticipated by end of January 2021.

- Curevac initiated a global Ph2b/3 trial to enroll 35,000 participants in December followed by dosing for a smaller Ph3 clinical study on 22nd December focused on healthcare workers at a selected site in Germany. In 2021, 10% of CureVac's total produced doses will be available to COVAX. Another 15% of total produced doses will be made available in 2022 and 2023.

- EMA granted a conditional marketing agreement for the Moderna vaccine on 6th January following similar emergency use agreements by the FDA and MHRA marking the second COVID-19 vaccine to be authorized across the EU within a year since the WHO declared the pandemic.

- MHRA becomes the first regulatory agency to grant temporary regulatory authorization for the Astrazeneca/Oxford vaccine on 30th December. The DCGI in India subsequently granted approval for emergency use of Covaxin, the Astrazeneca vaccine produced at SII.

- AstraZeneca signed an advance purchase agreement (APA) with the COVAX Facility to procure 170M by the end of 2021. Combined with other COVAX agreements with Johnson & Johnson, Serum Institute of India (for additional AstraZeneca or Novavax candidate vaccines) and Sanofi/GSK vaccine candidate; COVAX now has access to nearly 2 billion doses of several promising vaccine candidates across 2021-2022. Through access agreements with CEPI R&D partners, COVAX has Right of First Refusal (ROFR) on approximately 1 billion additional doses in 2021.

- CEPI is looking for senior scientific researchers and global health professionals to join its Scientific Advisory Committee, or SAC. We will be seeking applicants with extensive experience in disciplines relating to vaccine development, innovation, licensure, and deployment. The formal period for application will open later in January.

- Full report on the workshop regarding 'Pre- and Post-Licensure Assessments of COVID-19 Vaccine Efficacy/Effectiveness Against Infection & Transmission' has now been posted. Complete presentation materials for the workshop can also be found here. Upcoming workshops hosted by the SWAT groups are listed below and additional reports from previous vaccine science workshops can be found on the COVAX EpiHub site.

COVAX/ACT

- With WHO prequalification (PQ) for emergency use listing (EUL) granted for the Pfizer/BioNTech vaccine on 30th December, the vaccine supply becomes the first to be eligible for procurement by UNICEF and PAHO for distribution. In addition to WHO EUL/PQ, WHO has published the list of SRAs that, under exceptional circumstances, the Facility should consider. These are Australia-TGA; EU-EMA; Canada-Health Canada; Switzerland- Swissmedic; UK-MHRA and USA-FDA.

- This week a WHO Strategic Advisory Group of Experts (SAGE) meeting was held to discuss the Pfizer/BioNTech vaccine which concluded with interim recommendations for use under the Emergency Use Listing (EUL). The WHO has made available to the public domain the status of COVID-19 vaccines for which an expression of interest has been received by WHO/PQ.
- This week a WHO consultation on COVID-19 new variants: knowledge gaps and research priorities was held with researchers from around the world joining to share their expertise. A meeting report on the research priorities and actions will be published by the end of this week. A WHO Consultation on COVID-19 Vaccine R&D Priorities is scheduled for later today.
- An additional $4 Bn in funding was secured for Gavi and the COVAX AMC from the US government to ensure lower-income countries have equitable access to COVID-19 vaccines.
- The WHO COVID-19 vaccine safety surveillance manual has been published and all WHO Regional Offices are supporting countries to implement safety surveillance recommended in the manual.
- Our partners at UNICEF have launched their COVID-19 Vaccine Market Dashboard providing an overview of vaccines in the pipeline as well as reported production capacity and supply agreements.
- The Country Readiness and Delivery team has recently launched several tools and trainings to assist countries in readiness for vaccine deployment including:

  - the UNICEF Vaccine Misinformation Management Field Guide

  - COVID-19 vaccination training for health workers providing information that health workers need to know to conduct COVID-19 vaccination.

  - Orientation to national deployment and vaccination planning for COVID-19 vaccines providing orientation for national deployment and vaccination planning for COVID-19 vaccines.

Upcoming

15th January, WHO Global Consultation on a 2021 research agenda for COVID-19 vaccines
21st January, Monthly Regulatory Advisory Group meeting
27th January, Manufacturing SWAT to host a workshop on the topic of 'Best Practices for Tech Transfer'
28th January, Clinical Development and Operations SWAT to host a workshop to discuss new SARS-CoV2 variant and implications for vaccine development and licensure

Sensitivity: CEPI Internal

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Subject: RE: WHO COVID-19 Animal Models Group Call

Dear All,

Please find below the agenda for this week's WHO COVID-19 Animal Models group call.

Best,
Lauren – César, Simon, and Bill

Agenda WHO COVID-19 Animal Models group call Thursday January 14 3PM CET (Geneva time)

1. Martin Beer (FLI) - *Experimental infection of bank voles (Myodes glareolus) with SARS-CoV-2*

2. Michael Shotsaert (Mount Sinai) - *Neutralization of N501Y variant with vaccinee sera*

3. Quim Segalés (IRTA) - *Protection against reinfection with D614 or G614 SARS-CoV-2 isolates in Golden Syrian hamsters*

4. Discussion on available sera panels
   - Rafael Medina-Silva (Universidad Católica de Chile)
   - Babs Verstrepen (Biomedical Primate Research Centre)

-----Original Appointment-----
From: SCHWARTZ, Lauren
Sent: Sunday, January 10, 2021 2:22 PM
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Subject: WHO COVID-19 Animal Models Group Call

When: Thursday, January 14, 2021 6:00 AM-7:30 AM (UTC-08:00) Pacific Time (US & Canada).

Where: https://who.zoom.us/ (b)(6)

Agenda to follow.

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Subject: Re: WHO COVID-19 Animal Models Group Call

Dear all,

Small correction in the agenda below. See you all later

César

Agenda WHO COVID-19 Animal Models group call - Thursday January 7, 3PM CET (Geneva time)

1. Emily Speranza (NIAID)- *Single cell RNA sequencing reveals SARS-CoV-2 infection dynamics in lungs of African green monkeys.*

2. Luk Vandenberghe (Harvard)- *Mouse and NHP Immunogenicity of AAVCOVID: An AAV-based, single dose, room-temperature stable experimental COVID-19 vaccine*
3. Tony Schountz (CSU) - *Susceptibility of Deer Mice to SARS-CoV-2*

On 6. Jan 2021, at 22:26, SCHWARTZ, Lauren <schwartzl@who.int> wrote:

Dear All,

Please find below the agenda for this week's WHO COVID-19 Animal Models group call.

Best,
Lauren – César, Simon, and Bill

Agenda WHO COVID-19 Animal Models group call - Thursday January 7, 3PM CET (Geneva time)
1. Emmie de Wit, PhD (NIAID)- *Single cell RNA sequencing reveals SARS-CoV-2 infection dynamics in lungs of African green monkeys.*
2. Luk Vandenberghe (Harvard)- *Mouse and NHP Immunogenicity of AAVCOVID: An AAV-based, single dose, room-temperature stable experimental COVID-19 vaccine*
3. Tony Schountz (CSU) - *Susceptibility of Deer Mice to SARS-CoV-2*

-----Original Appointment-----
From: SCHWARTZ, Lauren
Sent: Sunday, January 3, 2021 8:34 PM
To: randy.albrecht@mssm.edu; Martha.Alexander-Miller@wakehealth.edu; AKelvin@dal.ca; danielle.anderson@duke-nus.edu.sg; s.a.arakelov@spbniivs.ru; baczenas@wisc.edu; Pearl.Bamford@health.gov.au; rbaric@email.unc.edu; dbarouch@bidmc.harvard.edu; (b)(6) @comcast.net; Martin.Beer@fli.de; Neil.Berry@nibsc.org; terry.k.besch.ctr@mail.mil; c.blank@nki.nl; dbolton@hivresearch.org; mopargal@rams.colostate.edu; SBradfute@salud.unm.edu; trbrasel@UTMB.EDU; (b)(6) @gmail.com; abukreye@utmb.edu; rcarrion@txbiomed.org; Miles.Carroll@phe.gov.uk; scartner@uab.edu; fcassels@path.org; Marco.Cavaleri@ema.europa.eu; lisa.chakrabarti@pasteur.fr; jfwchan@hku.hk; MONALISA.CHATTERJI@gatesfoundation.org; hlchen@hku.hk; carolyn.clark@cepi.net; scordo@qb.fcen.uba.ar; lisette.cornelissen@wur.nl; ian.crozier@nih.gov; kai.dallmeier@kuleuven.be; que.dang@nih.gov; jorgen.de.jonge@rivm.nl; emmie.dewit@nih.gov; mdiamond@wustl.edu; CDillen@som.umaryland.edu; edohm@uab.edu; Ruben.Donis@hhs.gov; william.dowling@cepi.net; mariette.ducatez@envt.fr; pduprex@pitt.edu; mmeitzen@utmb.edu; l.enjuanes@cnb.csic.es; Karl.Erlandson@hhs.gov; mesteban@cnb.csic.es; darryl.falzarano@usask.ca; feldmannh@niaid.nih.gov; clint.florence@nih.gov; joanne@pitt.edu; thomasf@primate.wisc.edu; MFrieman@som.umaryland.edu; Simon.Funnell@phe.gov.uk; jfgarcia@cnb.csic.es; Adolfo.Garcia-Sastre@mssm.edu; golinger@mriglobal.org; anna@thsti.res.in; Volker.gerdts@usask.ca; nora.gerhards@wur.nl; christiane.gerke@pasteur.fr; Hana.Golding@fda.hhs.gov; barney.graham@nih.gov; lgralins@email.unc.edu; fgrey@exseed.ed.ac.uk; ahgriff@bu.edu; CarlosAlberto.Guzman@helmholtz-hzi.de; b.haagmans@erasmusmc.nl; rhakami@gmu.edu; Yper.Hall@phe.gov.uk; kevinharrod@uabmc.edu; HENAO RESTREPO, Ana Maria; lisa.hensley@nih.gov; seos@cnu.ac.kr; sheri.hild@nih.gov; paul.hodgson@usask.ca; christian.c.hofer.mil@mail.mil; jhogan@uga.edu; Michael.holbrook@nih.gov; jay.w.hooper.civ@mail.mil; y.jacob.hou@unc.edu; REIRELAND@mail.dstl.gov.uk; tomeri@iibr.gov.il; mito@ciea.or.jp; Lakshmi.Jayashankar@hhs.gov; dustin.johnson@canada.ca; (b)(6) @hotmail.com; amelia.karlsson@duke.edu; Bernhard.Kerscher@pei.de; nadia.khelef@pasteur.fr; sekim@krict.re.kr; hwan.kim@stonybrook.edu; Jason.Kindrachuk@umanitoba.ca; Jacqueline.Kirchner@gatesfoundation.org; Harry.Kleanthous@

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Subject: WHO COVID-19 Animal Models Group Call
When: Thursday, January 7, 2021 6:00 AM-7:30 AM (UTC-08:00) Pacific Time (US & Canada).
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Agenda to follow.

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149.137.40.110 (Singapore)
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69.174.57.160 (Canada)
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Subject: [EXTERNAL] RE: WHO COVID-19 Animal Models Group Call

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Dear All,

Please find below a slightly revised agenda –

Agenda WHO COVID-19 Animal Models group call Thursday March 4 3PM CET (Geneva time)

1. Martin Beer (FLI) - *Immunization and challenge trial in K18-hACE2-transgenic mice with SARS-CoV-2 variant B1.351 in comparison to SARS-CoV-2 Muc-IMB-1*

2. Soumita Das (UCSD) - *Stem Cell-derived Complete Lung Organoid Models Emulate Lung Disease in COVID-19*

3. Kai Dallmeier (KU Leuven) - *Comparative infectivity and pathogenesis of emerging SARS-CoV-2 variants B1.1.7 and B.1.351 in Syrian hamsters*

Best,
Lauren

From: SCHWARTZ, Lauren
Sent: Wednesday, March 3, 2021 1:05 PM
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Subject: RE: WHO COVID-19 Animal Models Group Call

Dear All,

Please find below the agenda for this week's WHO COVID-19 Animal Models group call.

Best,
Lauren – César, Simon, and Bill

Agenda WHO COVID-19 Animal Models group call Thursday March 4 3PM CET (Geneva time)

1. Soumita Das (UCSD) - *TBD*
2. Kai Dallmeier (KU Leuven) - *Comparative infectivity and pathogenesis of emerging SARS-CoV-2 variants B1.1.7 and B.1.351 in Syrian hamsters*
3. Martin Beer (FLI) - *Immunization and challenge trial in K18-hACE2-transgenic mice with SARS-CoV-2 variant B1.351 in comparison to SARS-CoV-2 Muc-IMB-1*

-----Original Appointment-----
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Sent: Sunday, February 28, 2021 9:40 AM
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Subject: WHO COVID-19 Animal Models Group Call

When: Thursday, March 4, 2021 6:00 AM-7:30 AM (UTC-08:00) Pacific Time (US & Canada).

Where: https://who.zoom.us (b)(6)

Agenda to follow.

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Subject: [EXTERNAL] RE: WHO COVID-19 Animal Models Group Call

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Dear All,

Please find below the agenda for this week's WHO COVID-19 Animal Models group call.

Best,
Lauren – César, Simon, and Bill

Agenda WHO COVID-19 Animal Models group call Thursday March 4 3PM CET (Geneva time)

1. Soumita Das (UCSD) - *TBD*
2. Kai Dallmeier (KU Leuven) - *Comparative infectivity and pathogenesis of emerging SARS-CoV-2 variants B1.1.7 and B.1.351 in Syrian hamsters*
3. Martin Beer (FLI) - *Immunization and challenge trial in K18-hACE2-transgenic mice with SARS-CoV-2 variant B1.351 in comparison to SARS-CoV-2 Muc-IMB-1*

-----Original Appointment-----
From: SCHWARTZ, Lauren
Sent: Sunday, February 28, 2021 9:40 AM
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Subject: WHO COVID-19 Animal Models Group Call

When: Thursday, March 4, 2021 6:00 AM-7:30 AM (UTC-08:00) Pacific Time (US & Canada).

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Sent: 9/4/2020 3:36:48 AM
To: Ckeech@novavax.com; richard.hatchett@cepi.net; fg17882@bristol.ac.uk; ripley.ballou@gskbio.com; nicole.lurie@cepi.net; jlg251@georgetown.edu; tom.monath@crozetbiopharma.com; aabimiku@ihv.umaryland.edu; abarrett@utmb.edu; Ananda.Bandyopadhyay@gatesfoundation.org; cbrechot@usf.edu; chappi@hsph.harvard.edu; Connie.s.schmaljohn.civ@mail.mil; Damon, Inger K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42b35bd733a34c66a5698f43f7026e88-HHS-iad7-cd]; jamesrobinson@uchicago.edu; Jean.Lang@sanofipasteur.com; john.k.billington@gsk.com; kenji.shibuya@kcl.ac.uk; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; mlevine@som.umaryland.edu; moorthyv@who.int; Bryant, Paula R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3eb42f9318014bbb8c14d39ef311d8f9-HHS-paula.b]; tkariuki@africaonline.co.ke; yves.levy@aphp.fr; Mary.Wilson@ucsf.edu; Ingelfinger, Julie, M.D. [jingelfinger@nejm.org]; jpkrischer@epi.usf.edu; cjgreen@benaroyaresearch.org; anette.ziegler@tum.de; diane.wherrett@sickkids.ca; eva-tsalikian@uiowa.edu; jskyler@umail.miami.edu; schatda@peds.ufl.edu; bill.russell@vumc.org; hrodrig1@health.usf.edu; moran001@umn.edu; PLinsley@BenaroyaResearch.org; jkrische@health.usf.edu; peter.gottlieb@ucdenver.edu; sgitelma@ucsf.edu; mdufort@benaroyaresearch.org; dimeglio@iupui.edu; Jeff.Bluestone@ucsf.edu; along@benaroyaresearch.org; empoweredpatient@cnn.com; munro.peter@abc.net.au; beth.mole@arstechnica.com; news@axios.com; newswatch@bbc.co.uk; (b)(6) @gmail.com; cnn@cnn.com; news@coastnewsgroup.com; news@chron.com; letters@dailysignal.com; editor@dnews.com; newsroom@epochtimes.com; editorial@fatherly.com; myron.levin@fairwarning.org; info@eyeonannapolis.net; (b)(6) @gmail.com; news@fox17online.com; science@theguardian.com; (b)(6) @gmail.com; allergy-immunology@healio.com; stories@healthline.com; newsdesk@irishtimes.com; newsroom@idahostatesman.com; KHN-tips@kff.org; dhyde@kuow.org; feedback@thetimes.co.uk; cgoodman@sunsentinel.com; letters@theatlantic.com; info@thebureauinvestigates.com; editor@thehill.com; letters@time.com; press@verywell.com; lena.sun@washpost.com; mike.agogliati@wfsb.com; submit@wired.com; fox2newsdesk@foxtv.com; betsy.mckay@wsj.com; (b)(6) @gmail.com; investigate@ap.org; editor@bayareanewsgroup.com; (b)(6) @gmail.com; editorial@bigissue.com; tips@buzzfeed.com; stephen.colbert@cbs.com; cfrederick@duluthnews.com; scoops@huffpost.com; kotanews@kotatv.com; news@ksby.com; PRandhawa@KSDK.com; newstips@latimes.com; akrueger@mpr.org; editor@newatlas.com; kanderson@observer-reporter.com; news@politicshome.com; editors@sciam.com; jgoldsteinstreet@seattletimes.com; metro@sfchronicle.com; editors@texasobserver.org; tips@rollingstone.com; info@the-scientist.com; Blake.Montgomery@thedailybeast.com; sciencenetwork@ucsusa.org; newsroom@waaytv.com; newsroom@whyy.org; lrosenbaum@forbes.com; felice.freyer@globe.com; lgustus@sacbee.com; deidre@acbio.org.za; eva@i-sis.org.uk; jimmye@northsidesun.com; kbouffard@detroitnews.com; tips@propublica.org; slivio@njadvancemedia.com; peter.chianca@boston.com; Slater, Jay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2b00a57b0a747a9bc4f2317937a1022-slaterj]; Woo, Jane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f70d0e3a7aaf442fb4962b61dde9894b-WooJ]; Hess, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23ed9c01196f4765b89921c357f855f9-Hessma]; Forshee, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Walderhaug, Mark O [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14515448efee47098c38798d5c409b02-MWALDERH]; CBER OCOD Consumer Account [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6d1fb37325043bcbe25183a0aaece3c-CBEROCOD]; DeStefano, Frank (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a799ec222e8741e988566e6141cbf1ba-HHS-fxd1-cd]; Thompson, Mark (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b2302812fa541759657b0569509577d-HHS-isq8-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Walker, Tanja Y (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject: The Novavax COVID-19 vaccine is unsafe

Regarding:

Phase 1–2 Trial of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine
https://www.nejm.org/doi/full/10.1056/NEJMoa2026920

Flawed approach lacks vaccine safety engineering

As previously described, their approach to vaccine safety that depends on testing alone is fundamentally flawed (1–4).

Lack of design for safety, FMEA, means flawed trial design

They have another **fundamental safety flaw**. The vaccine is contaminated with Sf9 insect cells and baculovirus proteins. The vaccine is contaminated with saponin related proteins as part of the Matrix-M adjuvant. The vaccine can be contaminated with any viral/bacterial proteins of pathogens that infect *Spodoptera frugiperda* from which the Sf9 cells were derived.

They will cause IgE mediated sensitization directed against not only the SARS-CoV-2 spike protein but also against all the other contaminating proteins (5).

Figure 5. shows Th2 response is discernible and will make COVID-19 worse.

This is the current problem with COVID-19 severity where harmless coronavirus (CV) has become life-threatening due to IgE mediated sensitization using dirty, CV-like protein contaminated and infected animal tissue derived vaccines (6,7). Predictably, anaphylaxis treatments such as histamine H1/H2 blockers therefore help (8–10) and complications of such an allergic reaction include cardiac injury due to Kounis syndrome (11).

Th2 lung immunopathology was observed in mice following an experimental SARS vaccine (12). Why was IgE to vaccine antigens not measured in this trial to check for that? They only measured total specific IgG. To understand Th2 response, you have to separate IgG1,2,3 and 4 subclasses.

With a powerful adjuvant, the vaccine will also efficiently cause autoimmunity due to any homology between all these contaminating proteins and human self proteins (13,14).

Similar saponin based adjuvant used in the SHINGRIX vaccine (15) caused autoimmune diseases that were easily detected in the clinical trial itself (16).

Vaccines and Related Biological Products Advisory Committee Meeting

https://www.fda.gov/media/107538/download

Where is the bioinformatics, homology and immunogenicity analysis (17–19)? Where is the autoimmune serology pre/post vaccination (20,21)? If a design FMEA (Failure Modes and Effects Analysis) were performed, all these design issues would have been flagged. This would have informed appropriate trial design.

"rSARS-CoV-2 and Matrix-M1 were mixed just before use"

That is an unacceptable formulation as it further increases aeroallergen contamination of the vaccine. Aeroallergen contamination of a vaccine with a powerful adjuvant is even worse and will cause the development of numerous diseases such as asthma, allergies and gastrointestinal diseases (22).

"acceptable safety findings"

The authors are way too quick to jump to this conclusion. As detailed above, their claim is not supported by the evidence.

Nanoparticles

The FDA has proved that it is incompetent in regulating safety (4). From Vioxx to NDMA to unsafe vaccines (14). All new entities such as nanoparticles must be assumed unsafe until proven otherwise.

Repeating the Dengvaxia disaster?

Why do they think they will not have the same failure mode as the Dengvaxia vaccine (23)?

T cells are not created equal

T cells activated by an injected vaccine will be imprinted with skin homing markers and home to the skin due to the route of antigen exposure(24). This is not comparable to the T cell response during natural COVID-19.

