From: MURPHY, Brendan

To: r.macintyre@unsw.edu.au; Kristine MCartney; KELLY, Paul
Subject:

Re: Vaccine procurement strategy [SEC=OFFICIAL]

Date: Saturday, 12 December 2020 9:50:36 PM

Attachments: <u>image005.png</u>

image006.png image011.png image012.png

Thanks Raina

Brendan Murphy Secretary Department of Health +61 2 6289 s22

On 12 December 2020 at 6:47:57 pm AEDT, Raina MacIntyre

<r.macintyre@unsw.edu.au> wrote:

Dear Brendan s47C

Regards Raina

Professor Raina MacIntyre

Head | Biosecurity Research Program | Kirby Institute | UNSW Medicine Professor of Global Biosecurity & NHMRC Principal Research Fellow



Kirby Institute s47F Tel: s47F

Cell, Whatsapp & Signal: 84/F

| f: 84/F

| skype: s47F

e: r.macintyre@unsw.edu.au | w: kirby.unsw.edu.au







I'm proud to work at the Kirby Institute, where my colleagues and I are fast-tracking solutions to COVID-19. You can support this life-saving research today https://alumni.unsw.edu.au/giving/fb/KirbyInstitute





From: "MURPHY, Brendan" < Brendan. Murphy@health.gov.au>

Date: Friday, 11 December 2020 at 9:21 am

To: Raina MacIntyre <r.macintyre@unsw.edu.au>, Kristine MCartney

Subject: Re: Vaccine procurement strategy [SEC=OFFICIAL]

Thanks Raina

We are continuing to explore the mRNA vaccine field.

Brendan Murphy Secretary Department of Health +61 2 6289 \$22

On 11 December 2020 at 7:41:45 am AEDT, Raina MacIntyre <r.macintyre@unsw.edu.au> wrote:

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Brendan, Kristine,

Professor Raina MacIntyre
Head | Biosecurity Research ProProfessor of Global Biosecurity Head | Biosecurity Research Program | Kirby Institute | UNSW Medicine Professor of Global Biosecurity & NHMRC Principal Research Fellow



Kirby Institute \$47F

Tel: s47F Cell, Whatsapp & Signal: s47F | skype: s47F

e: r.macintyre@unsw.edu.au | w: kirby.unsw.edu.au







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[SEC=OFFICIAL]

[SEC=OFFICIAL]

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From: KELLY, Paul
To: KIDD, Michael

Subject: RE: Fwd: RE: NCHRAC advice - Reinfection and the implications for vaccines (18 December 2020)

[SEC=OFFICIAL]

Date: Monday, 21 December 2020 10:07:44 PM

Thanks Michael

Sent with BlackBerry Work (www.blackberry.com)

From: KIDD, Michael < Michael.Kidd@health.gov.au >

Date: Monday, Dec 21, 2020, 18:34

To: KELLY, Paul < Paul. Kelly@health.gov.au>

Cc: AHPPC Secretariat < AHPPC. Secretariat@health.gov.au>. \$22

@health.gov.au>

Subject: Fwd: RE: NCHRAC advice - Reinfection and the implications for vaccines (18 December

2020) [SEC=OFFICIAL]

Paul

Please find attached the NCHRAC advice on reinfection and implications for vaccination.

I have added a cover sheet for AHPPC if you would like to share this with members.

Michael

Professor Michael Kidd AM FAHMS

Deputy Chief Medical Officer and Principal Medical Advisor

Australian Government Department of Health

T: 02 6289 s22 | M: s22

E: michael.kidd@health.gov.au

Address: GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

Click here for the latest information on COVID-19

----- Forwarded message -----

From: \$22 @nhmrc.gov.au>

Date: 21 December 2020 at 12:56:02 pm ACDT

Subject: RE: NCHRAC advice - Reinfection and the implications for

vaccines (18 December 2020) [SEC=OFFICIAL]

To: KIDD, Michael

<Michael.Kidd@health.gov.au>. \$22

Cc: \$22 @nhmrc.gov.au>,

@nhmrc.gov.au>,522

@nhmrc.gov.au>,COVID-19 advisorycommittee <covid-

19advisorycommittee@nhmrc.gov.au>,SOMI, Masha <Masha.Somi@health.gov.au>

Dear all

Please use the attached versions, especially the AHPPC cover paper – noting that the Word document attached earlier was corrupted (recommend you delete earlier copy).

Thanks s22

From: S22

Sent: Monday, 21 December 2020 10:59 AM

To: Michael.Kidd@health.gov.au; \$22

Cc: \$22 @nhmrc.gov.au>; \$22

@nhmrc.gov.au>; s22

@nhmrc.gov.au>; COVID-19 advisorycommittee <covid-

19advisorycommittee@nhmrc.gov.au>; 'Masha.Somi@health.gov.au'

<Masha.Somi@health.gov.au>

Subject: NCHRAC advice - Reinfection and the implications for vaccines (18

December 2020) [SEC=OFFICIAL]

Dear Michael (and Sharon)

Please find attached the finalised NCHRAC advice on reinfection and the implications for vaccines (18 December 2020) for the information of the Chief Medical Officer. A cover paper for AHPPC is also provided.

