INTERNATIONAL SOS WEEKLY SCIENTIFIC UPDATE Focussing on immunity and vaccine development

Produced by Dr. Doug Quarry 11 DECEMBER 2020

A. Vaccine Development & Approval

- 1. Peer reviewed data for AstraZeneca/Oxford vaccine published in "The Lancet"
- 2. Sinopharm vaccine registered in the UAE; has 86% efficacy against COVID-19
- 3. Australian COVID vaccine terminated due to HIV 'false positives'
- 4. FDA Advisory Panel recommends broad distribution of the Pfizer/BioNTech vaccine
- 5. Canada approves Pfizer-BioNTech vaccine
- 6. Sinovac vaccine shows up to 97% efficacy in early trials, Bio Farma says
- 7. Universal influenza vaccine successful in Phase 1 trials
- 8. Pfizer's vaccine offers strong protection after first dose
- 9. Sinovac secures \$515m to double vaccine-production capacity
- 10. Moderna plans to begin testing its coronavirus vaccine in children
- 11. Britain becomes a giant experiment
- 12. Two patients had serious allergic reactions to the Pfizer-BioNTech COVID-19 vaccine

B. Vaccine Distribution

- 1. Supplies of Sputnik V vaccine to all remaining Russian regions to begin
- 2. Mexico to launch COVID-19 vaccinations this month
- 3. Air freight prices 'outrageous' as COVID-19 shots rolled out, says WHO expert
- 4. No alcohol for 2 months, Russia tells coronavirus vaccine recipients
- 5. UK Proof of Vaccination Card
- 6. WHO "Hundred-Hundred" initiative
- 7. Russia to begin mass COVID-19 vaccinations
- 8. Prediction of how many people can be vaccinated, and when, in the US
- 9. China to have 600 million doses of vaccines "ready for market this year"
- 10. Africa aims to have 60% of people vaccinated against COVID-19 in 2-3 years

C. Outbreaks and Epidemiology

- 1. UN warns of humanitarian catastrophe in 2021
- 2. US Faces "dark time" with holiday COVID-19 surges, Fauci says
- 3. Attack rate of 75% in the Brazilian Amazon
- 4. Mortality among adults ages 25-44 in the US during the COVID-19 pandemic

D. News

- 1. 3D printing in the COVID-19 supply chain response
- 2. Western Australia introduces mandatory QR code contact tracing requirements
- 3. Europol warning regarding fake COVID-19 vaccines

E. Travel

1. Airlines try COVID-19 tested transatlantic flights

F. When and which vaccines are likely to be available in Asia

A. Vaccine Development & Approval

1. Peer reviewed data for AstraZeneca/Oxford vaccine published in "The Lancet"

The AstraZeneca/Oxford vaccine will be important for COVID-19 vaccination programs in the developing world, as it is cheaper and easier to distribute than other leading vaccines.

However, peer-reviewed data published in <u>The Lancet</u> on 8 December did not fully explain why vaccine efficacy was 62% for trial participants given two full doses, but 90% for a smaller sub-group given a half, then a full dose. "[This] will require further research as more data becomes available from the trial," the study said.

Eric Topol** Tweeted that the higher efficacy with the lower dose looks real and not likely to be a statistical [aberrance]. He said that the one case of transverse myelitis was troubling but was impressed that the vaccine appeared to suppress viral transmission.

** Eric Topol is an American cardiologist, Director of the Scripps Research Translational Institute, Professor of Molecular Medicine at The Scripps Research Institute and is Editor-in-Chief of Medscape and TheHeart.org.

2. Sinopharm vaccine registered in the UAE; has 86% efficacy against COVID-19

The <u>Khaleej Times</u> reports that the UAE's Ministry of Health and Prevention (MOHAP), in collaboration with the Department of Health Abu Dhabi (DOH), have **announced the official registration** of Beijing Institute of Biological Products (Sinopharm) inactivated COVID-19 vaccine.

The registration follows a review of the Sinopharm interim analysis of the local Phase 3 trials, which shows the inactivated vaccine to have 86% efficacy against COVID-19 infection.

3. Australian COVID vaccine terminated due to HIV 'false positives'

University of Queensland (UQ), Australia, will abandon its COVID-19 vaccination program after several trial participants returned false positive HIV test results.