Conclusion

No safety or cellular immunity claims can be made. The team needs to go back to the drawing board.

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Bruce

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Briefing With Nerissa Cook, Deputy Assistant Secretary of State, Bureau of International Organization Affairs; Garrett Grigsby, Director of the Office of Global Affairs, Department of Health and Human Services; and Dr. Alma Golden, Assistant Administrator for Global Health, USAID On the U.S. Government's Next Steps With Regard to Withdrawal From the World Health Organization

09/02/2020 05:55 PM EDT

Nerissa J. Cook, Deputy Assistant SecretaryBureau of International Organization Affairs

Garrett Grigsby, Director of the Office of Global Affairs, Department of Health and Human Services

Dr. Alma Golden, Assistant Administrator for Global Health, USAID

Via Teleconference

MS ORTAGUS: Thank you so much and good afternoon, everyone, and thank you for joining us today for this on-the-record briefing regarding next steps in the U.S. withdrawal from the World Health Organization. Just a reminder that the – while this call is on the record, the contents of this call are embargoed until the end of the call. Also a reminder if you have a question to ask, you can go ahead and get in the queue at any time by dialing 1 and then 0.

So I'm joined today by briefers from the three agencies that are most relevant to this effort. For the Department of State, we have Deputy Assistant Secretary of State Nerissa Cook from the Bureau of International Organizational Affairs. From HHS we have Garrett Grigsby, director of that agency's Office of Global Affairs. And from USAID we have Dr. Alma Golden, assistant administrator for global health. Each of these experts will have a very brief opening remarks outlining recent decisions regarding the World Health Organization, and then we will turn to your questions. We'll begin with remarks from Deputy Assistant Secretary of State Nerissa Cook.

MS COOK: Thank you very much and good afternoon to all, and thank you for joining us today for this briefing. As mentioned, I'm Nerissa Cook and I'm a deputy assistant secretary for international organizations at the Department of State, and I help oversee the institutional relationship between the United States and the World Health Organization.

As you all know, in May the President announced that the United States would terminate its relationship with WHO and redirect its global health resources to other, more credible partners. This step was taken after the President gave WHO the opportunity to embrace crucial reforms, most notably to demonstrate its independence from the Chinese Communist Party. WHO leadership declined to take that opportunity, resulting in the President's decision. On July 6th of this year, the United States submitted its notice of withdrawal from the WHO effective on July 6, 2021. Today we are announcing significant steps to complete that process in and on that timeline, and including on matters related to funding.

I am pleased to be joined today by colleagues from USAID and HHS. Dr. Alma Golden and Director Garrett Grigsby are true experts on questions related to America's global health leadership and will address some of the specific actions we are announcing today.

Before we proceed, let me note in advance that the information we are providing today was also presented to WHO Director General Tedros during a meeting earlier today with our U.S. ambassador in Geneva, Andrew Bremberg.

To begin, I would like to discuss the status of U.S. assessed contributions to the WHO. These are the annual dues that member-states are required to pay as the price of membership. As with many UN organizations, the U.S. is assessed at 22 percent of the WHO's regular budget, which typically totals more than $100 million a year. For Fiscal Year 2020, the U.S. assessment was just over $120 million, of which 58 million had already been contributed at the time of the President's April decision to suspend additional funding. Today we are announcing the remaining portion of the 2020 assessment, slightly more than $62 million, will be reprogrammed to the UN to pay other assessments.

I would like to turn now to my colleagues to discuss some of the specific steps their agencies are taking to implement the President's decision, but let me make one additional comment about the U.S. institutional relationship with the WHO going forward: There may be instances in the future when the United States wishes to participate in particular meetings of the WHO's governing bodies and technical and advisory committees where we believe American interests need to be represented. We will consider those instances on a case-by-case basis.

Now for additional detail on questions related to funding of global health priorities, let me turn first to HHS and Doctor Garrett Grigsby.

MR GRIGSBY: Thanks, Nerissa. To correct the record, I'm actually not a doctor.

MS COOK: Director.

MR GRIGSBY: (Laughter.) Yeah, this is Garrett Grigsby with HHS. Good afternoon, everybody. A number of operating divisions of the Department of Health and Human Services traditionally have engaged with the World Health Organization and some of these interactions have included voluntary contributions. In the case of voluntary program funding, operating divisions of HHS have in some cases – many cases, really – found other recipients to carry out activities moving forward. As you know, the U.S. Government is the most generous funder of global health activities on Earth and has been for decades, with extensive partnerships all around the world working in virtually every issue area.

The WHO activities that HHS will support this year are one-time exceptions for funding, up to $40 million, in the program areas of immunization and influenza. These contributions would be to ensure continuity of activities important to the health security of Americans for which there was not immediate alternative programmatic partners. They'll ensure that activities critical – of critical concerns to the health of Americans will continue until appropriate alternative partners are secured. The one-year timeline for U.S. withdrawal from WHO allows time to find and secure partnerships to fund critical programs. HHS is well underway with this process to make this happen in advance of the one-year anniversary of Secretary Pompeo's letter to the UN Secretary-General making known U.S. intentions with regard to WHO.

Finally, HHS has a number of individuals detailed to WHO working on technical health issues. We're working with these individuals to bring them home or to send them to their next assignment in advance of 2021 when the U.S. will no longer be a member of WHO. So that's what I've got. Back to you, Nerissa.

MS COOK: Thank you very much, Garrett. And now I would like to turn to USAID and Dr. Alma Golden.

MS GOLDEN: Thank you so much. We appreciate you joining us this afternoon. I'm Dr. Alma Golden. I'm the assistant administrator for global health at the United States Agency for International Development, USAID. I'm pleased to join my colleagues from the Department of State and Health and Human Services to speak with you today.

As my colleague Garrett Grigsby just noted in his remarks, USAID has funded our work with the World Health Organization through voluntary contributions. My colleagues and I at the agency have worked diligently to identify appropriate partners to carry out this urgent and complex work on which we previously collaborated with WHO. Despite progress on the humanitarian reform, it is critical that the WHO better prepare for, prevent, detect, and respond to outbreaks of dangerous pathogens with transparency and with accountability. While in the vast majority of cases, USAID has identified strong and appropriate partners to carry forward this work, we will make a one-time disbursement of up to $68 million to the WHO to support humanitarian health assistance

in Libya and Syria as well as efforts to eradicate polio in priority countries. These exceptions reflect the few cases in which WHO has the unique capabilities that an alternate partner could not replicate at this time.

Since 2001, the U.S. Government has contributed more than $142 billion to help prevent, detect, and treat HIV/AIDS, malaria, tuberculosis, Ebola, and other dangerous diseases and conditions. We give an average of $10 billion per year for global health, and this year, it will be double that as we surge to fight COVID-19 worldwide.

USAID is determined to ensure that our withdrawal from WHO does not affect the level of our overall health assistance to the most vulnerable. The United States leads the world in health and humanitarian aid through an all-of-America effort, and we are committed to ensuring that our generosity directly reaches people around the world. We and the rest of the U.S. Government will continue to engage the WHO on a limited basis during this coming year of our withdrawal.

On a case-by-case basis, the United States will participate in specific meetings of the WHO's governing bodies and technical and advisory committees. Our priorities will be events and processes of a normative, regulatory and standard-setting nature that have a direct impact on Americans, on U.S. national security, on U.S. economic interests, U.S. companies, and on the U.S. Government's global health investments.

Thank you very much. Back to you, Nerissa.

MS COOK: Thank you, and I think we'll turn it back to Morgan to begin the Q&A.

MS ORTAGUS: Great. So we do have some people in the queue. We'll take as many questions as we can with the time allotted. Reminder to dial 1 and then 0 if you'd like to get in the queue. First up is Nick Wadhams from Bloomberg.

QUESTION: Hi, thanks very much. I had a couple questions. The first is: Is there any circumstance under which the U.S. would consider rejoining the WHO if it enacted reforms that the administration seeks? And then also, just to follow up on something you said, if the U.S. believes that the WHO is such a failed institution, why do you believe that you should stay involved with the organization?

And then secondly, in March, the Secretary said Americans "should be aware and proud of our vast commitments to important institutions" – that's a direct quote – including the WHO. That was March 31st after the extent of the virus was largely known, so I'm curious what changed between March 31st when Secretary Pompeo said that and July when the President decided to pull out of WHO. Thank you.

MS COOK: Well, let me take some of those questions and then open it up to my colleagues from HHS and USAID.

In terms of whether we would reconsider the decision, I think it's best to quote from the President. He did say in June that he was not reconsidering the decision unless WHO gets its act together, and he was not sure at that time that they can. He has also indicated in July that our withdrawal doesn't mean that someday we won't go back in. As he said, maybe we will when it is correctly run. The position of the White House is that the WHO needs to reform, and that is starting with demonstrating its independence from the Chinese Communist Party. And it needs to make improvements in its ability to prepare for, to prevent, to detect, and to respond to outbreaks of dangerous pathogens.

Let me see if either Garrett or Alma would like to add to that.

MR GRIGSBY: No, I think you covered it well, Nerissa.

MS GOLDEN: I agree. Thank you, Nerissa.

MS ORTAGUS: Great, thank you. Let's now turn it over to Toby Burns from NHK.

QUESTION: Hi there, thanks very much. I appreciate the briefing. The first question is for Ms. Cook. It's about the $62 million that were going to be reprogrammed to the UN. Do you have more details on how that money is going to be reprogrammed and what it's going to go to?

And then the second question is for Ms. Golden, which is just a clarification on the 68 million in contributions that you announced to Libya and Syria. How specifically – who's going to get that money specifically and how is it going to be deployed? Thank you very much.

MS COOK: Thank you for the question. The reprogramming of the balance of the FY 2020 assessed will be reprogrammed to partially pay an assessment to the UN. Right now, the department is in the process of notifying Congress of the reprogramming of the funds and we will have more specifically once that process is complete.

MS ORTAGUS: Great. Thank you. Over to Will Mauldin from *Wall Street Journal*.

QUESTION: Thank you so much. That previous question was along the lines of mine. But if you had any further – I just wanted to follow up if you had any further color on the 68 million one-time WHO support for humanitarian assistance in Syria plus polio. That's going to the WHO in addition to what was previously budgeted? How exactly does that work? Thank you.

MS GOLDEN: This is Alma Golden. Basically, USAID will provide up to 44 million for the eradication of polio. Particularly, we are concerned about assuring that Afghanistan and Pakistan, which have endemic polio, will be reached in this important campaign.

And then secondarily, there – we will – USAID could provide support to the WHO in Libya where it is the only organization able to manage the large-scale procurement of the essential pharmaceuticals for the humanitarian health response in that country.

And similarly, USAID could also provide support in Syria where the organization's cross-line and cross-border access are critical to the response for the humanitarian crisis, as well as what we're seeing in the COVID-19 pandemic in that area. Thank you.

MS ORTAGUS: Great. Thanks. Now let's turn it over to Jennifer Hansler, CNN.

QUESTION: Hi. Thank you for doing this. I was wondering if you could go into more specifics of what demonstrating independence from China would look like. And do you believe that Dr. Tedros is still the appropriate leader for the WHO? And then if I might on COVAX, can you explain why the U.S. feels that this is the most productive path, to not be involved with this global initiative? Thank you.

MS COOK: On the China issue, our view is that the WHO needs to be independent in its processes and procedures in dealing with pandemics. So we are advocating for greater transparency and greater accountability. And we want to see speedier and higher quality of communications in the face of pandemics. We want decision-making to be based on science and not on other considerations. And we want to see very strong management and a focus on the prevention and detection and response to pandemics.

Let me turn now on COVAX to Garrett Grigsby.

MR GRIGSBY: Thanks, Nerissa. I don't think it's actually well understood that the U.S. on a technical level is really in constant contact with countries that are participating in COVAX on these issues as well as the organizations like Gavi. In fact, we're a very generous funder of Gavi. So that really needs to be taken into account and understood. And as Secretary Azar has said on a number of occasions, once the American people – their needs with respect to the vaccine are met, hopefully, depending on how the vaccine trials turn out and the rest of it, there will be a good excess of vaccines and we certainly will be looking to do our fair share in terms of supporting the global need for vaccinations. And in addition to that, there's going to be significant manufacturing capacity that has been built because of this whole process, and of course that is going to remain available to the world as well. Over.

MS ORTAGUS: Great, thank you. I'm trying to squeeze in a few more questions here before we have to go. Carmen Paun, Politico. Carmen? Okay. Can we try Narise from NPR? AT&T, are we having trouble getting these? They're in our queue. Am I still on? Hello?

OPERATOR: Yes, I am. That's Narise.

MS ORTAGUS: Okay. We have Carmen and Narise in the queue. Can we unmute either one of their lines?

OPERATOR: Carmen is – your line is now open, please. Oh, she's dropped. What's going on here?

MS ORTAGUS: Why don't we try – I think I have Michelle Nichols up next from Reuters.

OPERATOR: Okay, your line is now open.

QUESTION: Oh, great. Thanks so much for this briefing. I'm just trying to harp on this. I just wanted to clarify some of the numbers. According – when was the $58 million paid earlier this year? Because I'm looking at a statement from the 31st of January which shows that the U.S. also owes about $80 million for last year. So what's your understanding of how much in arrears the U.S. was in assessed contributions to WHO, and will that be paid?

And also, regarding the withdrawal, the resolution by Congress on the withdrawal saying you have to give a year's notice also says that you have to pay what you owe. So how are you hoping to sort of satisfy that requirement? Is that why this money, the 62 million, is being redirected to just normal UN assessments? Thanks.

MS COOK: I would have to get back to you on the exact date when the 58 million was paid. So we will – we will look to do that. On the – could you repeat the question again, please, the second half? On the 62.

MS ORTAGUS: Yeah, AT&T, I think we'll need you to unmute Michelle again for her to repeat that question.

QUESTION: Hello?

MS COOK: Yes.

MS ORTAGUS: Yes, Michelle, we can hear you. Go ahead. She just was asking —

QUESTION: Yes, sorry, sorry. Just how much – how much in arrears is the U.S., not counting what you owe for this year? How much do you owe in arrears? And the 62 million, what – is that being redirected to just the usual United Nations here in New York assessed contribution? Is that what you're talking about? And under the decision by Congress on a withdrawal from WHO, the U.S. has to pay what it owes to WHO to be able to withdraw. So how are you sort of getting around that?

MS COOK: The – right. I think you referred to there's about 18 million in FY19 funding and 62 million in FY20, and those together are being reprogrammed to the UN to pay the regular UN assessment.

MS ORTAGUS: Great, thank you.

MS COOK: Yeah.

MS ORTAGUS: Okay. We have time for one more question, and it will come from the line of Tom Howell from *The Washington Times*.

QUESTION: Thank you for doing the call. You just talked about the regular dues, but I want to – I had a question about the other numbers, the 40 million for immunization and influenza, and the 68 million in the humanitarian aid. I just want to make sure I'm using the right terms. Is that what's called voluntary contributions? Are you saying that those monies will go to WHO partners, but in the future you hope to find other, non-WHO partners for that – those kind of missions? Do I have that right?

MR GRIGSBY: Yes, that's right. Those —

QUESTION: All right. Thank you.

MR GRIGSBY: Yeah.

QUESTION: Thanks.

MS ORTAGUS: All right. Well, since that was quick, I think we can sneak in one more. Conor Finnegan.

QUESTION: Hey, can you hear me?

MS ORTAGUS: You're good to go, Conor.

QUESTION: Good. So just to follow up on Jennifer's question, the specific reforms that you laid out, why was the – why would the administration think it's sort of realistic for WHO to make those reforms on its own in the middle of this crisis? And why do you believe that leaving the organization now gives you leverage to effect those changes? Thank you.

MR GRIGSBY: Nerissa, do you —

MS COOK: What? Yes, go ahead.

MR GRIGSBY: In terms of leaving the organization, I mean, that's – the U.S. has traditionally been, I think since the very beginning, the largest donor to WHO. And so I believe that we have actually a tremendous amount of leverage. And we will – we have been and we'll continue to work with other countries during this period where – before it's – we officially pull out of WHO to try to seek reforms. Because if WHO works better, that's – that'll be good for everybody. But I just – I guess I fundamentally disagree with your premise. We actually do have quite a bit of leverage, and if they're interested in seeing the United States stay, they will take that seriously and negotiate seriously.

What was your first – your first question? The first part of your question? Repeat that.

MS ORTAGUS: AT&T, that's Conor Finnegan. He'll need to be unmuted, please.

MS COOK: What I might just add as we're waiting for that to happen is that within the WHO membership, there was a lot of consensus back at the time of the May World Health Assembly about the need for reform and to do a better job in terms of the response to COVID-19. And this resulted with U.S. leadership in the World Health Assembly resolution that, among other things, called for the establishment of an inter – independent panel to evaluate the global response, including WHO's performance, and to investigate the origin and the spread of the coronavirus.

So there was consensus among WHO membership that changes needed to be made, and if you recall during the West Africa Ebola outbreak, there were also midterm reviews done with an – with the intent to strengthen the response at that time. So that is the idea of reforming and strengthening in the middle of a pandemic, is something that is part of public health policy.

MR GRIGSBY: Thanks, Nerissa. You actually did answer the first part of his question. And it – that's the same as what I would have answered. So, thanks.

MS ORTAGUS: Wonderful. Well, everybody, we're over our time limit. We'd just like to thank all of our reporters for dialing in, and thank you to our briefers. Have a wonderful afternoon.

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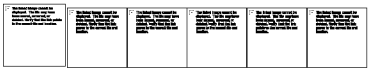

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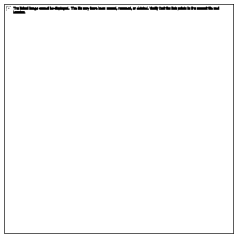

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Subject: [EXTERNAL] Re: Podcast on the Effect of Lockdowns on Residents of Long-Term Care Facilities During COVID-19

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Do not cast me off in old age; when my strength fails, do not forsake me! - Psalms 71:9

On Fri, Mar 5, 2021 at 9:34 PM Costa, Kevin <kevincosta@alumni.brown.edu> wrote:

---------- Forwarded message ---------
From: **National Consumer Voice for Quality Long-Term Care** <info@theconsumervoice.org>
Date: Fri, Mar 5, 2021 at 4:56 PM
Subject: Podcast on the Effect of Lockdowns on Residents of Long-Term Care Facilities During COVID-19
To: Kevin Costa <kevincosta@alumni.brown.edu>

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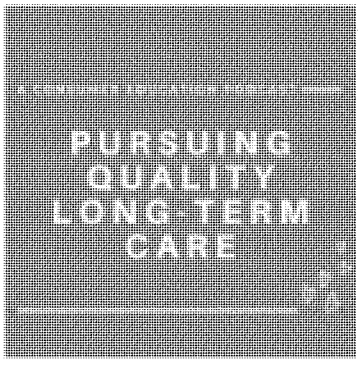
The National CONSUMER VOICE for Quality Long-Term Care



SHARE:

THE DEVASTATING EFFECT OF LOCKDOWNS ON RESIDENTS OF LONG-TERM CARE FACILITIES DURING COVID-19

Description

On March 13, 2021, it will be one year since the Center for Medicare & Medicaid Services (CMS) issued an order preventing everyone but essential healthcare workers from entering facilities. To date, despite some loosening of visitation restrictions, tens of thousands of residents have still not seen their families and loved ones in person. Chronic short-staffing of nursing homes that plagued facilities before the pandemic has gotten worse, with almost 1 in 5 facilities reporting staff shortages in aides. As a result, the lockdown has resulted in many residents suffering from isolation and neglect.

In late 2020, The Consumer Voice conducted an informal survey of families that had visited with their loved ones to learn how the lockdown has impacted residents' condition. The overwhelming response was that families met residents who had

experienced significant declines in their physical and mental health. In this episode of the *Pursuing Quality Long-Term Care* podcast, Sam Brooks and Lori Smetanka of Consumer Voice will discuss the survey results and Consumer Voice's call to safely reopen facilities so that families can provide necessary care and support to residents.

Resources: The Devastating Effect of Lockdowns on Residents of Long-Term Care Facilities During COVID-19: A Survey of Residents' Families | Voices from the Inside Consumer Voice Webpage

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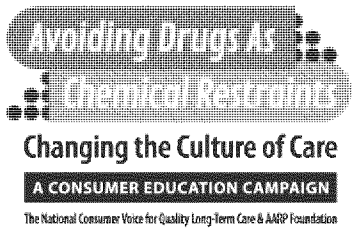
Below is a full list of past episodes that you can listen to on Apple Podcasts, SoundCloud, Facebook, or our website.