This report was reviewed by Professor Sharon Lewin AO (co-Chair of NCHRAC) and Professor Michael Good AO (NCHRAC member).

Key points:

s470

For info - the next advice paper (on s22 finalised on Wednesday this week.

) is expected to be

Kind regards Prue

s22

Executive Director Research Quality and Priorities Branch National Health and Medical Research Council 22 @nhmrc.gov.au

+61 s22

nhmrc.gov.au



Australian Government

National Health and Medical Research Council



BUILDING A HEALTHY AUSTRALIA

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Please consider the environment before printing this email, thank you.

[SEC=OFFICIAL]

From: Allen Cheng
To: KELLY, Paul

Cc: Christopher Blyth; MURPHY, Brendan; KIDD, Michael; s22

Subject: Re: Tweets? [SEC=OFFICIAL]

Date: Wednesday, 13 January 2021 12:02:20 PM

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Out already!

Α.

On Wed, 13 Jan 2021 at 12:01, KELLY, Paul < Paul.Kelly@health.gov.au > wrote: Thanks Allen

A few typos but otherwise a very clear and logical argument in support of current strategy

The only thing I would add is - this is not the end of the vaccine story, it's the beginning. We don't know how long protection will last for any of the vaccine candidates, so we may need to revaccinate. Having AZ this year doesn't stop anyone getting another vaccine with perhaps better efficacy for symptomatic disease in 2022 or beyond.

You should get these out today Allen

Sent with BlackBerry Work (www.blackberry.com)

From: Allen Cheng <allen.cheng@monash.edu<mailto:allen.cheng@monash.edu>>> Date: Wednesday, Jan 13, 2021, 09:32

To: KELLY, Paul < <u>Paul.Kelly@health.gov.au</u> < mailto: <u>Paul.Kelly@health.gov.au</u> >>, Christopher Blyth

>> christopher.blyth@uwa.edu.au>> Subject: Tweets?

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Why would we use a vaccine that mightn't prevent transmission?

Vaccines can protect people both directly and indirectly. If you get an effective vaccine, you have a reduced risk of getting the disease.

However, if enough people get vaccinated, then even if you don't (or can't) get

vaccinated, you have a reduced risk of getting infected.

This is known as "herd immunity". The proportion of people that need to be immune to achieve herd immunity depends on the infectiousness of the disease.

(We're familiar with R0 - the average number of secondary cases that result from a primary case. The herd immunity threshold is approximately 1 - 1/R0, but can be higher or lower).

So, can COVID vaccines give us herd immunity? We currently don't know. The AZ vaccine reduces symptomatic infection by 70% (62% in those that received the standard dose). However, in a small subgroup of participants that had routine tests while asymptomatic, it only reduced asymptomatic infection by 8%.

As overall infection was reduced, this would suggest that the AZ vaccine does reduce infectiousness so some degree, but even if all adults were vaccinated, it probably wouldn't achieve herd immunity.

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32661-1/fulltext

In the Moderna vaccine study they only did asymptomatic swabs routinely before the second dose and found a lower number of asymptomatic infections in the vaccine group (14/14134) than then control (38/14073)

https://www.fda.gov/media/144453/download

In the Pfizer vaccine study, they are planning to do N serology to see if participants get asymptomatic infection, but the results aren't available yet. https://pfe-pfizercom-d8-prod.s3.amazonaws.com/2020-09/C4591001 Clinical Protocol.pdf

So, these vaccines prevent disease, and some may reduce infectiousness to an uncertain and varying degree.

But there is still benefit in getting a vaccine that protects you, even if it may not block transmission. It means that you have a reduced risk of getting sick.

Australia has access to 10 million doses of the Pfizer vaccine that is being delivered over the year. We also have access to 53 million doses of the AZ vaccine (3.8 million doses available soon, and roughly 1 million doses a week). We also may have some more doses of different vaccines via the COVAX facility.

https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/about-covid-19-vaccines/australias-vaccine-agreements

The Pfizer vaccine looks about as good as it gets (it appears to reduce symptomatic infection by about 95%). But we if only used this vaccine, we could only vaccinate 5 million people (~20% of the population) over the next year. This wouldn't achieve herd immunity even if it completely prevented infection and infectiousness.

The AZ vaccine may not be as good (it reduces infection by about 62-70%) but this can be rolled out more quickly. Even if doesn't protect against transmission, it does protect against disease and that's a benefit.

There is also another vaccine that is under development (Novovax) but the phase 3 studies have only just commenced

https://www.nih.gov/news-events/news-releases/phase-3-trial-novavax-investigational-

covid-19-vaccine-opens

The choice we have is whether to roll out both these vaccines as broadly and quickly as we can, or to wait for a better vaccine. This is not unlike the flu vaccine - it reduces infection by about 50% but we don't get herd immunity.

