INTERNATIONAL SOS WEEKLY SCIENTIFIC UPDATE
Focussing on immunity and vaccine development

Produced by Dr. Doug Quarry
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In this edition:

A. Vaccine Development & Approval

1. Oxford / AstraZeneca vaccine prevents up to 90% of COVID-19

A dosing regimen of the Oxford/AstraZeneca vaccine candidate has been found to prevent up to 90% of COVID-19 infections.

Two dosing regimens were tested and differing efficacy was found:

- Half dose followed by a full dose at least one month apart: **90% efficacy**
- Two full doses given at least one month apart: **62% efficacy**

Average efficacy: 70%
There were a total of 131 COVID-19 cases in the interim analysis and no hospitalisations or severe cases of the disease were reported in participants receiving the vaccine. No serious safety events related to the vaccine were confirmed.

2. "Mistake" behind AstraZeneca/Oxford vaccine dosing success

The Oxford/AstraZeneca vaccine is most successful with a half dose followed by a full dose.
"'The reason we had the half dose is serendipity,' Mene Pangalos, head of AstraZeneca's non-oncology research and development, told Reuters.

"Two full doses were planned in UK trials but when side effects, such as fatigue, headaches, or arm aches turned out to be milder than expected, the dose was checked. 'We found out that they had under-predicted the dose of the vaccine by half.'

"He added: "'That, in essence, is how we stumbled upon doing half dose/full dose (group).'
"'Yes, it was a mistake.'"

However, protection of 90% was found in an analysis of around only 3,000 people on the trial. Further study is required.

3. Hint that AstraZeneca/Oxford vaccine may reduce viral transmission

Professor Andrew Pollard, Oxford Vaccines Group, told a Downing Street briefing that there is "a hint in the data" that the vaccine may also help stem viral transmission.

Professor Pollard said that their team swabbed over 8,000 volunteers in the UK trials every week, meaning they could also pick up the cases of asymptomatic infection. He said that there is "a hint" in the group that had the higher efficacy that there was less asymptomatic infection, and that could mean that vaccination could lead to a reduction in asymptomatic spreaders.

4. Some signs AstraZeneca vaccine durability could be a year

Reuters reports that "Scientists testing the efficacy of AstraZeneca's experimental COVID-19 vaccine said they cannot be sure if the virus will mutate in a way that would make it necessary to repeat vaccination every year, but that for now looks unlikely.

"'We don't know yet if this virus will be mutating away from the immune response,' the Oxford vaccine group's director, Andrew Pollard, told reporters on a briefing, adding, 'There is no evidence of that yet.'

"Asked whether the vaccine would be likely to give longer-term protection, Pollard said, 'We've got optimism about immune response lasting at least a year, but that trials needed more time to be able to give any confirmation of durability.'"

5. AstraZeneca to discuss with US FDA changing vaccine trial design

Reuters reports that "AstraZeneca will start discussions this week with the US Food and Drug Administration (FDA) to change the design of its experimental COVID-19 vaccine trial to add the half dose followed by full dose regime, a senior executive said on Monday.

"The design of its US trials, which are continuing, would change to include the potential for two different dose regimens:" 1) half dose followed by a full dose, and 2) full dose followed by a full dose.

6. Why is the half dose then full dose Oxford vaccine regimen more efficacious?

Professor Sarah Gilbert, widely acknowledged as having designed the Oxford vaccine, has said she was surprised by the result.

As to the explanation, Bloomberg reports Prof Gilbert as saying "'It's theoretically possible that a full initial dose generated antibodies to the adenovirus vector itself, which might have limited the immune response to the coronavirus spike protein', Gilbert said. However her team measured the antibodies to the adenovirus in earlier studies and found only a small effect.

"'I'm not really sure if that's the full answer. We'll look into it some more,' she said. 'But it may be something subtler in terms of inducing a high-quality immune response by giving just the right amount of vaccine antigen at the first dose and then expanding it with the second dose.'"

7. Sinopharm applies for regulatory approval to launch vaccine

The South China Morning Post reports that "China National Pharmaceutical Group, known as Sinopharm, and whose subsidiary company China National Biotec Group (CNBG), which is developing two inactivated coronavirus vaccines, has filed for regulatory approval to launch the vaccines.