- **Episode 1**: Avoiding Drugs as Chemical Restraints | *Kelly Bagby, AARP Foundation Litigation*
- **Episode 2:** Staying Connected from a Distance to People Living in Long-Term Care | *Kim Grier, Grier Dementia Training*
- **Episode 3:** Keeping Families Together/Bringing A Loved One Home | *Julie Schoen, Co-Director National Center on Elder Abuse*
- **Episode 4:** Putting a Stop to Poor Care | *Eden Ruiz-Lopez, Assistant Deputy Director, National Center on Elder Abuse*
- **Episode 5:** What to Look for and Questions to Ask as You Resume Visits in a Long-Term Care Facility | *Steven Levin, Michael Bonamarte, Levin & Perconti*
- **Episode 6:** What Does Family Advocacy Look Like During COVID-19? | *Robyn Grant, National Consumer Voice for Quality Long-Term Care*
- **Episode 7:** Understanding Person-Centered Care | *Sonya Barsness, Gerontologist*
- **Episode 8:** Finding Real Solutions for Behavioral Health Needs in Persons with Dementia | *Kelly Bagby, AARP Foundation Litigation and Sue Renz, Practice Associate Professor at the University of Pennsylvania School of Nursing*
- **Episode 9:** Advocating for Resident's Rights: About the Long-Term Care Ombudsman Program | *Beverley Laubert, Ohio State Long-Term Care Ombudsman and Patty Ducayet, Texas State Long-Term Care Ombudsman*
- **Episode 10:** The Impact of Social Isolation on Nursing Home Residents During COVID-19 | *Anne Montgomery and Sarah Slocum, Co-Directors of Eldercare Improvement at Altarum*

- **Episode 11:** The Devastating Effect of Lockdowns on Residents of Long-Term Care Facilities During COVID-19 | *Sam Brooks and Lori Smetanka, Consumer Voice*



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Subject: [EXTERNAL] Fwd: Podcast on the Effect of Lockdowns on Residents of Long-Term Care Facilities During COVID-19

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From: **National Consumer Voice for Quality Long-Term Care** <info@theconsumervoice.org>
Date: Fri, Mar 5, 2021 at 4:56 PM
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To: Kevin Costa <kevincosta@alumni.brown.edu>

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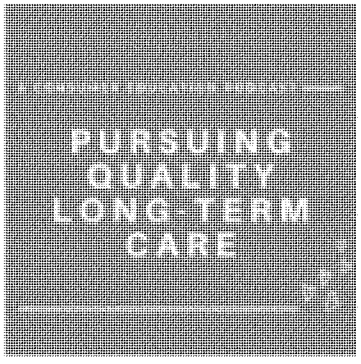

SHARE:

THE DEVASTATING EFFECT OF LOCKDOWNS ON RESIDENTS OF LONG-TERM CARE FACILITIES DURING COVID-19

Description

On March 13, 2021, it will be one year since the Center for Medicare & Medicaid Services (CMS) issued an order preventing everyone but essential healthcare workers from entering facilities. To date, despite some loosening of visitation restrictions, tens of thousands of residents have still not seen their families and loved ones in person. Chronic short-staffing of nursing homes that plagued facilities before the pandemic has gotten worse, with almost 1 in 5 facilities reporting staff shortages in aides. As a result, the lockdown has resulted in many residents suffering from isolation and neglect.

In late 2020, The Consumer Voice conducted an informal survey of families that had visited with their loved ones to learn how the lockdown has impacted residents' condition. The overwhelming response was that families met residents who had experienced significant declines in their physical and mental health. In this episode of the *Pursuing Quality Long-Term Care* podcast, Sam Brooks and Lori Smetanka of

Consumer Voice will discuss the survey results and Consumer Voice's call to safely reopen facilities so that families can provide necessary care and support to residents.

Resources: The Devastating Effect of Lockdowns on Residents of Long-Term Care Facilities During COVID-19: A Survey of Residents' Families | Voices from the Inside Consumer Voice Webpage

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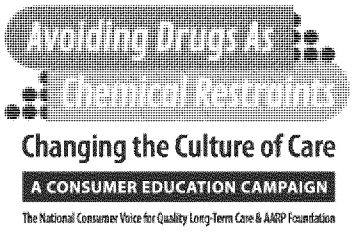
Below is a full list of past episodes that you can listen to on Apple Podcasts, SoundCloud, Facebook, or our website.

- **Episode 1**: Avoiding Drugs as Chemical Restraints | *Kelly Bagby, AARP Foundation Litigation*
- **Episode 2:** Staying Connected from a Distance to People Living in Long-Term Care | *Kim Grier, Grier Dementia Training*
- **Episode 3:** Keeping Families Together/Bringing A Loved One Home | *Julie Schoen, Co-Director National Center on Elder Abuse*
- **Episode 4:** Putting a Stop to Poor Care | *Eden Ruiz-Lopez, Assistant Deputy Director, National Center on Elder Abuse*
- **Episode 5:** What to Look for and Questions to Ask as You Resume Visits in a Long-Term Care Facility | *Steven Levin, Michael Bonamarte, Levin & Perconti*
- **Episode 6:** What Does Family Advocacy Look Like During COVID-19? | *Robyn Grant, National Consumer Voice for Quality Long-Term Care*
- **Episode 7:** Understanding Person-Centered Care | *Sonya Barsness, Gerontologist*
- **Episode 8:** Finding Real Solutions for Behavioral Health Needs in Persons with Dementia | *Kelly Bagby, AARP Foundation Litigation and Sue Renz, Practice Associate Professor at the University of Pennsylvania School of Nursing*
- **Episode 9:** Advocating for Resident's Rights: About the Long-Term Care Ombudsman Program | *Beverley Laubert, Ohio State Long-Term Care Ombudsman and Patty Ducayet, Texas State Long-Term Care Ombudsman*
- **Episode 10:** The Impact of Social Isolation on Nursing Home Residents During COVID-19 | *Anne Montgomery and Sarah Slocum, Co-Directors of Eldercare Improvement at Altarum*
- **Episode 11:** The Devastating Effect of Lockdowns on Residents of Long-Term Care Facilities During COVID-19 | *Sam Brooks and Lori Smetanka, Consumer Voice*



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Subject: [EXTERNAL] White House COVID-19 Response Team Holds Briefing - 3/5/21

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White House COVID-19 Response Team Holds Briefing

The White House COVID-19 response team held a virtual briefing on the administration's efforts to combat the pandemic. White House senior adviser Andy Slavitt spoke about the partnership between pharmaceutical companies Johnson & Johnson and Merck to produce the vaccine as well as new FEMA sites being established to administer the vaccine in underserved communities. CDC Director Dr. Rochelle Walensky spoke about current virus trends, which showed the U.S. was experiencing about 62,000 cases and 2,000 deaths per day. National Institute of Allergy and Infectious Diseases Director Dr. Anthony Fauci spoke about the nature of the virus and its variants, and touted the efficacy and safety of all three FDA-approved vaccines. The officials urged the public to continue to maintain mitigation measures while the vaccine becomes more readily available.

https://www.c-span.org/video/?509609-1/health-officials-urge-continued-mask-wearing-fema-supported-vaccine-sites-open#

Best regards,

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Subject: [EXTERNAL] Re: Johnson & Johnson CEO Alex Gorsky on Company's COVID-19 Vaccine

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Johnson and Johnson CEO Alex Gorsky spoke with the Washington Post about the company's newly approved COVID-19 vaccine. He defended its efficacy data compared to the other two vaccines available for emergency use. Other topics discussed included the company's partnership with Merck to ramp up vaccine production, vaccine hesitancy and education, and variants spreading in the U.S. and other countries.

On Wed, Mar 3, 2021 at 12:59 PM Costa, Kevin <kevincosta@alumni.brown.edu> wrote:

Johnson & Johnson CEO Alex Gorsky on Company's COVID-19 Vaccine

Johnson and Johnson CEO Alex Gorsky talks with the Washington Post about the company's newly approved COVID-19 vaccine.

https://www.c-span.org/video/?509480-1/johnson-johnson-ceo-alex-gorsky-discusses-shot-covid-19-vaccine

Best regards,

Kevin Costa

From: Costa, Kevin [kevincosta@alumni.brown.edu]
Sent: 3/3/2021 12:59:34 PM
To: Alex Gorsky [agorsky@its.jnj.com]; Xavier Becerra [xavier.becerra@doj.ca.gov]; Rachana Pradhan [rpradhan@kff.org]; Marcella Nunez-Smith [marcella.nunez-smith@yale.edu]; Rochelle Walensky [RWALENSKY@mgh.harvard.edu]; Sarah Mbaeyi [smbaeyi@cdc.gov]; Oliver, Sara E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f0c997e0cf747008bd722c00bbba4ab-HHS-yxo4-cd]; Dooling, Kathleen L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8eef7360160c4da7aeb330413a2e0f8f-HHS-vic9-cd]; Dariush Mozaffarian [orsolya.szabo@tufts.edu]; Junxiu Liu [junxiu.liu@tufts.edu]; Frederick Cudhea [Frederick.Cudhea@tufts.edu]; Renata Micha [renata.micha@tufts.edu]; Meghan O'Hearn [Meghan.O_Hearn@tufts.edu]; Yves Smith [yves@nakedcapitalism.com]; Jesse Goodman [jlg251@georgetown.edu]; Johan Van Hoof (b)(6) @gmail.com]; Gregory Poland [poland.gregory@mayo.edu]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Arnold S. Monto [asmonto@umich.edu]; Atreya, Prabhakara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f96e446284da421a91a4479bb6e553c1-AtreyaP]; Hayes, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb93ef79b3474f7099917a7d1ed56be9-Kathleen.Ha]; Vert, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dd920d5580d47e8881a9c325517a2f9-Christina.V]; Devine, Jeannette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae36f73172254da2bfb59e33b02426c3-Jeannette.D]; Hill, Monique [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2182de5e12b1484cb87ef70aff92de7f-Monique.Hil]; Cody Meissner [cmeissner@tuftsmedicalcenter.org]; Hayley Gans [hagans@stanford.edu]; Kurilla, Michael G (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa2de9594d594ed9b76b935545c26754-HHS-michael]; Paula Annunziato [paula.annunziato@merck.com]; Steven Pergam [spergam@fhcrc.org]; Oveta Fuller [fullerao@umich.edu]; Eric Rubin [erubin@hsph.harvard.edu]; James Hildreth [officeofthepresident@mmc.edu]; Jay Portnoy [Jportnoy@cmh.edu]; Jennette Lee [JYLee@uams.edu]; Mark Sawyer [mhsawyer@health.ucsd.edu]; Ofer Levy [ofer.levy@childrens.harvard.edu]; Patrick Moore [psm9@pitt.edu]; Stanley Perlman [stanley-perlman@uiowa.edu]; Macneil, Adam (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=569fde2cfac9431e848e63b192d30e14-HHS-aho3-cd]; Rachel Levine [rll12@psu.edu]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Brian Castrucci [castrucci@beaumont.org]; Eric Lander [eric.s.lander@ostp.eop.gov]; Rana Hogarth [rhogarth@illinois.edu]; David Schildmeier [DSchildmeier@mnarn.org]; Mary Lou Hennebry (b)(6) @hotmail.com]; Ezekiel Emanuel [zemanuel@upenn.edu]; Philip Landrigan [landrigp@bc.edu]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Robert R. Redfield [olx1@cdc.gov]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Brooks, John T (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=def0cf9cf9f84fc6a40c4dde8c51b199-HHS-zud4-cd]; Armstrong, Gregory L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67c30c93e434442a9c6786330560e995-HHS-gca3-cd]; Yong-Zhen Zhang [zhangyongzhen@shphc.org.cn]; George Gao [gaof@im.ac.cn]; Lawrence Gostin [gostin@law.georgetown.edu]; Yanzhong Huang [yanzhong.huang@shu.edu]; Ian Lipkin [wil2001@columbia.edu]; Edward Holmes [edward.holmes@sydney.edu.au]; Peter Daszak [daszak@ecohealthalliance.org]; Wang Linfa [linfa.wang@duke-nus.edu.sg]; Dake Kang [dkang@ap.org]; James Palmer [james.palmer@foreignpolicy.com]; Wang Guangfa (b)(6) @hotmail.com]; Gauden Galea [GaleaG@who.int]; Andrew Rambaut [a.rambaut@ed.ac.uk]; Maria Van Kerkhove [m.vankerkhove@imperial.ac.uk]; Ngozi Ezike [Ngozi.Ezike@illinois.gov]; Courtney Phillips [Courtney.Phillips@la.gov]; Jill Hunsaker Ryan [Jill.Ryan@state.co.us]; John Barry (b)(6) @aol.com]; Andrew Stanley Pekosz [apekosz1@jhu.edu]; Aaron David Miller [Aaron.Miller@ceip.org]; John Komlos [John.Komlos@gmx.de]; Libby Watson (b)(6) @gmail.com]; Peter Hotez [hotez@bcm.edu]; Orsega, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject: [EXTERNAL] Johnson & Johnson CEO Alex Gorsky on Company's COVID-19 Vaccine

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Johnson & Johnson CEO Alex Gorsky on Company's COVID-19 Vaccine

Johnson and Johnson CEO Alex Gorsky talks with the Washington Post about the company's newly approved COVID-19 vaccine.

https://www.c-span.org/video/?509480-1/johnson-johnson-ceo-alex-gorsky-discusses-shot-covid-19-vaccine

Best regards,

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Best regards,

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Subject: [EXTERNAL] President Biden Delivers Remarks on COVID-19

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President Biden Delivers Remarks on COVID-19

President Biden delivered remarks in the State Dining Room of the White House on his administration's response to the COVID-19 pandemic.

https://www.c-span.org/video/?509456-1/president-biden-us-track-vaccines-adult-end

Best regards,

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Subject: [EXTERNAL] Re: "Rachana Pradhan on Vaccine Supply Chains" and "White House COVID-19 Response Team Briefing"

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Johnson & Johnson Distributes COVID-19 Vaccine

The Johnson & Johnson COVID-19 vaccine was boxed and shipped from its McKesson distribution facility in Shepherdsville, Kentucky. Workers sorted and readied vials in the refrigerator which was kept between 36 and 46 degrees Fahrenheit. Vaccines were then moved to the packing area where they were placed in freezer boxes for shipping. The first Johnson & Johnson COVID-19 vaccine shipment was bound for Ohio and Indiana. https://www.c-span.org/video/?509422-1/johnson-johnson-distributes-covid-19-vaccine# (4 minute video)

On Mon, Mar 1, 2021 at 1:52 PM Costa, Kevin <kevincosta@alumni.brown.edu> wrote:

White House COVID-19 Response Team Briefing

The White House COVID-19 Response Team held a briefing focusing on the newly-approved Johnson and Johnson single-shot vaccine. Dr. Marcella Nunez-Smith, who leads health equity issues on the response team, talked about the benefits of the new vaccine but urged people to not wait to get vaccinated. “As a physician, I strongly urge everyone in America to get the first vaccine that is available to you when it is your turn,” she said during the briefing. Other questions focused on the lag in wait time for appointments to get vaccinated and questions on when the Centers for Disease Control and Prevention (CDC) will release guidance on what people can do once vaccinated, specifically traveling and social gatherings.

https://www.c-span.org/video/?509426-1/health-officials-urge-public-vaccinated-wait-single-shot-vaccine#

Rachana Pradhan on Vaccine Supply Chains
Rachana Pradhan talked about coronavirus vaccine supply chains.
https://www.c-span.org/video/?509360-4/washington-journal-rachana-pradhan-discusses-vaccine-supply-chains

Best regards,

Kevin Costa

From: Costa, Kevin [kevincosta@alumni.brown.edu]
Sent: 3/1/2021 1:53:37 PM
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Subject: [EXTERNAL] Fwd: Register to Attend a Rally to Lift the Lockdown

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Date: Mon, Mar 1, 2021 at 1:38 PM
Subject: Register to Attend a Rally to Lift the Lockdown
To: Kevin Costa <kevincosta@alumni.brown.edu>

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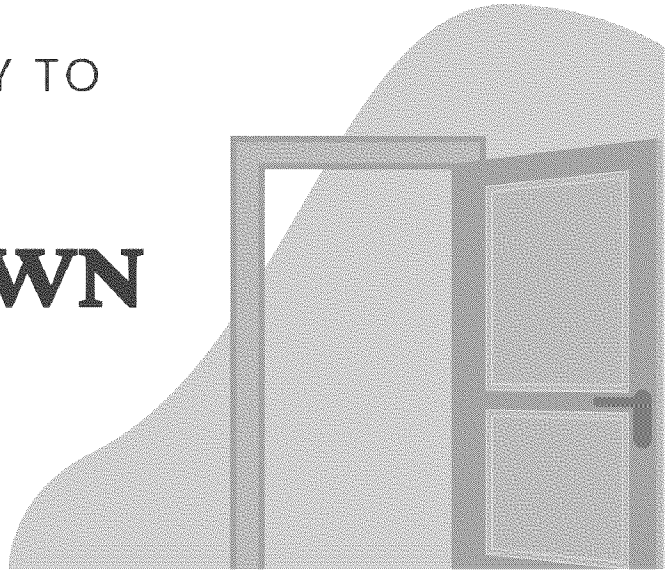
A VIRTUAL RALLY TO

LIFT THE LOCKDOWN

Friday, March 12th
12:00pm ET



Register Now

Join Consumer Voice for a rally Friday, March 12th at 12:00pm ET commemorating the one year anniversary of the nursing home visitation ban.

At the rally, we'll:

- **Honor** those we've lost;
- **Hear** directly from residents and family members about their experiences during the lockdown; and
- **Mobilize** family members, residents of long-term care, and advocates to ask their state and federal policymakers and the Centers for Medicare & Medicaid Services (CMS) to safely "open nursing home doors."

Register Now

Visit our website to learn more about why it's imperative to lift the lockdown.

Remembering Those Lost - At the rally, we will have a moment of silence with a remembrance collage of pictures of those who passed away in a nursing home during the COVID-19 pandemic. If you, or someone you know, has lost a loved one since the visitation lockdown began in March 2020 and would like them to be included in this special collage, please send a photo of your

loved one to info@theconsumervoice.org by March 9th, 2021, along with their name, your name, your relationship, and anything else you'd like to include. Thank you so much for helping us pay tribute to and show our respect for those who have died over the course of this tragic year.

Sign the Petition to Reunite Nursing Home Residents with Their Loved Ones

Initially put in place to protect residents from COVID-19, the visitation ban has resulted in thousands of residents suffering and dying from isolation, loneliness, and poor care. It is time to stop the suffering and open the doors.

Sign the petition to tell officials of the federal Centers for Medicare and Medicaid Services, Congress, your state legislators, and your Governor to lift the visitation ban now and open nursing home doors.

FOLLOW US

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Subject: [EXTERNAL] "Rachana Pradhan on Vaccine Supply Chains" and "White House COVID-19 Response Team Briefing"

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White House COVID-19 Response Team Briefing
The White House COVID-19 Response Team held a briefing focusing on the newly-approved Johnson and Johnson single-shot vaccine. Dr. Marcella Nunez-Smith, who leads health equity issues on the response team, talked about the benefits of the new vaccine but urged people to not wait to get vaccinated. “As a physician, I strongly urge everyone in America to get the first vaccine that is available to you when it is your turn,” she said during the briefing. Other questions focused on the lag in wait time for appointments to get vaccinated and questions on when the Centers for Disease Control and Prevention (CDC) will release guidance on what people can do once vaccinated, specifically traveling and social gatherings.
https://www.c-span.org/video/?509426-1/health-officials-urge-public-vaccinated-wait-single-shot-vaccine#

Rachana Pradhan on Vaccine Supply Chains
Rachana Pradhan talked about coronavirus vaccine supply chains.
https://www.c-span.org/video/?509360-4/washington-journal-rachana-pradhan-discusses-vaccine-supply-chains

Best regards,

Kevin Costa

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Subject: [EXTERNAL] Re: FDA Meeting on the Janssen Biotech COVID-19 Vaccine (unanimously approves emergency use authorization for the Johnson & Johnson COVID-19 vaccine)

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F.D.A.'s expert panel voted in favor of the Johnson & Johnson shot.

Empty vials of the Johnson & Johnson vaccine at a hospital in South Africa.Credit...Phill Magakoe/Agence France-Presse — Getty Images

Johnson & Johnson's Covid-19 vaccine was endorsed on Friday by a panel of experts advising the Food and Drug Administration, clearing the last hurdle before a formal authorization expected on Saturday, according to two people familiar with the agency's plans. The nation's first shipments will go out in the days after that.

It will be the third shot made available to the United States in the year since the first surge of coronavirus cases began washing over the country, and it will be the first vaccine to require just one dose instead of two.

Johnson & Johnson's formulation worked well in clinical trials, particularly against severe disease and hospitalizations, even though it did not match the sky-high efficacy rates of the first two vaccines made by Pfizer-BioNTech and Moderna.

The panel, made up of independent infectious disease experts, statisticians and epidemiologists, voted unanimously in favor of authorizing the vaccine.

"We're dealing with a pandemic right now," said Dr. Jay Portnoy, an allergist at Children's Mercy Hospital in Kansas City, Mo., and a member of the board. "It's great that we have this vaccine."

During Johnson & Johnson's presentation to the panel, Dr. Gregory Poland, a virologist at the Mayo Clinic and a paid external consultant for the company, noted the vaccine's efficacy, ease of use and low rate of side effects. It "nearly checks all the boxes," he said. "To me, it is clear that the known benefits vastly outweigh the known risks."