--

Allen Cheng, MB BS, FRACP, MPH, MBiostat, PhD

Director

Infection Prevention and Healthcare Epidemiology Unit, Alfred Health

Professor of Infectious Diseases Epidemiology

School of Public Health and Preventive Medicine, Monash University

Infectious Diseases Physician

Department of Infectious Diseases, The Alfred and Central Clinical School, Monash University

Monash University 553 St Kilda Road Melbourne VIC 3004

P: ^{s47F}

E: allen.cheng@monash.edu<mailto:allen.cheng@monash.edu>

Alfred Health 55 Commercial Road Melbourne VIC 3004

P: s47F E:s47F

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--

Allen Cheng, MB BS, FRACP, MPH, MBiostat, PhD Director

Infection Prevention and Healthcare Epidemiology Unit, Alfred Health

Professor of Infectious Diseases Epidemiology

School of Public Health and Preventive Medicine, Monash University

Infectious Diseases Physician

Department of Infectious Diseases, The Alfred and Central Clinical School, Monash University

Monash University

553 St Kilda Road Melbourne VIC 3004

P: \$47F

E: allen.cheng@monash.edu

Alfred Health
55 Commercial Road
Melbourne VIC 3004

P: s47F E:s47F



From: MURPHY, Brendan
To: MURPHY, Brendan

Subject: Fwd: COVID-19 Vaccines and Treatments - WoG talking points [SEC=OFFICIAL]

Date: Sunday, 24 January 2021 10:01:06 PM

Attachments: image001.png

COVID-19 Vaccine Talking Points - 22 January 2021.docx

Brendan Murphy Secretary Department of Health +61 2 6289^{s22}

----- Forwarded message -----

From: SCHOFIELD, Lisa <Lisa.Schofield@health.gov.au>

Date: 24 January 2021 at 4:17:10 pm AEDT

Subject: COVID-19 Vaccines and Treatments - WoG talking points

[SEC=OFFICIAL]

To:

Cc: COVID19VaccinePDO < COVID19VaccinePDO @Health.gov.au>

Colleagues,

Please find attached the latest talking points FYI.

Cheers Lisa

Lisa Schofield

Head, COVID-19 Vaccine Taskforce Division Australian Government Department of Health

P: 02 6289 S22 Mob. S22 E: lisa.schofield@health.gov.au

I acknowledge the traditional custodians of the lands and waters where we live and work and pay my respects to elders past, present and future.

EA: \$22 @health.gov.au

[SEC=OFFICIAL]

Talking points — COVID-19 Vaccines & Therapeutics — 22 January 2021 *Additions in red.*

Headline updates

- On 21 January 2021, the Minister for Health, Greg Hunt, announced the engagement of a panel of surge workforce providers. The providers are Aspen Medical, Healthcare Australia, International SOS, and Sonic Clinical Services.
 - The workforce will assist in the efficient and safe administration of vaccines, particularly to priority groups including residential aged care resident and workers, those living in disability care homes and their carers and some rural and remote locations. Additionally, support may be provided to jurisdictions for the vaccine rollout if required.
- On 21 January 2021, the Australian Government partnered with the Australian College of Nursing (ACN) to develop and deliver free accredited training modules for individuals involved in the administration of the COVID-19 vaccines (including GPs, nurses, pharmacists and other immunisers).
 - The training modules will cover handling, storage, delivery, reporting, safety, communication as well as vaccine specific training for vaccines in Australia.
 - To ensure accessibility to training across Australia, training modules will be available for delivery online for all Health Professionals involved in the administration of the COVID-19 vaccines
 - Healthcare professionals and the surge workforce will not be able to administer any COVID-19 vaccines without having first completed the required training.
- On 20 January 2021, Australian Technical Advisory Group on Immunisation (ATAGI) published advice on <u>Influenza and COVID-19 Vaccines</u>. Advice includes:
 - Not recommending healthcare professionals routinely scheduling and administering both the influenza and COVID-19 vaccine on the same day.
 - The recommended minimum timeframe between the different vaccines is 14 days
- On 20 January 2021, the Therapeutic Goods Administration (TGA) granted a
 provisional determination for to Biocelect Pty Ltd (on behalf of Novavax Inc) in
 relation to the COVID-19 Vaccine, NVX-CoV2373.
 - The granting of a provisional determination means that the TGA has made a decision that Biocelect (on behalf of Novavax) is now eligible to apply for provisional registration for the vaccine in the Australian Register of Therapeutic Goods (ARTG).
 - Provisional determination is the first step in the process and does not mean that an application has or will be made, or that the vaccine will be provisionally approved for inclusion in the ARTG.
 - The provisional pathway provides a formal and transparent mechanism for speeding up the registration of promising new medicines with preliminary clinical data. In order to apply for provisional registration, the sponsor must first apply for a provisional determination.