The two vaccine candidates have been being tested for broad safety and efficacy in ten countries across South America and the Middle East. The safety and efficacy data has not been published.

8. Sputnik V vaccine is 91.4% effective according to interim data

Russia has released interim research data from Phase 3 trials on its Sputnik V coronavirus vaccine which indicate that the vaccine more than 91% effective:

- Data obtained seven days after the second dose showed the vaccine to be 91.4% effective
- Data obtained 21 days after the second dose showed the vaccine's efficacy could be higher than 95%.

The Gamaleya National Research Centre for Epidemiology and Microbiology intends to publish the data from the Phase 3 trials in an international medical journal following a peer review.

9. Sputnik V vaccine to begin production in Korea this year

The Russian Direct Investment Fund (RDIF) and GL Rapha, one of the leading South Korean bio-tech companies, have agreed to produce over 150 million doses of Sputnik vaccine per year; production will commence in December 2020. RDIF and GL Rapha will supply over 150 million doses per year, produced in South Korea for global distribution.

Requests for more than 1.2 billion doses of the Sputnik V vaccine have been received by the RDIF from over 50 countries. The Sputnik V vaccine supplies for the global market will be produced by RDIF's international partners in South Korea, India, Brazil, China, and other countries. Cost is expected to be less than $10 per dose.

B. Vaccine Purchase & Distribution

1. Vaccinations in the European Union

European Commission President Ursula von der Leyen has said that the conditional marketing authorization from the European Medicines Agency (EMA) for BioNTech and Moderna could happen as early as the second half of December 2020.

Germany

- The Guardian reports Germany's Health Minister Jens Spahn that administration COVID-19 vaccines could start in December.

Spain

- The Guardian also reports Spanish Prime Minister, Pedro Sanchez, saying on 22 November that Spain will begin a comprehensive coronavirus vaccination programme in January. The program will have 13,000 vaccination points and expects to have covered a very substantial part of the population within three months.

2. EU could pay over $10 Billion for Pfizer and CureVac vaccines

The European Union could pay more than USD $10 billion to secure hundreds of millions of doses of the vaccines being developed by Pfizer-BioNTech and CureVac, an EU official told Reuters.
The bloc has agreed to pay €15.50 euros per dose for the Pfizer vaccine giving an overall price of up to €3.1 billion for 200 million doses, rising to €4.65 billion if another optional 100 million doses are purchased under the deal.

The EU has separately agreed to pay €10 euros per dose for an initial supply of 225 million doses of the CureVac vaccine, a discount from the €12 euros the company had set as the price. The Curevac deal secured up to 405 million doses, of which 180 million are optional

CureVac had committed to start delivery by the end of March 2021.

3. India may not need Pfizer vaccine

The Economic Times of India reports Indian Health Minister, Dr Harsh Vardhan, as saying "India may not need Pfizer COVID-19 vaccine."

Dr Vardhan continued; "The United States has not even given a license to Pfizer. So, it does not make sense for other countries like India to consider it. We are in touch with everyone but we feel that we may not need Pfizer vaccine."

Separately, Reuters reports "India hopes five locally-tested vaccines will help it control COVID-19…."
The five experimental vaccines that India is particularly following are:

- Russia's Sputnik-V whose Phase 3 trials in India are about to start
- AstraZeneca/Oxford University vaccine which is being manufactured by the Serum Institute of India
- Bharat Biotech and the Indian Government's COVAXIN
- Zydus Cadila's ZyCoV-D vaccine candidate
- A vaccine being developed by Biological E Ltd with Baylor College of Medicine and Dynavax Technologies Corporation

4. Brazil's Sao Paulo State to receive first doses of China's Sinovac COVID-19 vaccine

Reuters reports that Brazil's Sao Paulo State will begin importing 46 million doses of China's Sinovac vaccine this week.

Separately, Brazilian federal health officials recently met with Pfizer. “The Health Ministry said…that it would buy the Pfizer vaccine…if it was proven safe and was registered with Health Authority Anvisa. “The Ministry will also meet this week with Johnson & Johnson, India’s Bharat Biotech (makers of COVAXIN), and makers of Russia’s Sputnik V vaccine.”