The UQ vaccine candidate uses a protein and adjuvant platform, containing the COVID-19 spike protein and a "molecular clamp". A small component is derived from the human immunodeficiency virus, known as HIV, that is not able to infect people or replicate.

The program has been abandoned due to possible public perceptions regarding its safety.

4. FDA Advisory Panel recommends broad distribution of the Pfizer/BioNTech vaccine

The independent Advisory Panel of the US Food and Drug Administration (FDA) has recommended that the FDA approve broad distribution of the Pfizer/BioNTech COVID-19 vaccine.

It is likely that the FDA will grant Emergency Use Authorization (EUA) for the vaccine very soon.

5. Canada approves Pfizer-BioNTech vaccine

<u>Health Canada</u> has approved the Pfizer-BioNTech COVID-19 vaccine. Canada expects to receive 249,000 doses this month and these can be administered within days. Canada has 14 distribution sites equipped with the necessary cold storage for the vaccine.

The Canadian Government has purchased 20 million doses of the Pfizer vaccine with the option to buy 56 million more.

6. Sinovac vaccine shows up to 97% efficacy in early trials, Bio Farma says

The only vaccine manufacturer in Indonesia, state-owned Bio Farma, said on 8 December that: "...interim data on trials it was conducting on vaccines produced by the Chinese company, Sinovac, showed up to 97 per cent efficacy." the Straits Times reports.

"'Our clinical trial team found, within one month, that the interim data shows up to 97 per cent for its efficacy,' said Iwan Setiawan, a spokesman for Bio Farma, at a news conference.

"He did not elaborate whether the interim result was from a late-stage clinical trial, but another Bio Farma spokesman told Reuters later that the company is still gathering data on efficacy from the ongoing Phase 3 trial."

7. Universal influenza vaccine successful in Phase 1 trials

<u>Sciencemag.org</u> reports on the successful Phase 1 trials of a "universal influenza vaccine" that will work for most/all flu's indefinitely. A universal flu vaccine means that there will be no need to have an annual flu vaccination.

While influenza virus mutates frequently, there is one part of the virus, the "stalk", that usually does not change. The "universal influenza" vaccine targets, and produces an immune reaction, to stalk proteins. For this reason, the immunity produced by vaccines targeting the stalk protein be long lasting.

8. Pfizer's vaccine offers strong protection after first dose

<u>The New York Times</u> reports that the Pfizer coronavirus vaccine provides strong protection against COVID-19 within about 10 days of the first dose, referring to <u>documents</u> published by the US Food and Drug Administration (FDA). The FDA also found that the coronavirus vaccine worked well regardless of a volunteer's race, weight or age.

The FDA analysis came prior to the meeting of the "Vaccines and Related Biological Products Advisory Committee" to be held on 10 December which may recommend an Emergency Use Authorization (EUA) for the Pfizer vaccine; the meeting agenda can be found here.

The committee will hold another session on 17 December to consider an application for an EUA from Moderna.

9. Sinovac secures \$515m to double vaccine-production capacity

Al Jazeera reports that: "China's Sinovac Biotech has secured \$515m in funding to double the production capacity of its coronavirus vaccine, it said on Monday, with efficacy data on its experimental medicine due this month."

10. Moderna plans to begin testing its coronavirus vaccine in children

Moderna will soon begin testing its coronavirus vaccine in children ages 12 to 17. The study, listed on the website <u>clinicaltrials.gov</u>, is to include 3,000 children, with half receiving two shots of vaccine four weeks apart, and half saline placebo shots.

11. Britain becomes a giant experiment

Professor Catherine Bennett, Chair in Epidemiology at Deakin University told <u>The New Daily</u>: "By being forced really, to go early with the vaccine, Britain is trying to contain a massive wave. And that creates a really important opportunity for other countries ... to fully evaluate these vaccines. To learn from that practical roll-out."

"Professor Bennett said there will be a great deal of interest in how the 'cold chain' is managed; the need to keep the Pfizer vaccine at minus 70 degrees Celsius. This complicates the roll-out to rural areas or even to aged-care facilities."

12. Two patients had serious allergic reactions to the Pfizer-BioNTech COVID-19 vaccine

Two patients had serious allergic reactions to the COVID-19 vaccine made by Pfizer-BioNTech, prompting UK medical officials to advise people who have a "history of a significant allergic reaction" to avoid taking the vaccine.