- In making its decision to grant Biocelect (on behalf of Novavax) a provisional determination, the TGA considered all eligibility criteria, including factors such as the evidence of a plan to submit comprehensive clinical data and the seriousness of the current COVID-19 pandemic.
- On 15 January the Norwegian Medicines Agency (NMA) in Norway reported that around 30 aged care residents who had received the Pfizer/BioNTech vaccine had have died. Over 40,000 elderly individuals have received the Pfizer vaccine.
 - The Norwegian Medicines Agency (NMA) has stated that the individuals were very frail patients, some of which with medical conditions, and that they are currently investigating whether the vaccine is linked to their deaths.
 - The Australian Government has requested information from the NMA and Pfizer via the Therapeutic Goods Administration (TGA) and is also requesting information from Norwegian Government
 - The TGA's processes for vaccine approvals is extremely rigorous and comprehensive. The TGA is evaluating all of the scientific and clinical information provided by the vaccine's sponsor, Pfizer, as well as other available evidence (including from international experience with emergency use of the vaccine) prior to making a regulatory decision.
- On 7 January 2021, the Prime Minister announced Australia's Epidemiology and COVID-19 Vaccine Roadmap, which includes <u>Australia's COVID-19 Vaccine National</u> Rollout Strategy.
- Staged roll-out of the COVID-19 vaccine is expected to commence in mid-to-late February 2021.

COVID-19 vaccine agreements

- The Australian Government is committed to providing all Australians with access to safe and effective COVID-19 vaccines as soon as available.
- Access to these vaccines is subject to clinical trial outcomes on the safety and effectiveness of each candidate, and approval by Australia's Therapeutic Goods Administration (TGA).
- The vaccine agreements allow us to support our Pacific and South East Asian neighbours, as vaccine doses can be donated or on-sold (with no mark-up) to other countries or international organisations.

Novavax

- On 20 January 2021, the Therapeutic Goods Administration (TGA) granted a
 provisional determination for to Biocelect Pty Ltd (on behalf of Novavax Inc) in
 relation to the COVID-19 Vaccine, NVX-CoV2373.
- On 14 January 2021, it was reported that the **Novavax** COVID-19 vaccine could soon be made in Australia by manufacturer CSL.
 - CSL are currently producing the AstraZeneca/Oxford vaccines and have confirmed they do not have the capacity or capability to produce two COVID-19 vaccines concurrently.
- On 11 December 2020, the Australian Government announced it had secured a further 11 million doses of the Novavax COVID-19 vaccine.

- The purchase agreement with Novavax will enable Australia to access 51 million doses of its vaccine candidate.
- Provided the vaccine proves safe and effective, the first supply is expected to arrive from mid-2021.

Pfizer/BioNTech

- On 20 January, Pfizer and BioNTech announced results from an *in vitro* study that showed their vaccine is able to neutralise the UK COVID-19 strain.
- On 7 January 2021, the Australian Government announced the Pfizer/BioNTech
 vaccine is expected to be approved by the Therapeutic Goods Administration later in
 the month.
- The Government has entered into a purchase agreement with Pfizer/BioNTech, who will provide 10 million doses to Australia.
- Provided the vaccine proves safe and effective, the first supply is expected to arrive from early 2021.
- The Pfizer/BioNTech vaccine can be stored in an ultra-low temperature freezer for up to six months.
 - It can be transported in "thermal shippers" (boxes) containing dry ice for up to 15 days. Pfizer has invested significant resources into developing their thermal shipping technology and in establishing distribution networks.
 - At this stage of clinical testing, stability data provided by Pfizer supports storage in a standard vaccine refrigerator (between 2 and 8°C) for 5 days.

University of Oxford/AstraZeneca

- On 13 January 2021, the Chief Medical Officer, Professor Paul Kelly, addressed concerns that the AstraZeneca/Oxford COVID-19 vaccine will not be effective enough to achieve herd immunity.
 - The AstraZeneca/Oxford vaccine clinical trials demonstrated the vaccine is generally well tolerated and effective at preventing symptomatic COVID-19 and that it protects against severe disease and hospitalisation.
 - Further analysis of clinical trial data across multiple different dosing regiments showed that the vaccine efficacy is 70.4% effective at preventing symptomatic COVID-19 more than 14 days after the second dose.
 - The Therapeutic Goods Administration is currently evaluating the safety, quality and efficacy of the AstraZeneca/Oxford vaccine under its provisional approval pathway. A decision to provisionally approve the vaccine will be made following rigorous assessment of all the available data.
 - Further detail on vaccine efficacy is being collated now and includes data from many millions of vaccinations across countries that have used early authorisations, such as the US, Canada and the UK.
- On 7 January 2021, the Australian Government announced the University of Oxford-AstraZeneca vaccine is expected to be approved by the Therapeutic Goods Administration in February 2021.