C. Outbreaks and Epidemiology

1. Melbourne eliminates coronavirus

After its prolonged lockdown, Melbourne (and all of Victoria) have now had 28 days with no new COVID cases. As this period represents two full 14-day incubation periods, coronavirus has now been eliminated from Victoria.

D. Travel systems

1. Chinese President Xi Jinping proposes global QR code system for travel

The South China Morning Post (Hong Hong) reports that “’Chinese President Xi Jinping has proposed using a global QR code system to enable cross-border movement of people amid the coronavirus pandemic.

“Addressing the virtual G20 summit on Saturday night, Xi said a global mechanism involving mutual recognition of health certificates, including nucleic acid test results in the form of QR codes, could be used to enable cross-border travel.

“’We hope more countries will join this mechanism,’ Xi said, according to a transcript published by state news agency Xinhua.”

2. IATA** is releasing a mobile app

In a press release on 23 November, IATA announced that it is in the final development phase of the “IATA Travel Pass”, a digital health pass that will support the safe reopening of borders.
The Travel Pass will display test results, together with proof of vaccination, as well as listing national entry rules, and details on the nearest laboratories. It will also link to an electronic copy of the holder’s passport to prove their identity.

A test programme will begin with British Airways this year before being deployed on Apple devices in the first quarter of 2021 and Android from April. Travellers will be able to share their status with border authorities or present a QR code for scanning.

The platform is built on open source standards to help inter-operability with existing systems including its member airlines' own customer apps.

More information: IATA Travel Pass

**IATA: The International Air Transport Association

3. Qantas boss pushes for “no jab, no fly” rule

Qantas Airline CEO, Alan Joyce, has warned future international travel will require compulsory vaccinations. Mr Joyce told A Current Affair that once a vaccine becomes available, Qantas will change

its terms and conditions for travel. While Qantas has not decided about compulsory vaccination for domestic travel, COVID vaccination will be required for international travel, either coming to, or leaving Australia.

“What we are looking at is how you can have a vaccination passport, an electronic version of it, that certifies which vaccine the passenger has been given, and whether that vaccine is acceptable to the country being travelled to,” he said.

Mr Joyce said compulsory vaccination will not only be required in Australia, but also around the world.

4. Delta Air Lines will continue to block middle seats until 30 March

A press release by Delta Airlines committed the airline to blocking middle seats until 30 March 2021 to provide added confidence and reassurance for customers booking future travel plans.
“Several independent studies have validated the effectiveness of the Delta CareStandard’s multi-layered protection, like advanced ventilation and an extensive cleaning regimen, which together significantly reduces the risk of flight-related transmission,” said Bill Lentsch, Chief Customer Experience Officer. “However, we recognize some customers are still learning to live with this virus and desire extra space for their peace of mind. We are listening and will always take the appropriate steps to ensure our customers have complete confidence in their travel with us.”

E. Vaccines and Transmission

1. Vaccines shown to prevent illness, but what about viral transmission?

Data from the Pfizer/BioNTech, Moderna and now AstraZeneca/Oxford Phase 3 trials show that they lessen or prevent disease, but not whether they block transmission of the virus.

2. Can a vaccinated person still spread the virus?

Whether these three vaccines prevent people from becoming infected (sterile immunity) is a separate question that the studies have not answered.

It is possible that those who received the vaccine became infected but did not develop symptoms (asymptomatic infection). So, it could be that those who have been vaccinated could continue to asymptomatically and unknowingly shed virus and spread disease. (The best vaccines induce sterile immunity that totally prevents onward transmission of the virus.)

One an optimistic note, some experts postulate that even if vaccination does not induce sterile immunity, it should reduce the viral load in asymptomatically infected people and so reduce their likelihood of shedding the virus and infecting others.

3. Determining the effect of vaccination on transmission

Experts say that it may take a year or more to answer the transmission question. The studies required will examine the quantity and duration of nasal carriage and viral shedding of vaccinated individuals measured from nasopharyngeal swabs or nasal swabs over time.

In the ideal setting, researchers would vaccinate people and then deliberately expose them to the virus, to see if they get infected, even if they do not develop symptoms. However, in general, this methodology is only used if an effective treatment is available.