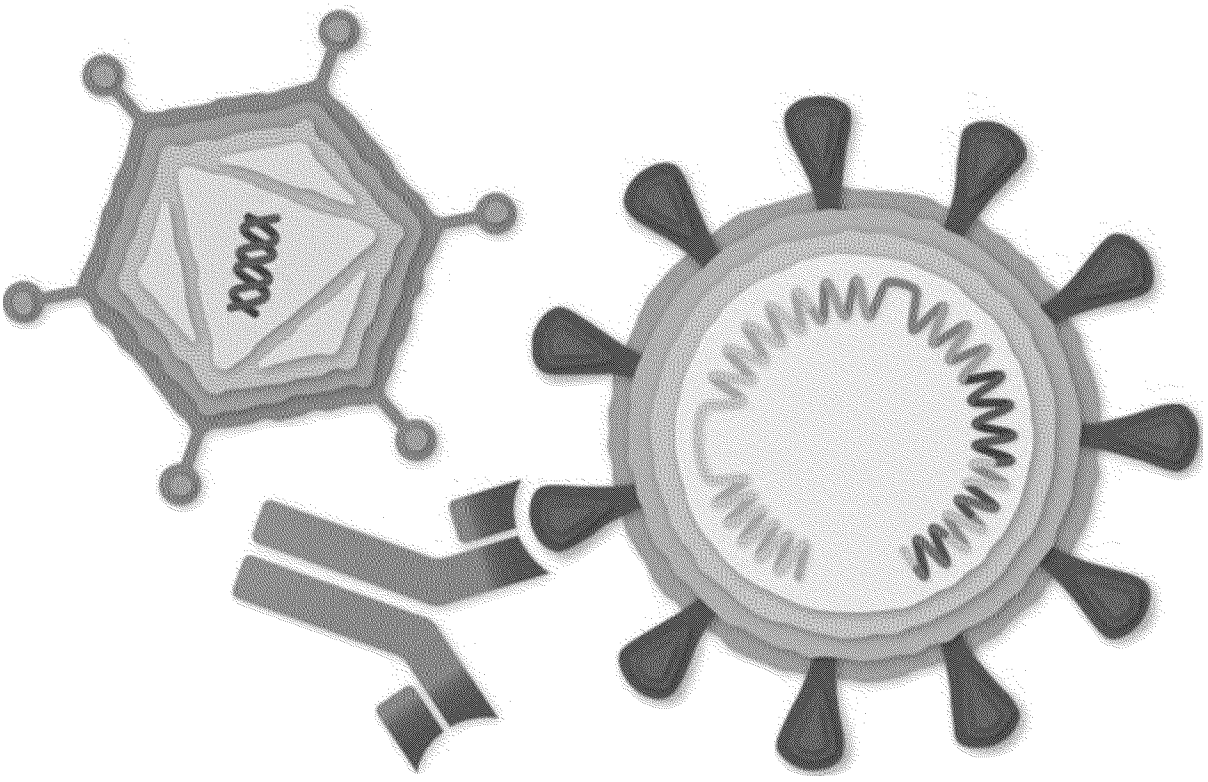
WHICH VACCINE SHOULD YOU GET?

From January: Even with lower efficacy, infectious disease doctors say the J & J vaccine would still be worthwhile.

The vaccine had an overall efficacy rate of 72 percent in the United States and 64 percent in South Africa, where a concerning variant emerged in the fall. The shot showed 86 percent efficacy against severe forms of Covid-19 in the United States, and 82 percent against severe disease in South Africa. Those are strong numbers, but lower than the roughly 95 percent efficacy rates of Pfizer-BioNTech and Moderna's vaccines against mild, moderate and severe cases of Covid.

Johnson & Johnson's vaccine is a single dose and uses a different kind of technology than the authorized vaccines. And the scale and size of the Johnson & Johnson trial was vast, spanning eight countries, three continents and nearly 45,000 participants.

Although the vaccine works with one shot, studies are underway to determine if a second dose would increase its protective effects.



How the Johnson & Johnson Vaccine Works

An adenovirus helps prime the immune system to fight the coronavirus.

Dr. Paul Offit, a pediatrician at the Children's Hospital of Philadelphia and one of the panelists, pointed out on Friday that in early clinical trials that took place over the summer, Johnson & Johnson found that a second dose led to levels of coronavirus antibodies that were almost three times higher than those produced by one dose alone.

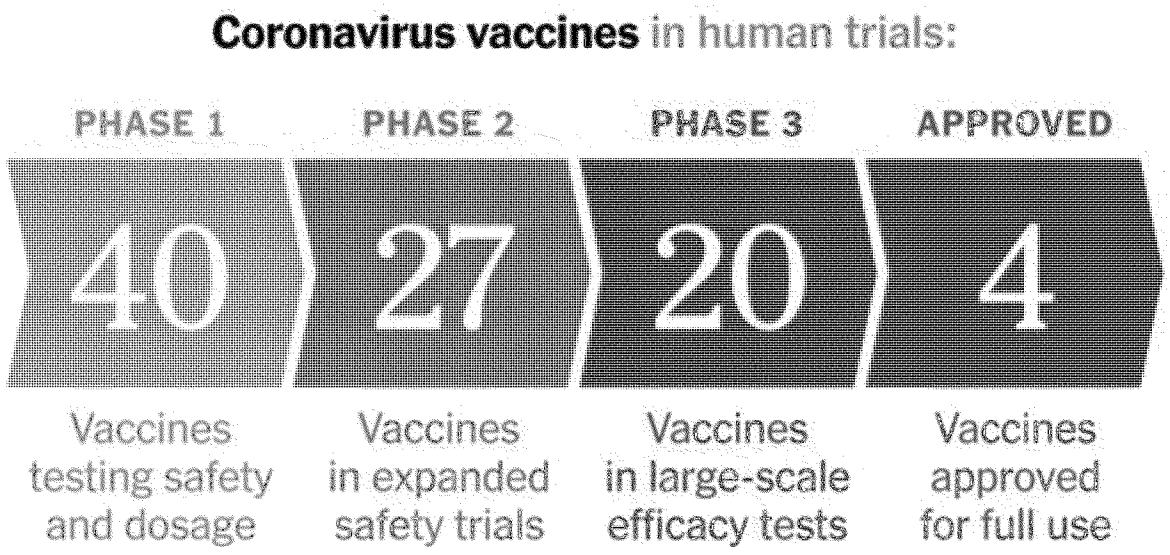
The results of Johnson & Johnson's two-dose, late-stage clinical trial are not expected until July at the earliest. If those results turn out to be better than a single dose, Dr. Offit asked, "Does this then become a two-dose vaccine?"

Dr. Johan Van Hoof, the global head of vaccine research and development at Janssen Pharmaceuticals, the drug development arm of Johnson & Johnson, said that the company decided to pursue the one-shot strategy after its studies on monkeys last spring showed that a single dose was enough to provide strong protection against the disease.

"It's clear that in a situation of an outbreak, in a raging epidemic, the big challenge is to get the epidemic under control," he said. "The regimen is extremely well positioned to be used in outbreak situations."

But Dr. Van Hoof also noted that it will be important to track volunteers who received a single dose to see if their immunity changes in the months to come. It might be necessary to deliver a booster shot for long-term protection. "The big question mark still is, how long does protection last?" he said.

After the vote, the F.D.A. told Johnson & Johnson that it "will rapidly work toward finalization and issuance of an emergency use authorization," according to a statement. The F.D.A. also said that it had notified other government agencies "so they can execute their plans for timely vaccine distribution."



Coronavirus Vaccine Tracker

A look at all the vaccines that have reached trials in humans.

— *Carl Zimmer, Noah Weiland and Sharon LaFraniere*

ANOTHER VACCINE
With this last hurdle cleared, formal authorization of Johnson & Johnson's one-dose vaccine is expected on Saturday and distribution within days.

On Fri, Feb 26, 2021 at 6:12 PM Costa, Kevin <kevincosta@alumni.brown.edu> wrote:

FDA Holds an Open Meeting on the Janssen Biotech COVID-19 Vaccine,
Part 1 The Food and Drug Administration holds a virtual open meeting to discuss emergency use authorization for the Janssen Biotech COVID-19 vaccine.
https://www.c-span.org/video/?509043-1/fda-holds-open-meeting-janssen-biotech-covid-19-vaccine-part-1

FDA Holds an Open Meeting on the Janssen Biotech COVID-19 Vaccine,
Part 2 Following a day-long meeting, the FDA Advisory Committee unanimously approves emergency use authorization for the Johnson & Johnson COVID-19 vaccine developed by its pharmaceutical division Janssen Biotech.
https://www.c-span.org/video/?509043-101/fda-advisory-committee-unanimously-approves-johnson-johnson-covid-19-vaccine

Best regards,

Kevin Costa

Virus-free. www.avast.com

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Subject: [EXTERNAL] Coronavirus Disease 2019 Hospitalizations Attributable to Cardiometabolic Conditions in the United States: A Comparative Risk Assessment Analysis

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Coronavirus Disease 2019 Hospitalizations Attributable to Cardiometabolic Conditions in the United States: A Comparative Risk Assessment Analysis

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Best regards,

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Subject: [EXTERNAL] Dr. Jesse Goodman Discusses COVID-19 Vaccines & Variants

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Dr. Jesse Goodman Discusses COVID-19 Vaccines & Variants

Georgetown University Medical Center's Dr. Jesse Goodman, former chief scientist at the FDA, discusses the latest on COVID-19 vaccines and coronavirus variants.

https://www.c-span.org/video/?509335-3/washington-journal-dr-jesse-goodman-discusses-covid-19-vaccines-variants

Best regards,

Kevin Costa

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Subject: [EXTERNAL] As the U.S. Crosses 500,000 Deaths from COVID-19, These 9 Documentaries Offer Context

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Best regards,

Kevin Costa

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Subject: [EXTERNAL] FDA Open Meeting on Johnson & Johnson COVID-19 Vaccine, Parts 1- 5

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Part 1: FDA Open Meeting on Johnson & Johnson COVID-19 Vaccine
The Food and Drug Administration (FDA) held a virtual open meeting to discuss emergency use authorization for the Johnson & Johnson COVID-19 vaccine. After a roll call of advisory board members, the FDA outlined the reason for emergency use authorization for this vaccine created by Janssen Biotech, which is the pharmaceutical division of Johnson & Johnson. The advisory board took a brief break to address technical difficulties. This was the first portion of the daylong advisory board hearing.
https://www.c-span.org/video/?509043-2/fda-open-meeting-johnson-johnson-covid-19-vaccine-part-1

Part 2: FDA Open Meeting on Johnson & Johnson COVID-19 Vaccine
The Food and Drug Administration (FDA) held a virtual open meeting to discuss emergency use authorization for the Johnson & Johnson COVID-19 vaccine. After a brief break to address technical difficulties, the advisory board heard an epidemiological update on COVID-19 and three specific variants of the disease. The board also heard a presentation on data regarding two previously approved COVID-19 vaccines from Moderna and Pfizer. This was the second portion of the daylong advisory board hearing.
https://www.c-span.org/video/?509043-3/fda-open-meeting-johnson-johnson-covid-19-vaccine-part-2#

Part 3: FDA Open Meeting on Johnson & Johnson COVID-19 Vaccine
The Food and Drug Administration (FDA) held a virtual open meeting to discuss emergency use authorization for the Johnson & Johnson COVID-19 vaccine. Janssen Biotech, which is the pharmaceutical division of Johnson & Johnson, presented the data from its vaccine study. Discussed were the efficacy of the vaccine, the importance of delivering a one-dose versus a two-dose vaccine, side effects experienced by study

participants, and possible complications related to unmasking trial participants. This was the third portion of the daylong advisory board hearing.
https://www.c-span.org/video/?509043-4/fda-open-meeting-johnson-johnson-covid-19-vaccine-part-3#

Part 4: FDA Open Meeting on Johnson & Johnson COVID-19 Vaccine
https://www.c-span.org/video/?509043-5/fda-open-meeting-johnson-johnson-covid-19-vaccine-part-4

Part 5: FDA Open Meeting on Johnson & Johnson COVID-19 Vaccine
https://www.c-span.org/video/?509043-6/fda-open-meeting-johnson-johnson-covid-19-vaccine-part-5#

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Subject: [EXTERNAL] Senate Republicans on Opposition to Xavier Becerra HHS Nomination

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Senate Republicans on Opposition to Xavier Becerra HHS Nomination

Senate Republicans speak to reporters at the U.S. Capitol about their opposition to Health and Human Services Secretary nominee Xavier Becerra, who they say is “radical” and “unqualified” for the job.

https://www.c-span.org/video/?509345-1/senate-republicans-speak-opposition-hhs-secretary-nominee-xavier-becerra

Best regards,

Kevin Costa

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Subject: [EXTERNAL] Media Statement from CDC Director Rochelle P. Walensky, MD, MPH, on Signing the Advisory Committee on Immunization Practices' Recommendation to Use Janssen's COVID-19 Vaccine in People 18 and Older

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Media Statement from CDC Director Rochelle P. Walensky, MD, MPH, on Signing the Advisory Committee on Immunization Practices' Recommendation to Use Janssen's COVID-19 Vaccine in People 18 and Older

https://www.cdc.gov/media/releases/2021/s0228-JJ-vaccine.html

Best regards,

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Subject: [EXTERNAL] President Biden Delivers Remarks at Houston Vaccine Site President Biden delivers remarks at the FEMA COVID-19 vaccine facility at NRG Stadium in Houston, Texas.

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President Biden Delivers Remarks at Houston Vaccine Site

President Biden delivers remarks at the FEMA COVID-19 vaccine facility at NRG Stadium in Houston, Texas.

https://www.c-span.org/video/?509373-1/president-biden-delivers-remarks-houston-vaccine-site

Best regards,

Kevin Costa

Virus-free. www.avast.com

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Subject: [EXTERNAL] What Clinicians Need to Know About Johnson & Johnson's Janssen COVID-19 Vaccine

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What Clinicians Need to Know About Johnson & Johnson's Janssen COVID-19 Vaccine

This COCA Call will give clinicians an overview of the J&J Janssen COVID-19 vaccine. Clinicians will learn about vaccine characteristics and administration, vaccinating special populations, and contraindications. They will also get answers to a number of clinical questions CDC has received about this new vaccine

Tuesday, March 2, 2021, 2:00 PM – 3:00 PM ET

https://emergency.cdc.gov/coca/calls/2021/callinfo_030221.asp

Best regards,

Kevin Costa

From: Costa, Kevin [kevincosta@alumni.brown.edu]
Sent: 2/26/2021 6:12:29 PM
To: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Arnold S. Monto [asmonto@umich.edu]; Atreya, Prabhakara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f96e446284da421a91a4479bb6e553c1-AtreyaP]; Hayes, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb93ef79b3474f7099917a7d1ed56be9-Kathleen.Ha]; Vert, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dd920d5580d47e8881a9c325517a2f9-Christina.V]; Devine, Jeannette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae36f73172254da2bfb59e33b02426c3-Jeannette.D]; Hill, Monique [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2182de5e12b1484cb87ef70aff92de7f-Monique.Hil]; Cody Meissner [cmeissner@tufts-nemc.org]; Hayley Gans [hagans@stanford.edu]; Kurilla, Michael G (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa2de9594d594ed9b76b935545c26754-HHS-michael]; Paula Annunziato [paula.annunziato@merck.com]; Steven Pergam [spergam@fhcrc.org]; Oveta Fuller [fullerao@umich.edu]; Kim, David W (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c56adb8863fa4365a8a5a465a58f2619-HHS-david.k]; Eric Rubin [erubin@hsph.harvard.edu]; James Hildreth [officeofthepresident@mmc.edu]; Jay Portnoy [Jportnoy@cmh.edu]; Jennette Lee [JYLee@uams.edu]; Mark Sawyer [mhsawyer@health.ucsd.edu]; Ofer Levy [ofer.levy@childrens.harvard.edu]; Patrick Moore [psm9@pitt.edu]; Stanley Perlman [stanley-perlman@uiowa.edu]; Macneil, Adam (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=569fde2cfac9431e848e63b192d30e14-HHS-aho3-cd]; Rachel Levine [rll12@psu.edu]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Xavier Becerra [xavier.becerra@doj.ca.gov]; Brian Castrucci [castrucci@beaumont.org]; Eric Lander [eric.s.lander@ostp.eop.gov]; Rana Hogarth [rhogarth@illinois.edu]; Marcella Nunez-Smith [marcella.nunez-smith@yale.edu]; Rochelle Walensky [RWALENSKY@mgh.harvard.edu]; David Schildmeier [DSchildmeier@mnarn.org]; Mary Lou Hennebry (b)(6) @hotmail.com]; Ezekiel Emanuel [zemanuel@upenn.edu]; Philip Landrigan [landrigp@bc.edu]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Robert R. Redfield [olx1@cdc.gov]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Brooks, John T (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=def0cf9cf9f84fc6a40c4dde8c51b199-HHS-zud4-cd]; Armstrong, Gregory L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67c30c93e434442a9c6786330560e995-HHS-gca3-cd]; Yong-Zhen Zhang [zhangyongzhen@shphc.org.cn]; George Gao [gaof@im.ac.cn]; Lawrence Gostin [gostin@law.georgetown.edu]; Yanzhong Huang [yanzhong.huang@shu.edu]; Ian Lipkin [wil2001@columbia.edu]; Edward Holmes [edward.holmes@sydney.edu.au]; Peter Daszak [daszak@ecohealthalliance.org]; Wang Linfa [linfa.wang@duke-nus.edu.sg]; Dake Kang [dkang@ap.org]; James Palmer [james.palmer@foreignpolicy.com]; Wang Guangfa (b)(6) @hotmail.com]; Gauden Galea [GaleaG@who.int]; Andrew Rambaut [a.rambaut@ed.ac.uk]; Maria Van Kerkhove [m.vankerkhove@imperial.ac.uk]; Ngozi Ezike [Ngozi.Ezike@illinois.gov]; Courtney Phillips [Courtney.Phillips@la.gov]; Jill Hunsaker Ryan [Jill.Ryan@state.co.us]; John Barry (b)(6) @aol.com]; Andrew Stanley Pekosz [apekosz1@jhu.edu]; Aaron David Miller [Aaron.Miller@ceip.org]; John Komlos [John.Komlos@gmx.de]; Libby Watson (b)(6) @gmail.com]; Peter Hotez [hotez@bcm.edu]; Orsega, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63ed25c8067c4b838dbb689460ce0486-HHS-Susan.O]; Jason L. Schwartz [jason.l.schwartz@yale.edu]; Amy Zheng [amzheng@ucsd.edu]; Atul Gawande [agawande@partners.org]; Atul Gawande [atul@atulgawande.com]; Julie Morita [jmorita@rwjf.org]; Robert Rodriguez [Robert.Rodriguez@ucsf.edu]; David Kessler [David.Kessler@ucsf.edu]; Brian Simpson [bsimpso1@jhu.edu]; Celine Gounder (b)(6) @gmail.com]; Ali Khan [Ali.Khan@unmc.edu]; Susan Bailey [Susan.Bailey@ama-assn.org]; William Schaffner [william.schaffner@vumc.org]; Leana Wen [lwen@gwu.edu]; Eric Goosby [Eric.Goosby@ucsf.edu]; David Michaels [dmm@gwu.edu]; Ingrid Katz [Ikatz2@partners.org]; Lisa Monaco [lisa.monaco@nyu.edu]; Alondra Nelson [anelson@ias.edu]; Kei Koizumi [kkoizumi@gwu.edu]; Frances Arnold [frances@cheme.caltech.edu]; Maria

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Subject: [EXTERNAL] FDA Meeting on the Janssen Biotech COVID-19 Vaccine (unanimously approves emergency use authorization for the Johnson & Johnson COVID-19 vaccine)

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FDA Holds an Open Meeting on the Janssen Biotech COVID-19 Vaccine,
Part 1 The Food and Drug Administration holds a virtual open meeting to discuss emergency use authorization for the Janssen Biotech COVID-19 vaccine.
https://www.c-span.org/video/?509043-1/fda-holds-open-meeting-janssen-biotech-covid-19-vaccine-part-1

FDA Holds an Open Meeting on the Janssen Biotech COVID-19 Vaccine,
Part 2 Following a day-long meeting, the FDA Advisory Committee unanimously approves emergency use authorization for the Johnson & Johnson COVID-19 vaccine developed by its pharmaceutical division Janssen Biotech.
https://www.c-span.org/video/?509043-101/fda-advisory-committee-unanimously-approves-johnson-johnson-covid-19-vaccine

Best regards,

Kevin Costa

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From: CSHA [conferencesasia@csh-asia.org]
Sent: 9/11/2020 12:58:35 AM
To: Weir, Jerry P. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d220ee1a49746899d88fd8077e08486-Weirj]
Subject: Upcoming CSHA virtual meeting on 'COVID19/SARS CoV2 Rapid Research Reports' - November 2-4, 2020

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COVID19/SARS CoV2 Rapid Research Reports

Virtual
Nov. 2-4, 2020
Abstract deadline: Sept. 30, 2020

REGISTRATION

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George Fu Gao, Chinese Academy of Sciences
Narry V. Kim, Seoul National University
Stanley Perlman, University of Iowa
Linfa Wang, Duke-NUS Medical School

Major Topics:

1. **Evolution and genomics**
2. **Species specificity**

3. Molecular Biology of coronavirus: replication and gene regulation
4. Cell Biology of coronavirus: entry, membrane organization, and assembly
5. Host-virus interaction
6. Immunological response
7. Vaccine development
8. Drug development

Keynote Speakers:

TBA

Invited Speakers:
Antonio Bartoletti, Duke-NUS Medical School
Christian Drosten, Charité-Universitätsmedizin Berlin
Chuan Qin, Peking Union Medical College
Dale Godfrey, The University of Melbourne
Eng Eong Ooi, Duke-NUS Medical School
Eric Snijder, Leiden University Medical Center
Eui-Cheol Shin, KAIST
Gavin Smith, Duke-NUS Medical School
Geroge Fu Gao, Chinese Academy of Sciences
Jae U. Jung, Lerner Research Institute - Cleveland Clinic
Jincun Zhao, the First Affiliated Hospital of Guangzhou Medical University
Katherine Kedzierska, The University of Melbourne
Kwok Yung Yuen, The University of Hong Kong
Linfa Wang, Duke-NUS Medical School
Narry V. Kim, Seoul National University
Pardis Sabeti, Harvard University
Patrick Cramer, Max Planck Institute
Pei-Yong Shi, University of Texas Medical Branch at Galveston
Shinji Makino, University of Texas Medical Branch at Galveston
Stanley Perlman, University of Iowa
Susan Weiss, University of Pennsylvania Perelman School of Medicine

Zhengli Shi, Wuhan Institute of Virology

And more...

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Subject: RE: WHO Working Group on COVID-19 Assays

Dear All,

Please find below the agenda for this week's WHO working group on COVID-19 assays group call.