The vaccine began being administered in the UK yesterday, with elderly people and frontline workers as the priority groups.

Both patients, who had anaphylactic-like reactions, are NHS employees, and have had had serious allergic reactions in their lives. The <u>Washington Post</u> reports NHS officials saying both carry epinephrine injectors, often called EpiPens. They patients were treated and are recovering.

People with a history of allergic reactions to vaccines were excluded from late-stage trials - as per the written protocol.

B. Vaccine Distribution

1. Supplies of Sputnik V vaccine to all remaining Russian regions to begin

<u>Tass</u> reports that about half of the Russian regions have already received supplies of Sputnik V COVID-19 vaccine and that delivery to all other regions will begin on 10 December.

Staff of medical establishments, teachers, social workers and people with chronic illnesses will be the first to be vaccinated.

2. Mexico to launch COVID-19 vaccinations this month

"Mexico plans to begin vaccinating its people against COVID-19 at the end of the third week of December, starting with health workers, the government announced Tuesday," <u>ABC News</u> reports.

"President Andrés Manuel López Obrador said the vaccines will be 'universal and free' - and also voluntary - and he hopes the full population will be vaccinated by the end of 2021.

"The government already has contracted for 34.4 million doses of the Pfizer-BioNTech vaccine and it said earlier that 250,000 of those are expected to arrive around 17 December.

"Officials said that starting in February, those over 60 will receive vaccinations, followed by those over 50 in April and over 40 in May. They urged people with risk factors to get vaccinated first."

3. Air freight prices 'outrageous' as COVID-19 shots rolled out, says WHO expert

Paul Molinaro, WHO chief of Operations Support and Logistics, told <u>Reuters</u>, "Distribution of vaccines to low- and middle-income countries will be tricky, due to grounded passenger air services in some places, and may rely on charters'.

'He cited a price quote just received for a dry ice shipment, needed to cool some lab re-agents, which is around 20 times the norm.

"I just had a quote from a cargo (company) - a big one that shall remain nameless - Dallas (Texas) USA to Sierra Leone, Freetown - at sort of \$105 a kilo, which is outrageous actually,' he said. 'The "normal price" would be \$4-\$6 per kilo,' he said."

4. No alcohol for 2 months, Russia tells coronavirus vaccine recipients

Rospotrebnadzor (Russian Federal Service for Surveillance of Consumer Rights) head Anna Popova has repeated recommendations from Deputy Prime Minister, Tatyana Golikova, to avoid alcohol and immunosuppressants for 42 days before and after immunization wit Sputnik V vaccine because the two doses are administered with a 21-day gap between doses, The Moscow Times reports.

5. UK Proof of Vaccination Card

With the UK having started the world's first mass coronavirus vaccination campaign, this is the "Proof of Vaccination Card" being used by the UK National Health System (NHS).



6. WHO "Hundred-Hundred" initiative

The WHO has announced a major vaccine sprint which aims to help 100 countries conduct rapid readiness assessments and country-specific plans within 100 days for vaccines and other COVID-19 tools.

WHO is asking all countries to do a country readiness assessment that takes into account cold-chain, health-worker capacity, micro-planning, initial target populations and training. These will form the basis of national roll-out plans.

The COVAX Facility intends to provide doses to enable the 189 countries and economies to vaccinate those at highest risk of the virus. In the first phase of the roll-out, sufficient doses will be provided to cover health and social care workers. As supply increases, COVID-19 vaccines will be rolled out to cover 20%

of the population of participating countries and economies, which will ensure further high-risk groups are covered.

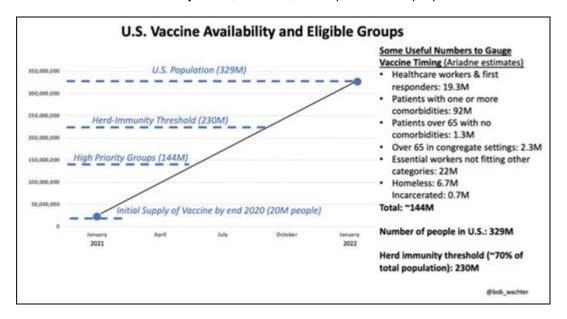
7. Russia to begin mass COVID-19 vaccinations

"President Vladimir Putin has ordered Russian authorities to begin mass voluntary vaccinations against COVID-19 next week as Russia recorded 589 new daily deaths from the coronavirus." NPR reports.