- On 11 December 2020, the Government announced it had secured an additional 20 million doses of the AstraZeneca COVID-19 vaccine, to be produced in Australia by CSL, bringing the total to 53.8 million Astra Zeneca vaccine doses in 2021.
- AstraZeneca announced on 27 November 2020, that an additional trial would be run
 to evaluate the efficacy of a lower dosage regimen that was found to have
 performed better than the full amount in AstraZeneca studies. This is due to the high
 efficacy in lower dosing regimen that warrant further assessment to establish the
 most effective regimen for evaluation and regulatory submission.
 - Further validation of clinical trial results is a strong signal of the robustness of the clinical trial process for this vaccine candidate. In addition, more data will continue to be collected and additional analysis conducted, which will provide further indication on efficacy and establishing the duration of protection.
- On 23 November 2020, Oxford University/AstraZeneca announced results from Phase 2/3 trials of the COVID-19 vaccine candidate (AZD1222). Results reported that across more than 11,000 people the vaccine is highly effective in preventing COVID-19, with one dosage schedule showing a better profile than another.
 - The more effective dosing schedule showed vaccine efficacy of 90% when AZD1222 was given as a half dose, followed by a full dose at least one month apart. This method was reported by AstraZeneca on 25 November 2020 as an error during the trial in vial quantity dosage (a mismeasurement of the number of viral vector particles contained within the initial doses), however resulted in a positive efficacy outcome
 - The data was reviewed by the independent Data Safety Monitoring Board and the UK regulator, both of whom approved the continuation of this dosing regimen. The regulator has publicly confirmed there is no concern.
- The news that a half dose/full dose regimen is potentially more effective means that this could potentially provide greater dose availability of the Oxford University / AstraZeneca vaccine candidate in Australia in 2021.
- The AstraZeneca vaccine can be transported and stored using ordinary refrigeration (2-8 degrees Celsius). This is important as the Australian Government is planning for a national roll-out.
- On 8 November 2020 CSL confirmed its Australian manufacturing schedule is ontrack to produce 30 million doses of the Oxford/AstraZeneca COVID-19 vaccine candidate and first doses would be ready for use early 2021, subject to regulatory approval.

University of Queensland/CSL

- The Australian Government supported the University of Queensland's research into a possible COVID-19 vaccine. This vaccine has undergone phase 1 clinical trials, however will not be proceeding to phase 3.
- This decision is related to how the vaccine interacts with a testing system and has not been based on the safety or effectiveness of the vaccine candidate.
 - As part of the vaccine's design, the university's researchers included a small fragment of a protein taken from the HIV virus, known as glycoprotein 41

- (gp41). This has been used to create a "molecular clamp" to hold the vaccine's synthetic virus in place.
- Although the university's researchers have confirmed the protein fragment poses absolutely no health risk to people who have taken the vaccine, they have identified a partial antibody response to it among trial participants
- This has the potential to interfere with some HIV screening tests that look for these antibodies – leading to a false positive test result.

COVAX Facility

- Australia has joined the COVAX Facility as a self-financing country, enabling the purchase of COVID-19 vaccine doses as they become available.
- The \$123.2 million commitment was announced by Minister Hunt on
 23 September 2020 and allows purchase of doses to cover up to 50 per cent of the population, in addition to existing agreements.
- The Government announced an investment of \$80 million in the COVAX Advance Market Commitment (AMC) to benefit the region.
 - This contribution, announced by the Foreign Minister on 24 August 2020, equates to sufficient COVID-19 vaccine doses to meet the needs of the highest risk populations in the Pacific and Timor-Leste, as well as a contribution to Southeast Asian needs.
 - We believe the COVAX AMC plays a critical role in supporting lower-income countries and eligible small economies to access safe, effective and affordable vaccines for their highest risk groups.
- The Gavi-led COVAX Facility is the centrepiece of global efforts to guard against 'vaccine nationalism':
 - It will pool purchasing power and risk, to prepare the most diverse portfolio of potential COVID-19 vaccines and fast track manufacturing.
 - It will support rapid, fair and equitable access to vaccines, aiming to mobilise one billion doses for developing countries by the end of 2021, addressing the acute phase of the pandemic.

Agreement with Becton Dickinson (BD)

- We have an agreement in place to buy needles, syringes and sharps containers from company Becton Dickinson.
- This will ensure Australia has access to peripherals for vaccine delivery and will prevent us being affected by international shortages of these consumables.
- BD currently supplies 70 per cent of Australia's needles, syringes and associated equipment.
- Sharps disposal containers will be manufactured on-shore, with needles and syringes manufactured off-shore.

Vaccine rollout

Australia's COVID-19 Vaccination Policy

- Staged roll-out of the vaccine is expected to commence in mid-to-late February 2021 and is supported by <u>Australia's COVID-19 Vaccine National Rollout Strategy</u>.
- The rollout of vaccines will be guided by Australia's COVID 19 Vaccination Policy, which was announced by the Prime Minister on 13 November 2020.
- While the Government supports immunisation, it is not mandatory and individuals maintain the option to choose not to vaccinate.

Regulatory approval

- It is expected the Therapeutic Goods Administration (TGA) will register the
 Pfizer/BioNTech vaccine in January 2021, and the University of Oxford/AstraZeneca vaccine in February 2021.
- Before any COVID-19 vaccine is approved for use in Australia it will be subject to the TGA's stringent assessment and approval processes
- The TGA rigorously assesses all vaccines for safety, quality and effectiveness. Vaccine candidates are subject to clinical and non-clinical assessments by technical experts.