Best,
Lauren - Bill, Simon and César

Agenda for WHO working group on COVID-19 assays group call Wednesday January 27 2:30PM CET (Geneva Time)

1. Meera Chand & Victoria Hall (PHE) – *The UK SIREN study first interim analysis: Do antibody positive healthcare workers have lower SARS-CoV-2 2 infection rates than antibody negative healthcare workers?*
2. Shane Crotty (LJI) - *Immunological memory to SARS-CoV-2 and COVID-19*
3. Theodora Hatziioannou (Rockefeller) - *Neutralizing antibody responses to SARS-CoV-2 following vaccination*

-----Original Appointment-----
From: SCHWARTZ, Lauren
Sent: Sunday, January 24, 2021 2:01 PM
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Subject: WHO Working Group on COVID-19 Assays
When: Wednesday, January 27, 2021 5:30 AM-7:00 AM (UTC-08:00) Pacific Time (US & Canada).
Where: https://who.zoom.us/ (b)(6)

Please note this meeting will be 1.5hrs instead of the usual one hour to allow for an additional presentation and discussion on the new variant.

Agenda to follow.

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Subject: RE: WHO Working Group on COVID-19 Assays

Dear All,

Please find below the agenda for our group call on Wednesday January 13, 2021 at 2:30PM CET (Geneva time).

Best,
Lauren - Bill, Simon and César

Agenda for WHO working group on COVID-19 assays

1. Alessandro Sette (LJI) - *Comprehensive analysis of T cell immunodominance and immunoprevalence of SARS-CoV-2 epitopes in COVID-19 cases*

2. Joe Campo (Antigen Discovery Inc) - *A Multi-Coronavirus Protein Microarray for Mapping SARS-CoV-2 Antibody Epitopes and Characterizing Immune Responses to Infection and Vaccination*

-----Original Appointment-----
From: SCHWARTZ, Lauren
Sent: Sunday, January 10, 2021 2:22 PM
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Subject: WHO Working Group on COVID-19 Assays
When: Wednesday, January 13, 2021 5:30 AM-6:30 AM (UTC-08:00) Pacific Time (US & Canada).
Where: https://who.zoom.us/ (b)(6)

Agenda to follow.

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Subject: RE: WHO Working Group on COVID-19 Assays

Dear All,

Please find below the agenda for our group call on Wednesday January 6, 2021 at 2:30PM CET (Geneva time).

Best,
Lauren - Bill, Simon and César

Agenda for WHO working group on COVID-19 assays

1. Kevin McCarthy and Paul Duprex (University of Pittsburgh)- *Natural deletions in the SARS-CoV-2 spike glycoprotein drive antibody escape*
2. Discussion on the UK variant

-----Original Appointment-----
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Subject: WHO Working Group on COVID-19 Assays

When: Wednesday, January 6, 2021 5:30 AM-6:30 AM (UTC-08:00) Pacific Time (US & Canada).

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Subject: [EXTERNAL] No call this week - WHO Working Group on COVID-19 Assays

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Hi All,

The WHO Working Group on COVID-19 Assays will not be held this week due to a conflict with the WHO Global consultation on COVID-19 therapeutics. Register with this link if you'd like to attend - https://who-e.zoom.us/webinar/register/WN_CNfywAEiTEWgqA_nEcjeow

Many thanks,
Lauren - Bill, Simon and César

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Subject: RE: WHO Working Group on COVID-19 Assays with Vaccine Developers

Attachments: MEDRXIV-2021-250224v1-Sigal.pdf; 3-Calibration to WHO International Standards.pptx; 1-Introduction.WHO standards.IK.18_Jan_2021.pptx; 2-Roles_and _Importance_of_Standards_in_Assays.pptx; Chat_Assays Call with Vaccine Developers_20Jan2021.docx

Dear All,

Many thanks for joining the discussion on Wednesday. See attached the presentations on standards, a summary of some of the questions from the zoom chat, and the pre-print from Alex Sigal.

Best,
Lauren

From: SCHWARTZ, Lauren
Sent: Monday, January 18, 2021 2:52 PM
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Subject: RE: WHO Working Group on COVID-19 Assays with Vaccine Developers

Hi All,

Before the call on Wednesday, if you have specific questions you can email Bill Dowling, Mark Page, and myself (click here for email). We will try and address these questions on the call.

Best,
Lauren

From: SCHWARTZ, Lauren
Sent: Friday, January 15, 2021 11:58 AM
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Subject: RE: WHO Working Group on COVID-19 Assays with Vaccine Developers

Dear All,

Please find below the agenda for our group call with vaccine developers on Wednesday January 20, 2021 at 2:30PM CET (Geneva time).

Best,
Lauren - Bill, Simon and César

Agenda for WHO working group on COVID-19 assays with vaccine developers

1. WHO standards for COVID-19 - I. Knezevic (WHO)
2. Roles and Importance of Standards in Assays – G. Mattiuzzo (NIBSC)
3. Calibration of secondary standards to WHO International Standards – P. Rigsby (NIBSC)
4. Discussion on standards
5. Update on 501Y.V2 variants – Alex Sigal (AHRI)

-----Original Appointment-----
From: SCHWARTZ, Lauren
Sent: Monday, December 21, 2020 10:47 AM
To: SCHWARTZ, Lauren; jboyer@inovio.com; acope@iavi.org; (b)(6) @gmail.com; akbulut@medicine.ankara.edu.tr; Alessandra.Vitelli@reithera.com; Stefania.Capone@reithera.com; annied@epivax.com; Anthony.Macaluso@tonixpharma.com; boulayi@medicago.com; brian.zabel@lakepharma.com; C.M.Smales@kent.ac.uk; christoph.rademacher@mpikg.mpg.de; CKeech@Novavax.com; coleman@codagenix.com; rajeev.dhere@seruminstitute.com; CVHerst@flowpharma.com; cyrus.yang@sbc-biotech.com; d.watterson@uq.edu.au; dapengzhoulab@tongji.edu.cn; dguyongellin@osivax.com; diane.vanhoorick@etherna.be; dong.shen@rnaimmune.com; dothuanthien@vabiotech.com.vn; dsz@imbcams.com.cn; dulin@zhifeishengwu.com; dailp@biols.ac.cn; ercument.karasulu@ege.edu.tr; fguirakhoo@geovax.com; farshad@covaxx.com; fguirakhoo@unitedneuroscience.com; fred@imophoron.com; Gary.Kobinger@crchudequebec.ulaval.ca; greanggrai.h@bionet-asia.com; guido.grandi@unitn.it; hasegawa@nih.go.jp; hendrikjan.thibaut@kuleuven.be; (b)(6) @gmail.com; hlchen@hku.hk; Holger.Martinius@neovii.com; hotez@bcm.edu; huyl@sinovac.com; james.hayward@adnas.com; James.Huleatt@sanofi.com; jarininger@lathambiopharm.com; jeff@stabilitech.com; jennifer@immunoprecise.com; yabdiche@immunoprecise.com; iroodink@immunoprecise.com; JHendri1@its.jnj.com; jkalil@usp.br; jlh66@cam.ac.uk; jprice@greffex.com; jwolf@heatbio.com; (b)(6) @hotmail.com; Kapil.Maithal@zyduscadila.com; khirullin@mail.ru; kmodjarrad@eidresearch.org; kovac@axon-neuroscience.eu; michelle.hoffmann@axon-neuroscience.eu;

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Subject: WHO Working Group on COVID-19 Assays with Vaccine Developers
When: Wednesday, January 20, 2021 5:30 AM-7:00 AM (UTC-08:00) Pacific Time (US & Canada).
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Escape of SARS-CoV-2 501Y.V2 variants from neutralization by convalescent plasma

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Abstract

New SARS-CoV-2 variants with mutations in the spike glycoprotein have arisen independently at multiple locations and may have functional significance. The combination of mutations in the 501Y.V2 variant first detected in South Africa include the N501Y, K417N, and E484K mutations in the receptor binding domain (RBD) as well as mutations in the N-terminal domain (NTD). Here we address whether the 501Y.V2 variant could escape the neutralizing antibody response elicited by natural infection with earlier variants. We were the first to outgrow two variants of 501Y.V2 from South Africa, designated 501Y.V2.HV001 and 501Y.V2.HVdF002. We examined the neutralizing effect of convalescent plasma collected from six adults hospitalized with COVID-19 using a microneutralization assay with live (authentic) virus. Whole genome sequencing of the infecting virus of the plasma donors confirmed the absence of the spike mutations which characterize 501Y.V2. We infected with 501Y.V2.HV001 and 501Y.V2.HVdF002 and compared plasma neutralization to first wave virus which contained the D614G mutation but no RBD or NTD mutations. We observed that neutralization of the 501Y.V2 variants was strongly attenuated, with IC_{50} 6 to 200-fold higher relative to first wave virus. The degree of attenuation varied between participants and included a knockout of neutralization activity. This observation indicates that 501Y.V2 may escape the neutralizing antibody response elicited by prior natural infection. It raises a concern of potential reduced protection against re-infection and by vaccines designed to target the spike protein of earlier SARS-CoV-2 variants.

Through genomic surveillance of the severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2), a number of new variants have recently been identified with multiple mutations in the spike glycoprotein [1, 2, 3]. We recently described the emergence of the N501Y.V2 variant in South Africa, characterised by the K417N, E484K, and N501Y mutations in the spike receptor binding domain (RBD) as well as four substitutions and a deletion in the N-terminal domain (NTD) [1]. This variant was first detected in October 2020, and has rapidly become the dominant variant in several parts of the country at a time of a rapid resurgence in infections.

The RBD is the main target of neutralizing antibodies (NAbs) elicited by SARS-CoV-2 infection, with the remaining activity directed at the NTD [4, 5, 6]. All three amino acid residues in the RBD that carry mutations in 501Y.V2 interact directly with the human angiotensin-converting enzyme 2 (hACE2) receptor and form part of the epitopes for hACE2-blocking NAbs [7]. The E484 residue specifically is a hotspot for binding of highly potent NAbs [7]. In a number of separate *in vitro* studies using monoclonal antibodies (mAbs), mutations at E484 have emerged as immune escape mutations, often conferring broad cross-resistance to panels of mAbs [8, 9, 10, 11]. E484K also emerged during passage with convalescent plasma, leading to substantial drops in neutralization with convalescent plasma samples [12, 13]. Using a deep mutation scanning approach to determine the effect of individual mutations on neutralization by polyclonal serum, mutations at E484 were associated with the largest drops in neutralization [14].

Here, using a microneutralization assay with authentic virus, we address the question of whether 501Y.V2 variants can escape the neutralizing response elicited by natural infection with previous variants. We outgrew and compared the neutralization of two SARS-CoV-2 501Y.V2 variants to a previously circulating variant derived from South Africa which does not have the 501Y.V2 defining mutations.

For neutralization, we used plasma samples from our ongoing longitudinal cohort study that tracks COVID-19 cases enrolled at two hospitals in Durban, South Africa [15]. We sampled participants weekly for the first month post-enrollment, and at each timepoint a blood draw and combined nasopharyngeal/oropharyngeal swab was performed to obtain both the plasma and the infecting virus.

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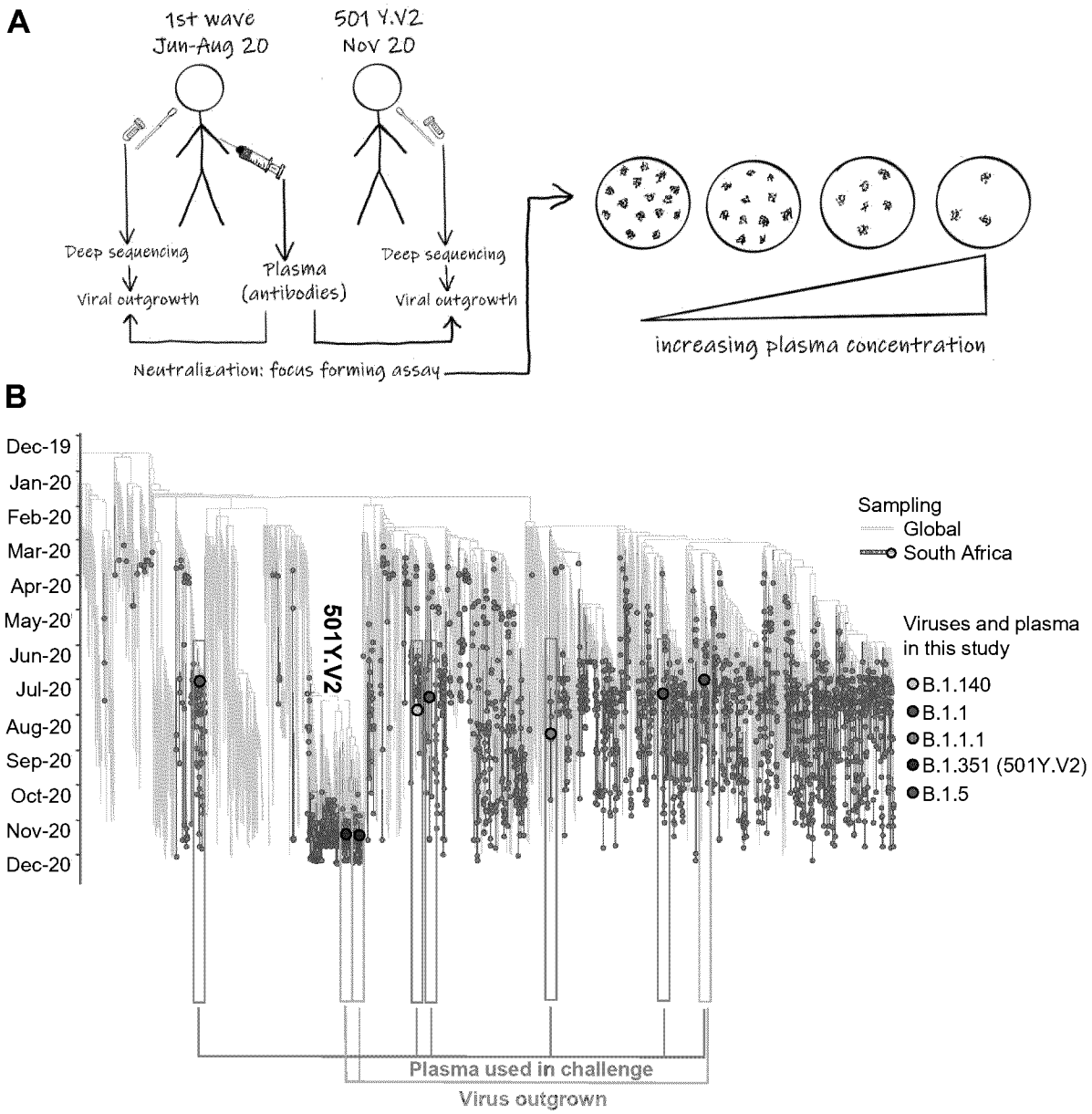

	Outgrown viral variants			Infecting variant sequences of blood plasma donors					
Lineage	B.1.1	501Y.V2 (B.1.351)		B.1.1	B.1.1	B.1.5	B.1.5	B.1.140	B.1.1.1
Sequence ID	K002868	K005321	K005325	K002868	K004289	K004285	K004291	K004295	K004302
Plasma ID	039-13-0013			039-13-0013	039-02-0014	039-13-0015	039-13-0033	039-02-0017	039-13-0062
Isolate designation	CoV2.V003	501Y.V2. HVdF002	501Y.V2. HV001						
Spike mutations	D614G A688V	D80A D215G K417N E484K N501Y D614G A701V	L18F D80A D215G K417N E484K N501Y D614G A701V	D614G A688V	D614G	D614G	D614G	D614G	D614G
Spike indels		242-244del	242-244del						

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Figure 1: Study design and sequences of SARS-CoV-2 variants. (A) We obtained convalescent plasma and detected the matching infecting variant in the first SARS-CoV-2 infection wave in South Africa. A blood draw and nasopharyngeal/oropharyngeal was performed on study participants. First wave virus was outgrown from one of the participants and compared to two viruses outgrown from the second wave, which were 501Y.V2 variants. A focus forming microneutralization assay was used to quantify neutralization. (B) Phylogenetic tree and mutations of variant sequences. Variants which infected the study participants who were plasma donors only for this study are marked in blue. Sequences of variants which were outgrown are marked in yellow. Participant 039-13-0013 was both a plasma donor and the donor from whom the first wave virus was outgrown. Y-axis denotes time of sampling for viral sequencing. Table shows mutations present in Spike for the 501Y.V2 variants and the first wave virus used in the study. See Table S2 for a complete list of mutations in the viral genomes.

We chose plasma from participants from the first infection wave where the infecting virus was successfully sequenced (Table S1) and where RBD binding was detected by ELISA. These viruses were from a variety of B.1 lineages circulating in South Africa and contained the D614G mutation but none of the spike mutations defining 501Y.V2 (Figure 1, see Table S2 for whole genome mutations). Plasma samples were from blood drawn approximately 1 month post-symptom onset (Table S1), shown to be close to the antibody response peak [16, 17].

We outgrew first wave virus (Materials and methods) from a sample obtained from a cohort participant (039-13-0013) in July 2020, and second wave 501Y.V2 virus from two samples obtained in November 2020 through our genomic surveillance program. We used a microneutralization live virus focus forming assay (FFA) [18]. This relies on a methylcellulose overlay to limit cell-free viral spread, resulting in a local infection focus then detected by an anti-SARS-CoV-2 Spike antibody (Materials and methods). Re-sequencing of the first 501Y.V2 variant after outgrowth revealed no changes in the RBD or NTD but a deletion in the furin cleavage site (Table S3) commonly observed after *in vitro* culture in Vero E6 cells [19, 20]. We designated this variant 501Y.V2.HVdF002. HV represents the outgrowth protocol which included initial outgrowth in a human H1299 cell line derivative overexpressing the ACE2 receptor, followed by a cell-to-cell infection of Vero E6 cells (Materials and methods). dF represents the deletion of the furin cleavage site. Deletion of the furin cleavage site may not affect neutralization [19]. However, we proceeded to test an additional 501Y.V2 variant. This variant, which we designated 501Y.V2.HV001, had an additional mutation, L18F, in the NTD prior to outgrowth and showed no changes in spike sequence after outgrowth.

We mixed the virus with serially diluted participant plasma, then added the mixture to Vero E6 cells and counted infection foci after 28 hours (Figure 2A, Materials and methods). There was a clear visual difference in the number of foci as a function of plasma dilution. 501Y.V2.HV001 also showed dramatically larger foci (Figure 2A).

We normalized the number of foci to the number of foci in the absence of plasma on the same plate to obtain the transmission index (Tx, [21]). In this context, it is the number of foci in the presence of plasma inhibition divided by the number of foci in the absence of plasma. This controls for experiment variability between plates and experiments. The data from the FFA approximated a normal distribution (Figure S1) and we therefore used parametric statistics to describe it. We observed neutralization of the first wave virus which varied between plasma samples (Figure 2B). To obtain the IC_{50}, we fitted the data for each participant to a sigmoidal function [22] with IC_{50} as the only free parameter (Materials and methods). Fitted IC_{50} values (Figure 2D) varied between 4×10^{-3} for participant 039-13-0013 to 1×10^{-4} for participants 039-13-0033 and 039-02-0015, consistent with the previously observed heterogeneity in neutralization between individuals [16, 17].

We next determined neutralization of 501Y.V2. A decline in plasma neutralization was clearly observed (Figure 2A). T501Y.V2.HV001 also showed attenuated neutralization likely greater than that of 501Y.V2.HVdF002 (Figure S2), ruling out the *in vitro* generated deletion in the furin cleavage site as being responsible for escape. We combined the data for both 501Y.V2 variants. Fitted IC_{50} values varied between 1×10^{-3} (1:100 dilution) for plasma from participant 039-13-0033 to a complete knockout of activity for plasma from participant 039-13-0013 (Figure 2D). The 501Y.V2 to first wave IC_{50} ratio ranged from 6 to 200-fold (Figure 2D). Averaging across all participants highlighted the dramatic decrease in sensitivity to neutralization of authentic 501Y.V2 variants (Figure 2E).