"Russia will have produced two million vaccine doses within the next few days,' President Putin said. Russia said last month that its Sputnik V vaccination was 92% effective at protecting people from COVID-19 according to interim results."

8. Prediction of how many people can be vaccinated, and when, in the US

<u>Professor Bob Wachter</u>, Chair, University of California San Francisco Department of Medicine, has estimated how many people in the US can be vaccinated at various times in 2021. The calculations are based on statements made by Pfizer, Moderna, and Operation Warp Speed.



In summary:

- 20 million by end-Jan
- 150 million by end-June
- All by end-Dec

9. China to have 600 million doses of vaccines "ready for market this year"

"China will have 600 million doses of COVID-19 vaccine ready this year", the <u>South China Morning Post</u> reports Wang JunZhi, from the Task Force on Vaccine Development, as saying in Wuhan. Mr Wang also said that there will be a major announcement in the next one to two weeks.

Two of these vaccines are being made by China National Biotec Group (CNBG) and a third by Sinovac Biotec.

These vaccines are in the final stages of Phase 3 trials in South America, the Middle East and Asia, however the drug makers have yet to release any Phase 3 data.

10. Africa aims to have 60% of people vaccinated against COVID-19 in 2-3 years

Africa aims to have 60% of its population vaccinated against COVID-19 within the next two to three years, the African Union's disease control group said on Thursday, <u>Reuters reports</u>. The control group said that vaccinations were unlikely to start in Africa until midway through 2021.

"If it takes us four to five years, then the virus will be endemic in our communities," said John Nkengasong, Director of the Africa Centres for Disease Control and Prevention.

He said there were logistical problems to overcome in Africa, including how to keep vaccines cold.

C. Outbreaks and Epidemiology

1. UN warns of humanitarian catastrophe in 2021

"Next year is shaping up to be a humanitarian catastrophe and rich countries must not trample poor countries in a "stampede for vaccines" to combat the coronavirus pandemic,' World Food Programme (WFP) Chief, David Beasley, told the UN General Assembly on 4 December.", Reuters reports.

"World Health Organization (WHO) head, Tedros Adhanom Ghebreyesus, told the General Assembly: We simply cannot accept a world in which the poor and marginalized are trampled by the rich and powerful in the stampede for vaccines. This is a global crisis, and the solutions must be shared equitably as global public goods."

2. US Faces "dark time" with holiday COVID-19 surges, Fauci says

"The United States could see an overwhelming surge in coronavirus cases in December and January as people meet to celebrate Hanukkah, Christmas, New Year's Eve and other winter holidays,' Anthony Fauci, MD, Director of the National Institute of Allergy and Infectious Diseases told the Milken Institute's Future of Health Summit.

"'We have a baseline of infections that literally is breaking records every day...the numbers are really stunning...this is our underlying infection rate...we have not yet felt the surge from the Thanksgiving holiday,' Fauci said."

• International SOS recommends this interview: Dr. Fauci starts about 3 minutes in...

3. Attack rate of 75% in the Brazilian Amazon

A new article in <u>Science.sciencemag.org</u> reports that SARS-CoV-2 spread rapidly in the Brazilian Amazon.

The first case in Manaus was detected on 13 March; an explosive epidemic followed, peaking in early May with a 4.5-fold excess mortality (increased number of deaths compared to the same period in other years).

By June, 44% of the population had detectable IgG antibodies to SARS-CoV-2. Correcting for cases without a detectable antibody response and antibody waning, the study estimates a 66% attack rate (percentage of population infected) in June, rising to 76% in October.

This attack rate is higher than in São Paulo, in south-eastern Brazil, where the estimated attack rate in October was 29%.

These results confirm that, when poorly controlled, COVID-19 can infect a high proportion of the population causing high mortality.

4. Mortality among adults ages 25-44 in the US during the COVID-19 pandemic

A new analysis shows that COVID-19 is now the leading cause of death for young adults in many parts of the US, surpassing unintentional overdose.