Prioritisation of populations

- Vaccine prioritisation is required due to the initial limited supply of vaccine doses.
- The Australian Technical Advisory Group on Immunisation (ATAGI) has provided advice on prioritisation, informed by data on risk factors for COVID-19 morbidity and mortality, as well as disease epidemiology.
 - Quarantine and border workers have been prioritised as the main threat of current and future outbreaks is from overseas travellers. Prioritisation is linked to transmission reduction potential.
 - High-risk frontline healthcare workers are those most likely to encounter people with COVID-19. Vaccination can prevent transmission of the virus to other vulnerable people in these settings.
 - Aged care and disability care residents are at serious risk of severe outcomes if they were to contract COVID-19.
 - Residential aged care and disability workers are prioritised to prevent transmission of the virus to vulnerable residents in these settings.
- The first priority group is estimated at 1.4m doses.
- There are a number of at-risk groups identified by ATAGI which are also being prioritised for vaccination and will be next-in-line.
- The next groups for prioritisation, estimated at 14.8m doses, are:
 - Aboriginal and Torres Strait Islander people over 55
 - o Adults over 70
 - Younger adults with an underlying medical condition, including those with a disability

- Essential services personnel and those in settings with higher risk transmission. This includes defence force personnel, police, fire, emergency services and those working in meat processing.
- The following groups for prioritisation, estimated at 15.8m doses, are:
 - o Aboriginal and Torres Strait Islander people between 18-54
 - Adults aged over 50
 - Other critical and high risk workers such as public transport workers.
- Vaccination of the remaining general population will follow these priority groups.
 Additional data is required to support the use of a vaccine in children and adolescents.

Communications

- On 20 November 2020, the Australian National University released results from a study of 3000 Australian participants examining how demographic, attitudinal, political and social attitudes and COVID-19 health behaviour correlates with vaccine hesitancy and resistance to a COVID-19 vaccine.
 - When asked if a safe and effective vaccine for COVID-19 is developed almost 3 in 5 Australians (58.5%) would definitely get the vaccine, 28.7% were likely to get a vaccine, 7.2% unlikely and 5.5% resistant.
- The study results are consistent with current immunisation views and our understanding on public confidence around safety of a COVID-19 vaccine.
- A comprehensive communications strategy is being implemented by the Australian Government to support COVID-19 vaccine uptake.
- Key messages are in the categories of: community benefit; effectiveness; science and safety; government response and oversight; availability, cost and administration; information and consent; and processes for the health sector.

International travel

- We recognise that safe and effective vaccines are an important step to free movement within Australia and enable us to work towards international travel.
- Achieving community protection through immunisation would see people connecting with family and friends, transitioning back to their workplaces, and continue rebuilding our job market – all vital components to improving the lives of many Australians.
- While Australia has been able to manage localised outbreaks so far, many countries overseas are experiencing widespread community transmission. Quarantine of Australians returning home, remains an important tool to prevent further outbreaks occurring in Australia.
- Once a vaccine is available, Health may consider establishing new entry requirements for incoming travellers. There has been no decision to mandate vaccination for all arriving travellers to date.

 An Australian requirement for proof of COVID-19 vaccination upon entry would be made in consideration of any new recommendations from the World Health Organization

Distribution and logistics

- DHL Supply Chain and Linfox have partnered with the Australian Government to safely distribute COVID-19 vaccines to all Australians.
- They will support vaccination for all, including people in rural, remote and very remote areas and others who are hard to reach. They will also be required to track and report the temperature of the vaccine at all times. The required temperature could be 2 to 8 degrees (standard cold chain temperatures) to as low as minus 70, which is needed for the Pfizer/BioNTech vaccine.
- Data partner Accenture has been engaged to design, develop, and implement a software solution to enable 'point in time' visibility of COVID-19 vaccine doses across the deliver chain, including receipt of the vaccine by health services, vaccination of patients, and subsequent monitoring for adverse reactions.

COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group

- The COVID-19 Vaccines and Treatments for Australia Science and Industry
 Technical Advisory Group provides advice to the Australian Government on the
 purchasing and manufacturing of COVID-19 vaccines and treatments.
- The advisory group is chaired by Professor Brendan Murphy, Secretary of the Department of Health and Professor Paul Kelly, the Department of Health Chief Medical Officer is Deputy Chair. The advisory group provides advice on:
 - the safety and effectiveness of potential COVID-19 vaccines, tests and treatments
 - o purchasing COVID-19 vaccines, tests and treatments for Australia
 - the options available for manufacturing and packaging COVID-19 vaccines and treatments in Australia
 - o distribution and logistics associated with potential COVID-19 vaccines, and
 - o other technical matters related to COVID-19 vaccines and treatments.
- A <u>full membership</u> list and <u>Terms of Reference</u> are published on the Health website

COVID-19 Vaccine and Treatment Strategy

- The Australian Government's COVID-19 Vaccine and Treatment Strategy, welcomed by National Cabinet on 7 August 2020, provides a framework for securing early access to safe and effective vaccines and treatments. This will save Australian lives, allow us to consider reopening borders, rebuild the economy, and assist our region.
- The <u>strategy</u> and <u>key developments</u> are published on the Department of Health website.
- The strategy is focused around research and development; purchase and manufacturing; international partnerships; regulation and safety, and immunisation administration and monitoring.