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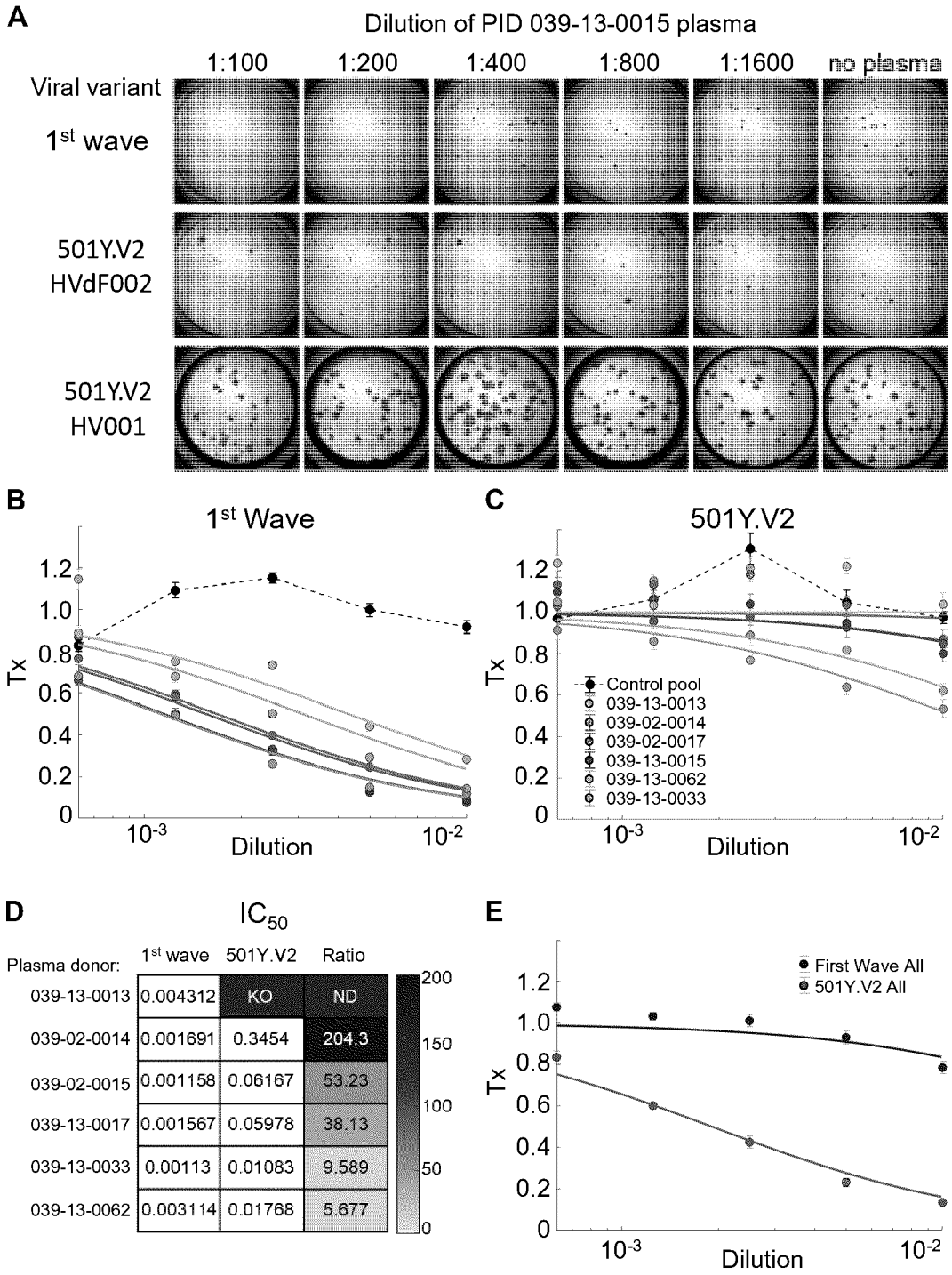

Figure 2: Neutralization of first wave and 501Y.V2 variants by convalescent plasma from first wave infections. (A) A representative focus forming assay using plasma from participant 039-13-0015. Plasma neutralization of (B) first wave virus and (C) the combined results from the two 501Y.V2 variants. Colored circles represent means and standard errors from 8 independent neutralization experiments using plasma from 6 convalescent participants who were infected by first wave variants in the first peak of the pandemic in South Africa. Correspondingly colored lines are fits of the sigmoidal equation with IC_{50} as the fitted parameter. Black points represent a pool of plasma from three uninfected controls. The transmission index (Tx) is the number of foci in the presence of the plasma dilution normalized by the number of foci in the absence of plasma. (D) Plasma IC_{50} values and ratios for first wave and 501Y.V2 variants. Knockout (KO) was scored as $IC_{50} > 1$. ND, not defined. (E) Mean and standard error across all plasma donors.

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As we have entered the second year of the SARS-CoV-2 pandemic with high levels of transmission in many parts of the world, variants with mutations at key residues in the spike glycoprotein have emerged. Here we present clear evidence using authentic SARS-CoV-2 that the 501Y.V2 variant first detected in South Africa is associated with reduced neutralization by plasma collected from patients infected in the first wave with SARS-CoV-2 variants without the 501Y.V2 defining RBD and NTD mutations. While our findings are based on plasma samples from six convalescent study participants, the relative consistency of the effect argues that the potential to escape neutralizing antibodies elicited by prior SARS-CoV-2 infection may be widespread.

The reduced neutralization is most likely related to the mutations in the spike RBD and NTD that characterize the 501Y.V2 variant. While the E484K mutation has the clearest association with immune escape, the other mutations in the RBD (K417N, N501Y) are also located within residues targeted by some class 1 and class 2 NAbs [7]. Information about the significance of NTD mutations is also emerging. NAbs targeting this site have been shown to be potent neutralizers of SARS-CoV-2 [5, 6]. The deletion at residues 242-244 is just outside an antigenic supersite loop (residues 245-264) and L18 also falls within the antigenic supersite. Furthermore, mutations at L18 and D80 have been selected during passage with mAbs [5]. Our second variant contains the L18F mutation. This may be associated with the trend to lower neutralization sensitivity relative to the first 501Y.V2 variant (Figure S2). This variant also has strikingly larger foci (Figure 2A).

The reasons for the rapid emergence and fixation of potential immune escape mutations in South Africa remain unclear. The 501Y.V2 variant was first detected in the Eastern Cape Province of South Africa, in Nelson Mandela Bay, an urban municipality with a population of just over one million. While we have no SARS-CoV-2 seroprevalence data from this area, there were 1909 excess natural deaths (approximately 1600 per million population) by the end of the first wave in mid-September (https://www.samrc.ac.za/reports/report-weekly-deaths-south-africa). In the context of a young population (over 80 percent of the population under 50 years), this data would suggest a high attack rate from the first wave. While circumstantial, this provides some support to a hypothesis of high levels of population immunity driving the selection of variants with capacity to evade natural immunity. This area also has high HIV prevalence, and has amongst the lowest proportions of people with HIV who have viral suppression (http://www.hivdata.org.za/). We have not observed evidence of chronic SARS-CoV-2 infection in people living with HIV in our longitudinal cohort [15]. However, most cohort participants had sustained virological suppression with antiretroviral therapy (ART). We did observe altered immune dynamics after SARS-CoV-2 infection in HIV viremic participants relative to those who were virologically suppressed, and we are currently enrolling additional participants to examine SARS-CoV-2 clearance in the HIV viremic subset.

The implications of these results for re-infection and vaccine efficacy are still unclear. Our findings emphasize the need to understand whether the 501Y.V2 variant, and other similar variants, are associated with an increased rate of re-infection. Vaccines such as the Oxford/Astra Zeneca ChAdOx1 [23] and the Pfizer-BioNTech BNT162b2 [24] elicit neutralization titers in a similar range to the convalescent plasma in this study. However, these vaccines may elicit a broader antibody response and protective T cell immunity [25]. Protective T cell immunity also likely occurs following natural infection. Furthermore, it is unclear what degree of neutralization mediates protection, and infection may be particularly sensitive to inhibition at exposure [26].

In conclusion, we present data suggesting that the 501Y.V2 variant first detected in South Africa is able to escape the neutralizing antibody response elicited by natural infection with earlier variants. We expect data in the next weeks from phase 3 vaccine trials being conducted in South Africa. If the variant does have an effect on vaccine efficacy, then there may be a signal in the data from these clinical trials.

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Material and methods

Ethical statement

Nasopharyngeal/oropharyngeal swab samples and plasma samples were obtained from six hospitalized adults with PCR-confirmed SARS-CoV-2 infection enrolled in a prospective cohort study approved by the Biomedical Research Ethics Committee (BREC) at the University of KwaZulu-Natal (reference BREC/00001275/2020). The 501Y.V2 variants were obtained from residual nasopharyngeal/oropharyngeal samples used for routine SARS-CoV-2 diagnostic testing by the National Health Laboratory Service, through our SARS-CoV-2 genomic surveillance program (BREC approval reference BREC/00001510/2020).

Whole genome sequencing, genome assembly and phylogenetic analysis

cDNA synthesis was performed on the extracted RNA using random primers followed by gene specific multiplex PCR using the ARTIC V3 protocol. Briefly, extracted RNA was converted to cDNA using the Superscript IV First Strand synthesis system (Life Technologies, Carlsbad, CA) and random hexamer primers. SARS-CoV-2 whole genome amplification was performed by multiplex PCR using primers designed on Primal Scheme (http://primal.zibraproject.org/) to generate 400bp amplicons with an overlap of 70bp that covers the 30Kb SARS-CoV-2 genome. PCR products were cleaned up using AmpureXP purification beads (Beckman Coulter, High Wycombe, UK) and quantified using the Qubit dsDNA High Sensitivity assay on the Qubit 4.0 instrument (Life Technologies Carlsbad, CA). We then used the Illumina® Nextera Flex DNA Library Prep kit according to the manufacturer's protocol to prepare indexed paired end libraries of genomic DNA. Sequencing libraries were normalized to 4nM, pooled and denatured with 0.2N sodium acetate. 12pM sample library was spiked with 1% PhiX (PhiX Control v3 adapter-ligated library used as a control). We sequenced libraries on a 500-cycle v2 MiSeq Reagent Kit on the Illumina MiSeq instrument (Illumina, San Diego, CA). We have previously published full details of the amplification and sequencing protocol [27].

We assembled paired-end fastq reads using Genome Detective 1.126 (https://www.genomedetective.com) and the Coronavirus Typing Tool [28]. We polished the initial assembly obtained from Genome Detective by aligning mapped reads to the references and filtering out low-quality mutations using bcftools 1.7-2 mpileup method. Mutations were confirmed visually with bam files using Geneious software (Biomatters Ltd, Auckland, New Zealand). All of the sequences were deposited in GISAID (https://www.gisaid.org/). We retrieved all South African SARS-CoV-2 genotypes from the GISAID database as of 11 January 2021 (N=2704). We initially analyzed South African genotypes against the global reference dataset (N=2592) using a custom pipeline based on a local version of NextStrain. The pipeline contains several python scripts that manage the analysis workflow. It performs alignment of genotypes in MAFFT [29], phylogenetic tree inference in IQ-Tree20, tree dating and ancestral state construction and annotation (https://github.com/nextstrain/ncov).

Cells

Vero E6 cells (ATCC CRL-1586, obtained from Cellonex) were propagated in complete DMEM with 10% fetal bovine serum (Hylone) containing 1% each of HEPES, sodium pyruvate, L-glutamine, and non-essential amino acids (Sigma-Aldrich). Cells were passaged every 3-4 days. H1299 cells were propagated in complete RPMI with 10% fetal bovine serum containing 1% each of HEPES, sodium pyruvate, L-glutamine, and non-essential amino acids and and passaged every second day.

H1299-E3 cell line for first passage SARS-CoV-2 outgrowth

The H1299-H2AZ clone with nuclear labelled YFP [30] was constructed to overexpress ACE2 as follows: VSVG-pseudotyped lentivirus containing the human ACE2 was generated by co-transfecting 293T cells with the pHAGE2-EF1alnt-ACE2-WT plasmid along with the lentiviral helper plasmids HDM-VSVG,

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HDM-Hgpm2, HDM-tat1b and pRC-CMV-Rev1b using TransIT-LT1 (Mirus) transfection reagent. Supernatant containing the lentivirus was harvested two days after infection, filtered through a 0.45μm filter (Corning) and used to spinfect H1299-H2AZ at 1000 rcf for 2 hours at room temperature in the presence of 5 μg/mL polybrene (Sigma-Aldrich). ACE-2 transduced H1299-H2AZ cells were then subcloned at the single cell density in 96-well plates (Eppendorf) in conditioned media derived from confluent cells. After 3 weeks, wells were trypsinized (Sigma-Aldrich) and plated in two replicate plates, where the first plate was used to determine infectivity and the second was stock. The first plate was screened for the fraction of mCherry positive cells per cell clone upon infection with SARS-CoV-2 mCherry expressing Spike pseudotyped lentiviral vector 1610-pHAGE2/EF1a Int-mCherry3-W produced by transfecting as above. Screening was performed using a Metamorph-controlled (Molecular Devices, Sunnyvale, CA) Nikon TiE motorized microscope (Nikon Corporation, Tokyo, Japan) with a 20x, 0.75 NA phase objective, 561 laser line, and 607 nm emission filter (Semrock, Rochester, NY). Images were captured using an 888 EMCCD camera (Andor). Temperature (37°C), humidity and CO2 (5%) were controlled using an environmental chamber (OKO Labs, Naples, Italy). The clone with the highest fraction of mCherry expression was expanded from the stock plate and denoted H1299-E3. This clone was used in the outgrowth.

Viral Outgrowth

All live virus work was performed in Biosafety level 3 containment using AHRI Institutional Biosafety Committee approved protocols for SARS-CoV-2. For first wave virus, a T25 flask (Corning) was seeded with Vero E6 cells at 2×10^5 cells/ml and incubated for 18-20 hours. After 1 DPBS wash, the sub-confluent cell monolayer was inoculated with 500μL universal transport medium (UTM) diluted 1:1 with growth medium and filtered through a 0.45μM filter. Cells were incubated for 1 hour. Flask was then filled with 7mL of complete growth medium and checked daily for cytopathic effect (CPE). Four days post infection, supernatants of the infected culture were collected, centrifuged at 300 rcf for 3 minutes to remove cell debris, and filtered using a 0.45μM filter. Viral supernatant was aliquoted and stored at -80°C. For 501Y.V2 variants, we used H1299-ACE2-E3 cells for initial isolation followed by passage into Vero E6 cells. H1299-ACE2-E3 cells were seeded at 1.5×10^5 cells/ml and incubated for 18-20 hours. After 1 DPBS wash, the sub-confluent cell monolayer was inoculated with 500μL universal transport medium (UTM) diluted 1:1 with growth medium and filtered through a 0.45μM filter. Cells were incubated for 1 hour. Wells were then filled with 3mL of complete growth medium. 8 days post-infection, cells were trypsinized, centrifuged at 300 rcf for 3 minutes and resuspended in 4mL growth medium. 1mL was added to Vero E6 cells that had been seeded at t 2×10^5 cells/ml 18-20 hours earlier in a T25 flask (approximately 1:8 donor-to-target cell dilution ratio) for cell-to-cell infection. Coculture of H1299-ACE2-E3 and Vero E6 cells was incubated for 1 hour and flask was then filled with 7mL of complete growth medium and incubated for 6 days. Viral supernatant was aliquoted and stored at -80°C or further passaged in Vero E6 cells as above.

Microneutralization using focus forming assay

Vero E6 cells were plated in an 96 well plate (Eppendorf) at 30,000 cells per well 1 day pre-infection. Plasma was separated from EDTA-anticoagulated blood by centrifugation at 500 rcf for 10 minutes and stored at -80°C. Aliquots of plasma samples were heat-inactivated at 56°C for 30 minutes, and clarified by centrifugation at 10,000 rcf for 5 minutes, where the clear middle layer was used for experiments. Inactivated plasma was stored in single use aliquots to prevent freeze-thaw cycles. For experiments, plasma was serially diluted two-fold from 1:100 to 1:1600. Virus stocks were used at approximately 50 focus-forming units (FFU) per microwell and added to diluted plasma; antibody-virus mixtures were incubated for 1 hour at 37°C, 5% CO2 . Cells were infected with 100μL of the virus-antibody mixtures, to allow adsorption of virus. Subsequently, 100μL of a 1x RPMI 1640 (Sigma-Aldrich R6504), 1.5% carboxymethylcellulose (Sigma-Aldrich C4888) overlay was added to the wells without removing the inoculum. Cells were fixed at 28 hours post-infection using 4% paraformaldehyde (Sigma-Aldrich) for 20 minutes. For staining of foci, a rabbit anti-Spike monoclonal antibody (mAb BS-R2B12, GenScript

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A02058) was used at 0.5μg/mL as the primary detection antibody. Antibody was resuspended in a permiabilization buffer containing 0.1% saponin (Sigma-Aldrich), 0.1% BSA (Sigma-Aldrich), and 0.05% tween (Sigma-Aldrich) in PBS. Plates were incubated with primary antibody overnight at 4°C, then washed with wash buffer containing 0.05% tween in PBS. Secondary goat anti-rabbit horseradish peroxidase (Abcam ab205718) was added at 1 μg/mL and incubated for 2 hours at room temperature with shaking. The TrueBlue peroxidase substrate (SeraCare 5510-0030) was then added at 50μL per well and incubated for 20 minutes at room temperature. Plates were then dried for 2 hours and imaged using a Metamorph-controlled Nikon TiE motorized microscope with a 2x objective. Automated image analysis was performed using a Matlab2019b (Mathworks) custom script, where focus detection was automated and did not involve user curation. Image segmentation steps were stretching the image from minimum to maximum intensity, local Laplacian filtering, image complementation, thresholding and binarization. For the second 501Y.V2 variant, a dilation/erosion step was introduced to prevent the large foci from fragmenting into smaller objects.

Statistics and fitting

All statistics and fitting were performed using Matlab2019b. Neutralization data was fit to

$$Tx = 1/1 + (D/IC_{50}).$$

Here Tx is the number of foci normalized to the number of foci in the absence of plasma on the same plate at dilution D. Fit to a normal distribution using Matlab2019b function normplot, which compared the distribution of the Tx data to the normal distribution (see https://www.mathworks.com/help/stats/normplot.html).

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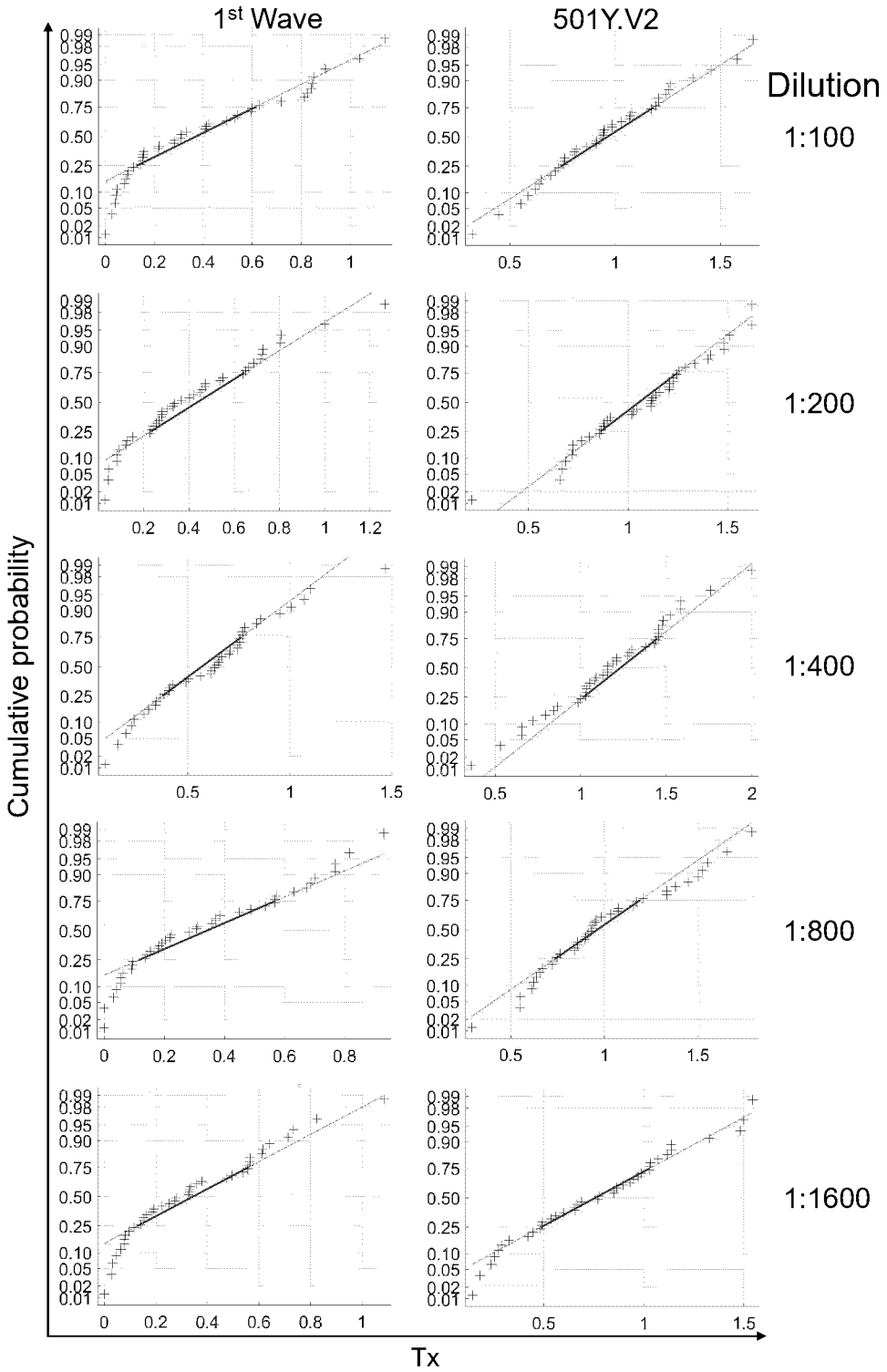

Figure S 1: Fit of combined data for each plasma dilution to a normal distribution. The Matlab2019b function normplot was used to assess the fit of the data (blue crosses) to a normal distribution (solid red line). Lack of pronounced curvature of the data in the range of the solid line indicates that a the data is a reasonably good fit to a normal distribution. see https://www.mathworks.com/help/stats/normplot.html for additional information.