A preprint non-peer-reviewed <u>observational cohort study</u> published by the University of Washington looking at all-cause mortality among adults age 25-44 during the COVID-19 pandemic in the US found that 14,155 more deaths occurred in this age group from 1 March 1 to 31 July than during the same period of 2019, representing a 23% relative increase (incident rate ratio 1.23).

In states including New York, New Jersey, Arkansas, Louisiana, New Mexico, Oklahoma, Texas, Arizona, California, Hawaii, and Nevada, COVID-19 deaths exceeded 2018 unintentional opioid overdose deaths during at least one month.

D. News

1. 3D printing in the COVID-19 supply chain response

The US Department of Health and Human Services (HHS) has <u>published a detailed guide</u> to support the manufacturing of personal protective equipment (PPE) and other necessary medical devices in short supply using 3D printing.

<u>Hundreds of 3D-printed devices</u> that have been proposed are listed and icons provide guidance to whether they have passed a clinical review.

Of particular importance has been the 3D printing of nasal swabs. Detailed guidance on $\frac{\text{design and}}{\text{testing}}$ is provided.

2. Western Australia introduces mandatory QR code contact tracing requirements

West Australians are <u>now required to check in</u> at pubs, nightclubs, gyms, restaurants and cafes, hairdressers, cinemas, hotels and churches.

On arrival at the venue, people can either download the free "SafeWA" app on their phone and scan the business's QR code, which will be displayed at venues, or they can manually sign in using a paper system.

3. Europol warning regarding fake COVID-19 vaccines

<u>Europol</u> issued a warning on Friday against the risk of organised crime scams linked to COVID-19 vaccines, including the potential that criminals will try to sell dangerous counterfeit vaccines.

"Once a legitimate vaccine enters the market, counterfeited versions of the specific vaccine brand are expected to circulate rapidly.

"Counterfeit COVID-19 vaccines may represent a significant public health threat if they are ineffective at best, or toxic at worst, given their production in underground labs without hygiene standards."

Europol said it was aware of criminals placing advertisements on dark web marketplaces "using the brands of genuine pharmaceutical companies that are already in the final stages of testing."

E. Travel

1. Airlines try COVID-19 tested transatlantic flights

Reuters reports that: "KLM, the Dutch arm of Air France-KLM, on Friday said it would begin offering COVID-19 tested flights to Atlanta, the latest example of a European airline adopting a testing strategy to increase passenger confidence in flying amid the coronavirus pandemic.

"Under the KLM plan, passengers receive one test five days before their flight, another shortly before the flight, and a third after landing."

F. When and which vaccines are likely to be available in Asia

Reuters has produced a summary of <u>vaccine supply agreements</u> for most Asian countries.

Australia:

AstraZeneca: 34 million doses
Novavax: 40 million doses
Pfizer: 10 million doses
CSL/UQ: 51 million doses

• First delivery: AstraZeneca 3.8 million doses in February 2021

Bangladesh

AstraZeneca: 30 million doses
GAVI: 68 million doses

India:

- Serum Institute of India (SII) has applied for Emergency Use Approval (EUA) of the its variant of the AstraZeneca vaccine (which SII is manufacturing in India) named "<u>Covishield</u>". The Indian Government plans to purchase 100 million doses per month, starting February 2021
- Bharat Biotech, developers of locally developed vaccine "<u>Covaxin</u>", which "<u>stores well at 2-8 degrees C</u> and so may be more suitable for the Indian climate has applied for an EUA
- Pfizer has applied for an EUA of its vaccine

Indonesia

- Has received 1.2 million doses of Chinese Sinovac vaccine, with 1.8 million more due in January 2021
- Via COVAX, is entitled to vaccine for 20% of its population

Japan

AstraZeneca: 30 million doses by March 2021

Novavax: 250 million doses

• Pfizer: 120 million doses in first half of 2021

Philippines

• Is in talks with AstraZeneca to supply at least 20 million doses

South Korea

 Aims to secure 20 million doses from COVAX and 72 million additional doses from other drug makers, including Pfizer, Moderna, AstraZeneca and Johnson & Johnson, by end 2021

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Taiwan

 Aims to secure 15 million doses from COVAX and 15 million additional doses from other drug makers by end 2021

Vietnam

• Via COVAX, is entitled to vaccine for 20% of its population