Investments in COVID-19 research and development

- The Government continues to make considerable investments in COVID-19 research and development (R&D), drawing on Australia's strong domestic capabilities in this area.
- Overall the Government has committed \$372 million to vaccine development and capability, and treatments for COVID-19, comprising:
 - Over \$96 million from Medical Research Future Fund
 - \$2 million to APPRISE (the Australian Partnership for Preparedness Research on Infectious Disease Emergencies)
 - o \$20 million to an Australian Defence Force anti-viral (chloroquine) trial
 - \$15 million to Coalition of Epidemic Preparedness Innovations (CEPI) and the Foundation for Innovative New Diagnostics (FIND)
 - o \$230 million investment in the CSIRO's vaccine development capability
 - \$3.5 million of a total \$11.7 million investment (with Brandon Capital Partners) from the Biomedical Translation Fund to develop an innovative nasal treatment.
 - \$5.8 m for 10 research projects relevant to coronavirus research (including COVID-19) funded through the National Health and Medical Research Council (NHMRC) Ideas Grants and Postgraduate Scholarships schemes

International engagement

- Australia is working internationally to forge bilateral and multilateral partnerships to support not only Australia but the world, including the Indo-Pacific, to access and effective COVID-19 vaccine.
- Australia is committed to ensuring affordable and equitable access to effective COVID-19 vaccines, treatments and diagnostics once they become available.
 - The May 2020 World Health Assembly resolution on the COVID-19 Response, co-sponsored by a record-breaking 145 countries including Australia, acknowledges the critical need for equitable and affordable access to quality, efficacious medical products, medicines, and vaccines.
 - We strongly support international efforts under the multilateral Access to COVID-19 Tools Accelerator (ACT Accelerator) process to develop, manufacture and fairly allocate these urgently needed tools.
- On 31 October 2020, the Foreign Minister announced Australian support for COVID 19 vaccine access in the Pacific and Southeast Asia.
 - The Australian Government will provide a range of support including supplying safe and effective vaccine doses and delivering technical support to our regional partners. Australia will assist with assessment of vaccine safety, efficacy and quality by national regulatory authorities, informed by WHO advice.
 - An additional \$500 million has been committed over three years towards this effort on top of the \$23.2 million committed in the Budget.

 The funding will further help ensure that the countries of the Pacific and Timor-Leste are able to achieve full immunisation coverage, and will make a significant contribution toward meeting the needs of Southeast Asia.

Ethical concerns about COVID-19 Vaccine production

- We are aware that the Oxford University COVID-19 vaccine candidate is produced from a cell line that was developed from foetal tissue in the 1970s.
- This cell line has been growing under laboratory conditions and there has been no new tissue taken since the 1970s.
- There are strong ethical regulations for the use of any human cell, particularly foetal human cells.
- Many vaccines available in Australia are manufactured using cell lines that originally came from foetal tissue, including vaccines for rubella, hepatitis A, chickenpox and rabies.
- The Australia Government has negotiated access to the University of Queensland and Novavax protein COVID-19 vaccine candidates, which do not make use of a cell line derived from a human foetus.

Global vaccine development overview

- There are 237 vaccine candidates in pre-clinical and clinical trials, including 64 undergoing clinical trials in humans.
- Within Australia, six vaccine candidates are in clinical trials, including one developed by Flinders University and Adelaide company Vaxine, and three being developed by international companies (Novavax, Clover Biopharmaceuticals, SpyBiotech/Serum Institute of India and Symvivo).
- On 16 November 2020, the Therapeutic Goods Administration (TGA) granted a
 provisional determination to Janssen-Cilag Pty Ltd. in relation to its COVID-19
 Vaccine, Ad26.COV2.S. The granting of a provisional determination means that the
 TGA has made a decision that Janssen-Cilag Pty Ltd is now eligible to apply for
 provisional registration for the vaccine in the Australian Register of Therapeutic
 Goods (ARTG).
- The Australian Government does not currently have an advanced purchase agreement for doses of the Janssen-Cilag vaccine.

Therapeutics

Remdesivir

- On 20 November 2020, the World Health Organisation (WHO) issued a conditional recommendation against the use of remdesivir in hospitalised patients, regardless of disease severity, as there is currently no evidence that remdesivir improves survival and other outcomes in these patients.
- On 15 October 2020, the Solidarity Trial published interim results. It found that all 4 treatments evaluated (remdesivir, hydroxychloroquine, lopinavir/ritonavir and

- interferon) had little or no effect on overall mortality, initiation of ventilation and duration of hospital stay in hospitalised patients.
- Remdesivir was approved by the Therapeutic Goods Administration (TGA) as the first treatment option for COVID-19 in Australia, on July 10.
- It has not been shown to prevent coronavirus infection or relieve milder cases of infection.
- Australia was one of the first regulators to authorise the use of remdesivir for the treatment of COVID-19.

Dexamethasone

- A peer-reviewed study showed that dexamethasone reduced deaths in severely unwell patients on ventilators by one third, and by one fifth in patients receiving oxygen only. It has not been proven as an effective treatment in patients with mild to moderate symptoms.
- Australia's National COVID-19 Clinical Evidence Taskforce has provided up-to-date information on using dexamethasone to our doctors to ensure it is used safely and effectively.