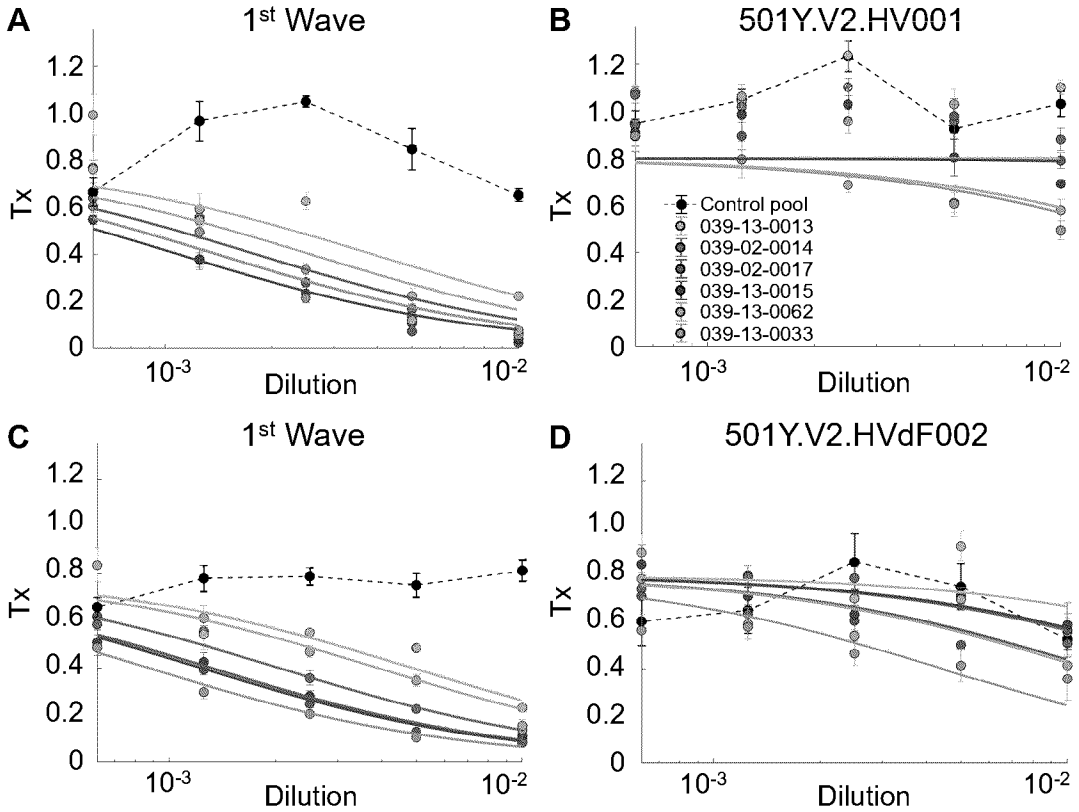

Figure S 2: Neutralization of first wave and 501Y.V2 by convalescent plasma from first wave infections separated by variant. Four sets of independent experiments were performed per 501Y.V2 - first wave pair, where the matched first wave variant results are shown to the left of the 501Y.V2 neutralization results. 501Y.V2 variant 2 contained the L18F mutation in addition to the mutations of variant 1 , and did not have the furin cleavage site deletion from outgrowth in Vero E6 cells. Colored points represent means and standard errors from 4 independent experiments for each 501Y.V2 variant/first wave pair of neutralization activity of plasma from 6 convalescent participants infected by first wave viruses. Corresponding lines are fits of the sigmoidal equation with IC_{50} as the fitted parameter. Black points represent a pool of plasma from three uninfected controls. The transmission index (Tx) is the number of foci in the presence of the plasma dilution normalized by the number of foci in the absence of plasma.

Table S 1: Plasma donor characteristics

Cohort ID	Sex	Age	Supplemental oxygen	Date of symptom onset	Days between symptom onset and diagnostic swab	Days between symptom onset and plasma collection
039-02-0014	F	66	No	01-Jul-2020	13	27
039-02-0017	F	66	Yes	21-Jul-2020	7	28
039-13-0013	F	54	No	29-Jun-2020	3	30
039-13-0015	F	42	No	21-Jun-2020	12	26
039-13-0033	F	37	No	24-Jun-2020	23	30
039-13-0062	M	67	No	06-Aug-2020	12	26

Table S 2: Mutation profile for the genomes of the outgrown viruses and for the infecting viruses of convalescent plasma donors

	Outgrown virus			Infecting virus from plasma donors					
Lineage	B.1.1	B.1.351 (510Y.V2)	B.1.351 (501Y.V2)	B.1.1	B.1.1	B.1.5	B.1.5	B.1.140	B.1.1.1
Sequence ID Accession ID Cohort ID	K002868 EPI_ISL_602622 039-13-0013	K005321 EPI_ISL_678570 -	K005325 EPI_ISL_678615 -	K002868 EPI_ISL_602622 039-13-0013	K004289 EPI_ISL_660170 039-02-0014	K004285 EPI_ISL_660167 039-13-0015	K004291 EPI_ISL_660172 039-13-0033	K004295 EPI_ISL_660167 039-02-0017	K004302 EPI_ISL_660181 039-13-0062
Spike amino acid substitutions	S:D614G S:A688V	S:D80A S:D215G S:K417N S:E484K S:N501Y S:D614G S:A701V	S:L18F S:D80A S:D215G S:K417N S:E484K S:N501Y S:D614G S:A701V	S:D614G S:A688V	S:D614G	S:D614G	S:D614G	S:D614G	S:D614G
Spike deletions		S:242-244del	S:242-244del						
Other amino acid substitutions	N:L139F N:R203K N:G204R ORF14:G50N ORF1a:D1481N ORF1b:P314L	E:P71L N:T205I ORF14:L52F ORF1a:T265I ORF1a:K1655N ORF1a:K3353R ORF1b:P314L ORF3a:Q57H ORF3a:S171L	E:P71L N:T205I ORF14:L52F ORF1a:T265I ORF1a:K1655N ORF1a:K3353R ORF1b:P314L ORF3a:Q57H ORF3a:W131L ORF3a:S171L ORF7a:V93F	N:L139F N:R203K N:G204R ORF14:G50N ORF1a:D1481N ORF1b:P314L	E:L73P N:R203K N:G204R ORF14:G50N ORF1b:P314L ORF1b:T1522I	E:L73P ORF1a:D3728N ORF1b:P314L	N:T148A ORF10:A28V ORF1a:K2511R ORF1a:V3858I ORF1b:P314L	ORF1a:F1178S ORF1b:P314L	N:R203K N:G204R ORF14:G50N ORF1a:T1246I ORF1a:G3278S ORF1b:P314L
Other deletions		orf1ab:3675-3677del	orf1ab:3675-3677del						

Lineage classification was performed by Pangolin software application version v2.1.7 (https://cov-lineages.org/pangolin.html).
Accession ID refers to GISAID EpiCoV™ database (www.gisaid.org)
Amino acid mutation nomenclature includes open reading frame, wild-type amino acid, ORF position and amino-acid mutation (e.g. S:D80A, Spike D to A substitution at position 80). del refers to deletion between stated positions. Amino acid mutations are annotated based on mature protein region of coding sequence (CDS) of SARS-CoV-2 reference sequence NC_045512.2.

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Table S 3: Mutation profile for the genomes of the outgrown 501Y.V2 viruses, showing the original genome produced from the nasopharyngeal swab specimen and the genomes generated following passage in VeroE6 cells

	Outgrown 501Y.V2 Original	**Outgrown 501Y.V2 After passage 2**	**Outgrown 501Y.V2 After passage 3**	**Outgrown 501Y.V2 Original**	**Outgrown 501Y.V2 After passage 3**
Sequence ID	K005321	K007776	K007624	K005325	K007621
Spike amino acid substitutions	S:D80A S:D215G S:K417N S:E484K S:N501Y S:D614G S:A701V	S:D80A S:D215G S:K417N S:E484K S:N501Y S:D614G S:A701V	S:D80A S:D215G S:K417N S:E484K S:N501Y S:D614G S:A701V	S:L18F S:D80A S:D215G S:K417N S:E484K S:N501Y S:D614G S:A701V	S:L18F S:D80A S:D215G S:K417N S:E484K S:N501Y S:D614G S:A701V
Spike deletions	S:242-244del	S:242-244del **S:677-681del**	S:242-244del **S:677-681del**	S:242-244del	S:242-244del
Other amino acid substitutions	E:P71L N:T205I ORF14:L52F ORF1a:T265I ORF1a:K1655N ORF1a:K3353R ORF1b:P314L ORF3a:Q57H ORF3a:S171L	E:P71L N:T205I ORF14:L52F ORF1a:T265I ORF1a:K1655N ORF1a:K3353R **ORF1a:Q3878R** ORF1b:P314L ORF3a:Q57H ORF3a:S171L	E:P71L N:T205I ORF14:L52F ORF1a:T265I ORF1a:K1655N ORF1a:K3353R **ORF1a:Q3878R** ORF1b:P314L ORF3a:Q57H ORF3a:S171L	E:P71L N:T205I ORF14:L52F ORF1a:T265I ORF1a:K1655N ORF1a:K3353R ORF1b:P314L ORF3a:Q57H ORF3a:W131L ORF3a:S171L ORF7a:V93F	E:P71L **N:R32H** N:T205I ORF14:L52F ORF1a:T265I ORF1a:K1655N ORF1a:K3353R **ORF1a:N4358K** ORF1b:P314L ORF3a:Q57H ORF3a:W131L ORF3a:S171L ORF7a:V93F **ORF9b:A29T**
Other deletions	orf1ab:3675-3677del	orf1ab:3675-3677del	orf1ab:3675-3677del	orf1ab:3675-3677del	orf1ab:3675-3677del

Amino acid mutation nomenclature includes open reading frame, wild-type amino acid, ORF position and amino-acid mutation (e.g. S:D80A, Spike D to A substitution at position 80). del refers to deletion between stated positions. Amino acid mutations are annotated based on mature protein region of coding sequence (CDS) of SARS-CoV-2 reference sequence NC_045512.2. Substitutions and deletions in bold are those emerging during passage

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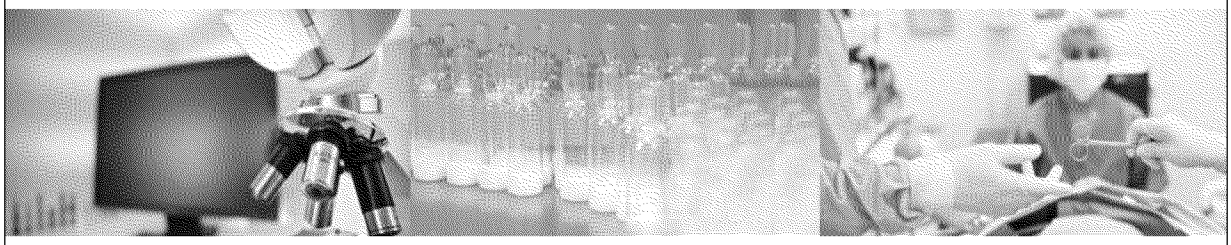
NIBSC

Calibration of secondary standards to WHO International Standards

Peter Rigsby, Analytical & Biological Sciences, NIBSC



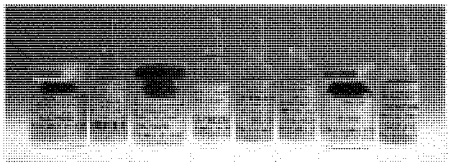
Medicines & Healthcare products Regulatory Agency

WHO International Standards (IS)

- World Health Organization International Standards: highest order standards used to enable biological & immunological assay results to be expressed in the same way worldwide
- WHO Expert Committee on Biological Standardization (ECBS) establishes and assigns a value to an IS
- "An international collaborative study must be carried out before any candidate biological reference standard can be considered for establishment by the WHO ECBS" *(WHO Technical Report Series, No. 932, 2006)*

WHO International Standards (IS)

- Most IS define International Units (IU) of biological activity
  - Arbitrary units representing content of ampoule or vial; no uncertainty assigned
  - Often not dependent on assay method used
- Often lyophilized, giving highly stable preparations



- Not intended for routine use
  - Secondary standards calibrated directly against (and traceable to) the relevant IS are required

Guidance documents

Post ECBS version

ENGLISH ONLY

MANUAL FOR THE PREPARATION OF SECONDARY REFERENCE MATERIALS FOR IN VITRO DIAGNOSTIC ASSAYS DESIGNED FOR INFECTIOUS DISEASE NUCLEIC ACID OR ANTIGEN DETECTION:

CALIBRATION TO WHO INTERNATIONAL STANDARDS

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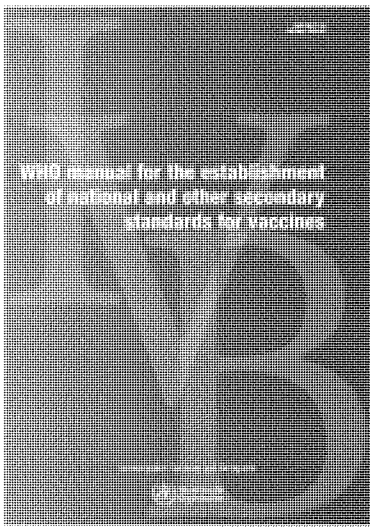


Key properties of different standards

	WHO International Standard	Secondary standard	Tertiary standard
Alternate names	Highest order, International calibrator	Regional or national working reference materials, working reagents, manufacturer's working calibrator	Working reagents, in-house calibrators, in-house controls, manufacturer's product calibrator
Calibration	Established by WHO international collaborative study	Calibrated against the WHO International Standard	Calibrated against the secondary standard
Unitage	IU/mL	IU/mL	IU/mL
Traceability	N/A	Yes	Yes
Uncertainty of measurement	No	Yes (assay specific)	Yes (assay specific)
Final format	Lyophilised (generally)	Lyophilised or liquid	Liquid (generally)
Usage	Calibration of secondary standards, Initial validation of new assay/platform	Calibration of tertiary standards, working reagent, limited use as run control or calibrator	Working reagent, run control, calibrator
Establishment of standard	International agreement through WHO international collaborative study including laboratories worldwide, different assays, different types of test laboratories (approximately 15-30 participants)	May be calibrated in several ways: • In parallel with a study to establish the International Standard • Regional or national collaborative study similar to the WHO collaborative study but with fewer participants from regional laboratories • Small study by a single or limited number of laboratories with a single or limited number of different assays/platforms	Assay-specific study, normally by a single laboratory for use with a specific test/platform Small study by a single or limited number of laboratories with a single or limited number of different assays/platforms

(WHO Technical Report Series, No. 1004, Annex 6, 2017)

Calibration principles

- Test secondary standard multiple times on different occasions in parallel with the WHO IS under exact same test conditions
- Assess validity of individual assays e.g. linearity and parallelism
- Estimate potency (IU/mL) for secondary standard in all valid assays
- Combine estimates and assign combined estimate as potency

Notes on calibration

- Use optimal test system (e.g. commercial assay, validated laboratory test)
- Use only qualified operators, equipment etc.
- No general guidance regarding number of assay runs to perform
  - Decision will depend on various factors
  - E.g. sufficient testing may be performed to give Uncertainty of Measurement (UoM) that is negligible in comparison to the expected precision of the routine assay

Assuming appropriate assay conditions, UoM can be expressed as 95% Confidence Interval (CI) for combined estimate. In such cases, this will account for imprecision but not any inherent bias so care should be taken with assay design etc.

Calibration example

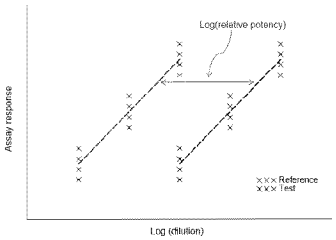
- Samples tested:
  - WHO IS for anti-SARS-CoV-2 immunoglobulin (20/136)
    - *Potency 250 IU/ampoule for neutralising antibody assays*
    - *Reconstituted to concentration of 1000 IU/mL*
  - In-House Standard (IHS)
- Aim: Calibrate IHS in IU/mL using IS
- Samples initially tested in 3 independent assay runs

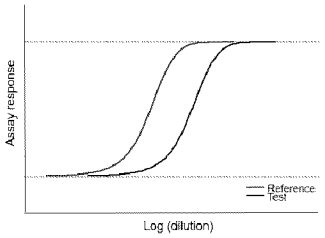
Calibration example – assay 1

IS 20/136				IHS			
1000 IU/mL				20 IU/mL (assumed)			
Dilution	Responses			Dilution	Responses		
1/60	30	80	360	1/1	40	30	30
1/180	70800	92400	2510	1/3	580	2730	71600
1/540	142000	280000	64700	1/9	280000	200000	524000
1/1620	465000	844000	581000	1/27	863000	701000	924000
1/4860	953000	941000	843000	1/81	1170000	1490000	971000
1/14580	1060000	1680000	1340000	1/243	1560000	1920000	1600000
1/43740	870000	1480000	1290000	1/729	1210000	1410000	1310000

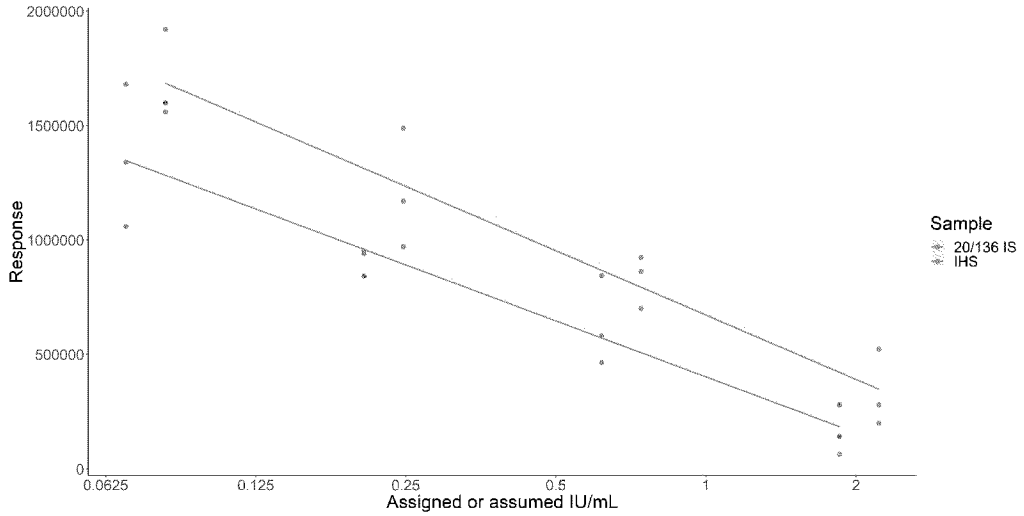
Data analysis

- Objectives of dose-response data analysis:
  - Assess assay validity e.g. linearity/parallelism for linear model
  - Estimate potency of IHS relative to WHO IS
- Various possible analysis methods, including:
  - Parallel line (parallel curve) analysis [recommended]
  - Interpolation from fitted dose-response curve for WHO IS
- Software options will depend on analysis method:
  - Specialised software for bioassay analysis
  - General statistical software packages, Excel





Calibration example – assay 1



Calibration example – assay 1 analysis

- Analysis output for assay 1:

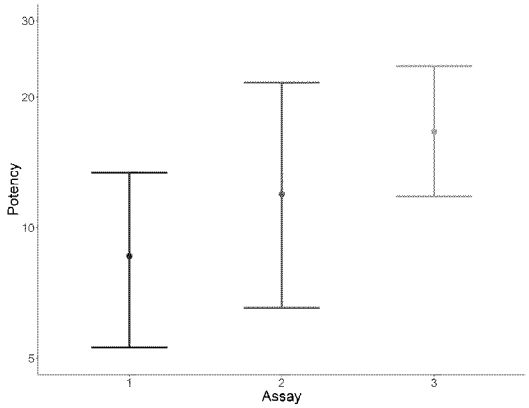
Source	Df	Sum of Sq	Mean Sq	F-ratio	P-Value
Treatments	7	5.63597E+12	8.05139E+11	21.549	<0.001 ***
Preparations	1	3.77329E+11	3.77329E+11	10.099	0.006 **
Regression	1	5.20746E+12	5.20746E+12	139.372	<0.001 ***
Non-parallelism	1	2.53490E+10	2.53490E+10	0.678	0.422
Non-linearity	4	2.58375E+10	6.45937E+09	0.173	0.949
Residual error	16	5.97818E+11	3.73637E+10		
Total	23	6.23379E+12	2.71034E+11		

IHS Potency (IU/mL)		
Estimate	95% LCL	95% UCL
8.60	5.29	13.40

Calibration example – combined estimate

- Combined estimate (IU/mL) from assays 1-3:

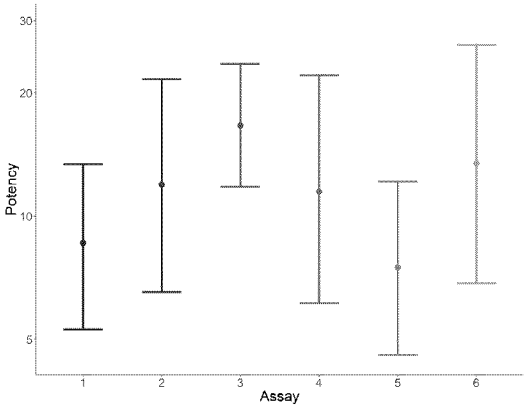
Estimate	95% LCL	95% UCL	LCL as %	UCL as %
12.3	8.5	17.9	68.9%	145.2%



Calibration example – after additional assays

- Combined estimate (IU/mL) from assays 1-6:

Estimate	95% LCL	95% UCL	LCL as %	UCL as %
11.5	9.2	14.4	79.9%	125.1%



Calibration example – conclusions

- Assigned value to internal standard = 11.5 IU/mL
- Assay currently states µg/mL unitage for internal standard
  - Neat concentration used is 5 µg/mL
  - Calibration exercise estimated neat concentration as 11.5 IU/mL
  - Any existing results reported in µg/mL (from this assay platform, using this internal standard) can now be converted to IU/mL

Summary

- Expression of assay results in International Units (IU) requires use of the WHO International Standard (IS) directly, or the use of a secondary standard calibrated using the IS
- A calibration exercise can be performed to assign an IU value to the secondary standard
- Existing assay results already reported relative to a secondary standard (in µg, EU, relative titre etc.), can then be reported as IU
  - In most cases, existing assay analysis methods are unaffected

World Health Organization

WHO standards for COVID-19: update from WHO ECBS

Dr Ivana Knezevic, Norms and Standards for Biologicals (WHO/MHP/HPS)

20 Jan 2021, WG on COVID-19 assays

WHO norms and standards for biologicals

https://www.who.int/groups/expert-committee-on-biological-standardization

Global written standards

Total 103 docs (Recommendations/ Guidelines)
General docs that apply to vaccines & biologicals: 10
General documents that apply to all vaccines: 12
Vaccine specific: 71
BTP specific: 9

Scientific evidence

1) Standardization of assays
2) Further development and refinement of WHO texts
3) Scientific basis for setting specifications

WHO Expert Committee on Biological Standardization

Global measurement standards

Measurement standards essential elements for development, licensing and lot release

Main outcomes of 73rd ECBS meeting in 2020

World Health Organization

1. ECBS meeting on 9-10 Dec 2020 (focused on COVID-19): published on WHO web site:

- Executive Summary posted on WHO web site on 16 Dec 2020:

https://www.who.int/groups/expert-committee-on-biological-standardization

3 new WHO International reference preparations established

Standards for use in public health emergencies		
SARS-CoV-2 RNA for NAT-based assays	7.40 $\log_{10}$ IU/ampoule	First WHO International Standard
Anti-SARS-CoV-2 immunoglobulin	250 IU/ampoule (neutralizing antibody activity)	First WHO International Standard
Anti-SARS-CoV-2 immunoglobulin panel	[no assigned units]	First WHO International Reference Panel

- Proposal to develop a standard for SARS-CoV-2 antigens to support the development, assessment and comparability of antigen-based rapid diagnostic tests.

- Update on written standards provided

Measurement standards for COVID-19

World Health Organization

Aim: to facilitate the development, validation and assessment of molecular and antibody assays. This will facilitate the comparability of results from different assays/labs and help harmonize the evaluation of diagnostics, vaccines and other products. Expression of the results of neutralization assays in the International Units would also contribute to the establishment of the correlates of protection.

Timeline: Feb to Dec 2020 is the absolute record for developing and establishing WHO International Standards in 9 months instead of 2-3 years.

Antibody standards during the COVID-19 pandemic: research reagents and WHO International Standards: joint effort by CEPI, NIBSC and WHO

WHO International Antibody Standards:

- help interpreting results from vaccine CTs by providing the basis for the expression of the antibody titers in the International Units, particularly results from efficacy trials for various vaccine candidates. For instance, correlate of protection can be defined as IU/mL
- IS permits datasets across a range of assays to be compared by reference to the IU. This is especially important with the large number of vaccine candidates.

Uptake of WHO Ab standards - way forward

World Health Organization

1. **Why WHO Ab standards have not been used as expected?**

- Lack of information on the existence of these standards
- Misunderstandings regarding the intended use
- Labour intense calibration of secondary standards
- Lack of expertise for the use of standards and for the assays in CTs
- Other reasons?

2. **Need for secondary standards calibrated against WHO IS**

- Several initiatives ongoing
- How many vaccine developers plan to express results of neutralization assays in IU?

How can we help users of standards to express CT results in the International Units?

World Health Organization

1. ECBS – Executive Summary and report in WHO TRS

2. Collaborative study report provides lots of information about the standards but also about the assays

3. Instruction for use

4. WHO EUL: "Considerations for the Assessment of COVID-19 Vaccines for Listing by WHO" ( )

4.1. The assays used for immunogenicity evaluation should be validated for their intended purpose and calibrated against WHO international standards, where available (section 3.2)

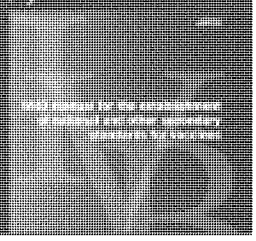
4.2. Assay results should be reported in international units wherever possible (section 3.3.8)

5. Webinars

6. Case studies with the examples

7. Manual for secondary standards for vaccines – Update and/or specific advice for COVID-19 standards

8. Other opportunities?



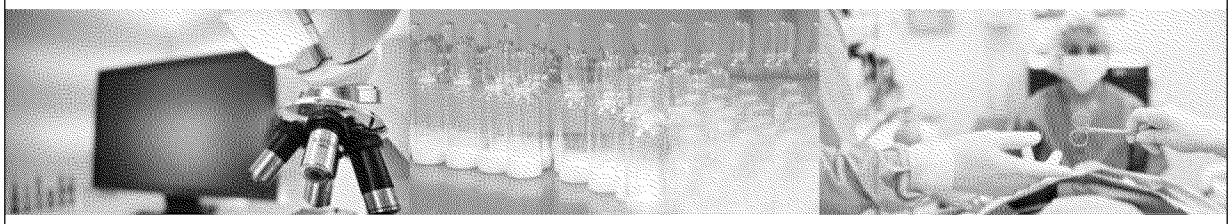
Medicines & Healthcare products
Regulatory Agency

NIBSC

Roles and Importance of Standards in Assays

Giada Mattiuzzo

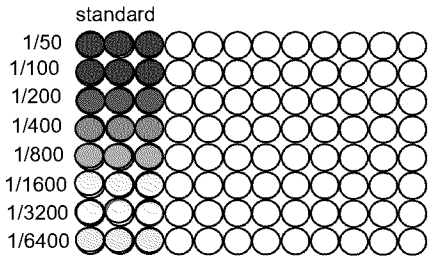
20th January 2021

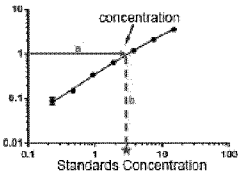


Standards in assays

- 44 laboratories participated to the CS establishment of WHO IS for anti-SARS-CoV-2 immunoglobulin;
- 8 laboratories did not use an assay internal standard – results reported based on dilution factor
- Difficult to compare with other assays

- Internal calibrator/standard;
- run control;
- working reagent
- Secondary or tertiary reagent





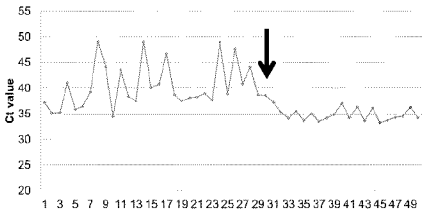
Most commercial assays have a calibrant

External controls

Allow to check for performance drifting of the assay over time/between operators

Monitoring data from diagnostic lab starting using NIBSC Working Reagent for Norovirus GII (↓)

Kindly provided by NIBSC Diagnostics Group, IDD

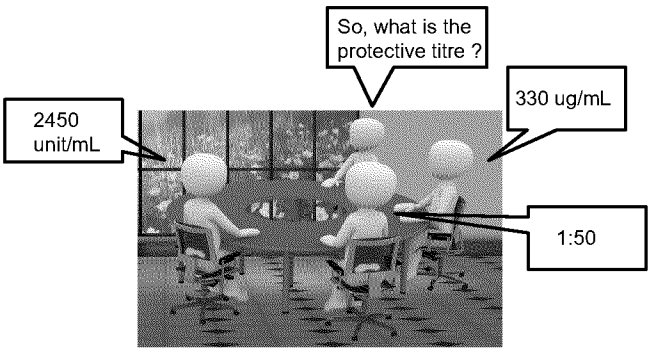


Examples are: national standards, commercially available secondary reagents

Can be used to compare assay between laboratory

Primary calibrant

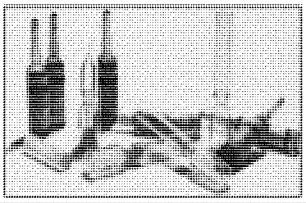
- WHO International Standard – established by the WHO ECBS
- Define the common language to expressed potency of the samples



Common language already reduces the difference between labs

Why International units? A bit of history

- 1890's First Biological: Diphtheria antitoxin
  No reliably produced. Lot to lot variation as biological activity differed from physical property
- Paul Ehrlich: STANDARD ANTITOXIN PREPARATION – calibrated in Units and used to calibrate future batches
- Henry Dale applied concept to insulin and other biologics (1920s) and on International level – appearance of International Units (IUs) as measure of strength or activity of a product

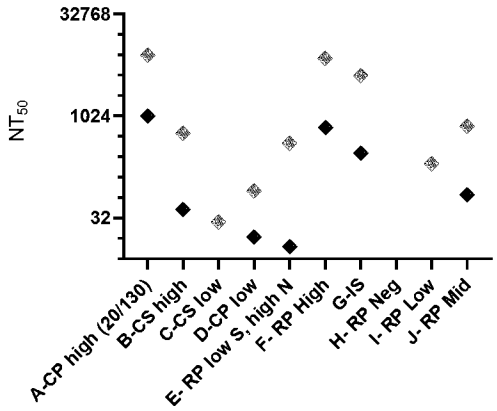


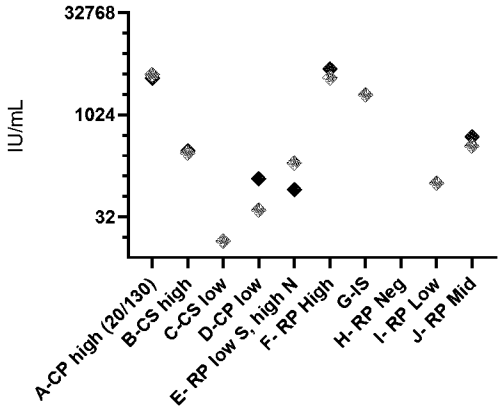
https://www.who.int/bloodproducts/ref_materials/en/

This is to answer the popular question on what's the conversion factor to ng/mL

A recent example: SARS-CoV-2 antibody

Foci reduction neutralisation assay





Binding antibody assay- Spike ELISA

output	lab	A-20/130	B-CS High	C- CS Low	D- CP low	E-low S,high N	F-High	G-IS	H- neg	I - low	J- mid
Dil fact	22b	10159	5081	-	100	1270	12800.0	18102.0	-	635	2851
AU/mL	37a	3464	1764	-	42	510	5284	7215	-	340	1812
ug/mL	9a	25.2	13.3	0.4	0.8	4.5	47.4	55.4	-	2.6	13.3
ratio S/CO	38	18.7	13.9	-	-	4.1	21.4	23.7	-	3.1	11.9

output	lab	A-20/130	B-CS High	C- CS Low	D- CP low	E-low S,high N	F-High	G-IS	H- neg	I - low	J- mid
IU/mL	22b	457	284	-	8	114	949	1000	-	47	154
	37a	480	244	-	6	71	732	1000	-	47	251
	9a	463	246	8	13	85	836	1000	-	47	230
	38	787	585	-	-	175	900	1000	-	131	503

2000 fold difference when expressed with different unitage vs less than 5 fold when expressed relative to IU

Unitage assign to the International Standard

- WHO IS established by WHO ECBS on 10th December 2020;
- Available in NIBSC catalogue on 18th December 2020;
- On 18th January 2021, approximately 50 end users have acquired the IS (tot shipped ampoules 162)

Medicines & Healthcare products Regulatory Agency

WHO International Standard
First WHO International Standard for anti-SARS-CoV-2 immunoglobulin (human)
NIBSC code: 20/136
Instructions for use
(Version 2.0, Dated 17/12/2020)

1. INTENDED USE
The First WHO International Standard for anti-SARS-CoV-2 immunoglobulin is the freeze-dried equivalent of 0.25 mL of pooled plasma obtained from eleven individuals recovered from SARS-CoV-2 infection. The preparation has been evaluated in a WHO International Collaborative study (1). The intended use of the International Standard is for the calibration and harmonisation of serological assays detecting anti-SARS-CoV-2 neutralising antibodies. The preparation can also be used as an internal reference reagent for the harmonisation of binding antibody assays. The preparation has been solvent-detergent treated to minimise the risk of the presence of enveloped viruses (2).

2. CAUTION
This preparation is not for administration to humans or animals in the human food chain

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

3. UNITAGE
The assigned potency of the WHO International Standard for SARS-CoV-2 is 250 IU/ampoule for neutralising antibody activity. After reconstitution in 0.25 mL of distilled water, the final concentration of the preparation is 1000 IU/mL.
For binding antibody assays, an arbitrary unitage of 1000 binding antibody units (BAU)/mL can be used to assist the comparison of assays detecting the same class of immunoglobulins with the same specificity (e.g. anti-RBD IgG, anti-N IgM, etc.)

CEPI

First WHO International Reference Panel for anti-SARS-CoV-2 immunoglobulin (20/268)

Reference Panel will comprise 4 pools of COVID-19 convalescent plasma and a negative; freeze-dried equivalent of 0.25 mL

High (NIBSC code 20/150)

Mid (NIBSC code 20/148)

Low S, high N (NIBSC code 20/144)

Low (NIBSC code 20/140)

Negative (NIBSC code 20/142)

Representative data

	High 20/150	Mid 20/148	low S, high N 20/144	low 20/140	
Neut Ab	1473	210	95	44	**IU/mL**
anti-RBD IgG	817	205	66	45	**BAU/mL**
anti-S1 IgG	766	246	50	46	**BAU/mL**
anti-Spike IgG	832	241	86	53	**BAU/mL**
anti-N IgG	713	295	146	12	**BAU/mL**

The candidate Reference Panel samples were ranked similarly in almost all the assays used with very few exceptions

No unitage will be assigned for the Reference Panel, but representative data from CS include in IFU

CEPI

Reseach Reagent 20/130

- Made available end April 2020 for the development of assay for the detection of SARS-CoV-2 antibody
- Secondary standard which allows assay to report data in IU/mL, retrospectively
- Calibrated to the WHO IS as part of the CS

	GM	95% CI	
Neut Ab	1300	981-1719	**IU/mL**
anti-RBD IgG	502	382-660	**BAU/mL**
anti-S1 IgG	588	398-870	**BAU/mL**
anti-Spike IgG	476	418-542	**BAU/mL**
anti-N IgG	747	214-2606	**BAU/mL**

Slides available, however this data are also included in the revised Datasheet available in our website; less than 130 vials left-cannot be used as run control

Intended use the standards

- WHO International Standard 20/136 is primary calibrant; distribution restricted to 5 ampoules per end user per year
- Availability of secondary reagents- 20/130 is almost depleted; few example of national standards;
- other secondary standard (?)
- Internal Standard/run control can be calibrated to the IS or to secondary reagents- no need for a CS
- How?

May Chu: We have been promoting the NIBSC Ab reference panel and would be happy to list this through our hub to the users in the network have using the COVID-19 Serology Control Panel (these are dried tube specimens) but sure that some of our users would be keen to have this for their testing regime.

When the standards will be available?

Our CSCP experience from the chat note above is that there are different neutralization assays developed for detecting SARS-CoV2 antibodies, especially the pseudoviral assays that are hard to compare, one test platform to another. What has been WHO/NIBSC solution or guidance?

Mark Page - NIBSC: The materials are available here https://www.nibsc.org/products/brm_product_catalogue/detail_page.aspx?catid=20/136 [HYPERLINK "https://www.nibsc.org/products/brm_product_catalogue/detail_page.aspx?catid=20/268"]

Related materials are listed here too https://www.nibsc.org/science_and_research/idd/cfar/covid-19_reagents.aspx

ZHOU, Tiequn: SARS-CoV-2 standards- related information are also available on WHO website: [HYPERLINK "https://www.who.int/news-room/feature-stories/detail/standardization-of-vaccines-for-coronavirus-disease-covid-19"].

Marc Salit: The Coronavirus Standards Working Group is conducting a study intended to make the International Unit widely and easily available by doing a secondary collaborative study that calibrates a panel of commercially available reference samples against the WHO IS. Our "Harmonization Study" is underway with 14 labs comparing a panel of 8 materials against the WHO IS. This puts all the materials on the same "ruler" — the IU — and will make propagation of the IU easy. Each commercial material will then come with a Certificate of Analysis that includes the value of that material in IU. This can be "leapfrogged" with metrological traceability. Think of it as the *kilogram* of SARS-CoV-2 virus content. Much much more on this work is here: [Coronavirus Standards Working Group — The Joint Initiative for Metrology in Biology](https://jimb.stanford.edu/covid-19-standards) All are welcome to join our open working group. Our results will be published in the open literature, and the manufacturers and distributors of the materials will be promoting the IU as features of their products. Here is a link to the précis for the Coronavirus Standards Working Group 'Harmonization Study': [20201111 CSWG Harmonization Study Description.pdf - Google Drive](https://drive.google.com/file/d/1XrjXsGqt81rilmyRuvMK-qeyn6kK08Re/view?usp=sharing)

How much can developers get IS at once? Is the quantity of IS limited?

Marc Salit: Our study is intended to make the supply of the IU inexhaustible by making it so you don't need the IU, but can buy a commercial material from your preferred vendor. There is a limited supply of the IS, so having commercial materials makes them available to everyone.

Mark Page - NIBSC: We have to limit each requestor to 5 ampoules per lab per year to preserve the standard for many years.

Are the neutralising antibody standards 250IU/ampoule polyclonal? (I see the panel is from pooled so will be polyclonal)

Ligia Pinto: We have a US serology standard available ([HYPERLINK "https://frederick.cancer.gov/seronet/serology-standard"])

Is the international standard tested in assays the include "all isotopes IgG, IgM, IgA" ?

Mark Page - NIBSC: The IS is a pool of convalescent plasma from 11 donors. The IS contains IgG, IgA and IgM

How was the neuralizing activity of the IS assessed?

Any SAF/BRA virus strain available?

We have used anti-SARS-CoV-2 Ab NIBSC code 20/130 standard during the clinical trail and calibrated an In-house standard. How different is the new standard from the already provied NIBSC standard i.e., 20/130?

If there is no regional or national standard, should the secondary standard use NIBSC's reference material(20/130)? Can I use the in-house standard instead of the sencondary standard?

Is the international standard tested with a real SARS-CoV-2 virus?

Giada Mattiuzzo-NIBSC: [HYPERLINK "https://www.who.int/publications/m/item/WHO-BS-2020.2403"] (report of collaborative study). The IS has been characterised in 23 neutralisation assay, 15 of those used live virus covering 9 isolates

Is it possible to use serum from horses immunized with RBD as secondary standards?

How much of a reduction in neutralisation would justify a new standard should a new variant arise with limited cross-neutralisation?

What would be acceptable uncertainty in calibration of secondary standard - if secondary standard was non-parallel uncertainty may be higher and dilution bias could result.

How can this IS approach be applied to "titer-based" neutralizing Ab assays? As in such assay, Ab levels are determined against a "cut-point" instead of a reference standard.

Do you think that the vaccine developers will be willing to make available the vaccine responses from clinical trials converted in IU?

Can we use the standard to standardise sera from experimental animals where we are looking at correlates of protection in animal models?

Is it possible to calibrate in-house pooled covalescent serum material against NIBSC's research reagent (20/130)?

Giada Mattiuzzo-NIBSC: Yes, 20/130 now is considered as a secondary standard and can be used to calibrated your in house pool of convalescent serum

Richard r.tedder@imperial.ac.uk: the use of human plasma/serum does have the confounding effect of IgM which may behave differently and non parallel

Our laboratory is developing a chemiluminescence immunoassay (qualitative). Could we use the IS to standardize the test?

Giada Mattiuzzo-NIBSC: The IS in qualitative assay can be used to express the limit of detection of the assay by serially dilution below endpoint. LOD for qualitative assays.

We also need to validate the test, to PCR (gold standard), Do you have a protocol that we can use?

Can you say more on your interpretation of the very different results seen in FFA with 501.v2 (L18F) ?

Do you have convalescent plasma from the latest wave and have you tested on the 501Y V2 variant?

The large plaque phenotype virus does not have any mutation in the multibasic cleavage site?

How are you evaluating reinfections with the new strain?

Have you tested sera from vaccinees against this variant?

Pfizer published a note claimed that their vaccine sera can neutralize the N501Y isogenic strain, do you think other mutations are important in this reduction in neutralizing the field isolates?

Do you have a comparison of all published IgG and NAb levels from several vaccines finished phase 3 trials?

FDA-CBER-2020-5341-0007215

From: CSHA [conferencesasia@csh-asia.org]
Sent: 9/21/2020 4:10:56 PM
To: Schmitt, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b7941ca742d4cc094a2a1edc35cbce0-Schmitt]
Subject: Upcoming CSHA virtual meeting on 'COVID19/SARS CoV2 Rapid Research Reports' - November 2-4, 2020

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冷泉港·亚洲
Cold Spring Harbor Asia

COVID19/SARS CoV2 Rapid Research Reports

Virtual
Nov. 2-4, 2020
Abstract deadline: Sept. 30, 2020

REGISTRATION

Organized by:

Christian Drosten, Charité - Universitätsmedizin Berlin
George Fu Gao, Chinese Academy of Sciences
Narry V. Kim, Seoul National University
Stanley Perlman, University of Iowa
Linfa Wang, Duke-NUS Medical School

Major Topics:

1. **Evolution and genomics**
2. **Species specificity**

3. Molecular Biology of coronavirus: replication and gene regulation
4. Cell Biology of coronavirus: entry, membrane organization, and assembly
5. Host-virus interaction
6. Immunological response
7. Vaccine development
8. Drug development

Keynote Speakers:

TBA

Invited Speakers:
Antonio Bartoletti, Duke-NUS Medical School
Christian Drosten, Charité-Universitätsmedizin Berlin
Chuan Qin, Peking Union Medical College
Dale Godfrey, The University of Melbourne
Eng Eong Ooi, Duke-NUS Medical School
Eric Snijder, Leiden University Medical Center
Eui-Cheol Shin, KAIST
Gavin Smith, Duke-NUS Medical School
Geroge Fu Gao, Chinese Academy of Sciences
Jae U. Jung, Lerner Research Institute - Cleveland Clinic
Jincun Zhao, the First Affiliated Hospital of Guangzhou Medical University
Katherine Kedzierska, The University of Melbourne
Kwok Yung Yuen, The University of Hong Kong
Linfa Wang, Duke-NUS Medical School
Narry V. Kim, Seoul National University
Pardis Sabeti, Harvard University
Patrick Cramer, Max Planck Institute
Pei-Yong Shi, University of Texas Medical Branch at Galveston
Shinji Makino, University of Texas Medical Branch at Galveston
Stanley Perlman, University of Iowa
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