Corticosteroids

- An analysis of 7 randomised trials for the use of corticosteroids (dexamethasone, hydrocortisone or methylprednisolone) was published in the Journal of the American Medical Association (JAMA), on 2 September.
- The study included data from the Australian-led REMAP-CAP platform trial.
- The study concluded that administration of systemic corticosteroids compared with placebo reduced 28-day mortality in critically ill patients.
- Based on these results the WHO has issued new treatment guidance strongly recommending steroids to treat critically ill patients, but not those with mild disease.

Monoclonal antibody treatments (Eli Lilly, Regeneron)

- On 21 January 2021 the New England Journal of Medicine published a paper reporting on an ongoing double-blind phase 1-3 trial involving non hospitalised patients with COVID-19. It concluded that the REGN-COV2 antibody cocktail reduced viral load, with a greater effect in patients whose immune response had not yet been initiated or who had a high viral load at baseline.
- On 21 November 2020, the US Food & Drug Adminstration (FDA) issued an emergency use authorisation for casirivimab and imdevimab (REGN-COV2) to be administered together for the treatment of mild to moderate COVID-19 in adults and paediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalisation.
- On 9 November Ly-CoV555 (bamlanivimab) was granted emergency use authorisation by the FDA for treating mild to moderate COVID-19 in adults and children not admitted to hospital.

- On 7 October, Regeneron announced it had applied for US FDA Emergency Use Authorisation its single antibody therapy, LY-CoV555 and for its dual antibody cocktail, REGN-COV2. This antibody therapy has received considerable media attention following reports US President Donald Trump was receiving a combination of experimental treatments for COVID-19: REGN-COV2, the corticosteroid dexamethasone, and the antiviral remdesivir.
- Australia is aware of several large clinical trials evaluating monoclonal antibody therapy for COVID-19 and will continue to monitor these treatments.



From: MURPHY, Brendan

To: s22 ; KELLY, Paul

Cc: SCHOFIELD, Lisa; \$22; GRIEVE, Jodie; News; \$22

Subject: RE: Urgent lines re the TGA"s approval of AstraZeneca [SEC=OFFICIAL]

Date: Tuesday, 16 February 2021 4:47:25 PM

What is our response to the question, if asked:

Does this mean everyone over 65 should discuss with their GP whether they should or should not have this vaccine

My answer would be No – unless of course the patient is very frail when any vaccination should be discussed with the GP

Brendan Murphy

Secretary

Department of Health Phone: +61 2 6289 s22

From: S22

@health.gov.au>

Sent: Tuesday, 16 February 2021 4:24 PM

To: KELLY, Paul <Paul.Kelly@health.gov.au>; MURPHY, Brendan

<Brendan.Murphy@health.gov.au>

Cc: SCHOFIELD, Lisa <Lisa.Schofield@health.gov.au>; \$22

@health.gov.au>; GRIEVE, Jodie <Jodie.Grieve@health.gov.au>; News

<News@health.gov.au>; s22

@health.gov.au>; s22

@health.gov.au>

Subject: Urgent lines re the TGA's approval of AstraZeneca [SEC=OFFICIAL]

Paul,

Hi there. As discussed, here is our first cut at some lines ahead of 7.30 tonight and for media tomorrow.

Let me know if you would like any further assistance.

Kind regards,

s22

- The TGA has assessed the AstraZeneca vaccine to be safe and effective for all people over the age of 18.
- In the TGA's rigorous assessment of the AstraZeneca vaccine, we have not come across any evidence that indicates it is not safe or effective for people over the age of 65.
- The TGA has now approved two vaccines for used in Australia: Pfizer and AstraZeneca.
- Both are safe and will prevent serious illness.
- The experience and evidence from the rollout of both vaccines in the UK is that they have been very effective among older people.

If asked ...

• The Provider Information statement is highly precautionary and highly cautious – based on current clinical trial information.

• But we are absolutely confident this vaccine is safe will protect against COVID-19 among elderly people – particularly against severe disease – and our priority is to protect all older Australians as soon as possible.



From: <u>Jeannette Young</u>

To: AHPPC Secretariat; Nicola.spurrier Contact; andrew.robertson Contact; Dr Brett Sutton (Vic); hugh.heggie Contact;

kerryn.coleman Contact; VEITCH, Mark; KELLY, Paul; kerry.chant Contact

Subject: Re: For info: TPs - TGA approval of AstraZeneca for Australians over 65 [SEC=OFFICIAL]

Date: Wednesday, 17 February 2021 9:06:59 AM

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Isn't it 18 years and over? Thank you

Get Outlook for iOS

From: AHPPC Secretariat <AHPPC.Secretariat@health.gov.au>

Sent: Wednesday, February 17, 2021 7:56:17 AM

To: Nicola.spurrier Contact >; AHPPC Secretariat

<AHPPC.Secretariat@health.gov.au>; andrew.robertson_Contact <</pre>

Dr Brett Sutton (Vic) >; hugh.heggie_Contact >; kerryn.coleman_Contact < ; VEITCH, Mark < >

Jeannette Young < J >; KELLY, Paul < Paul. Kelly@health.gov.au>;

kerry.chant_Contact

Subject: For info: TPs - TGA approval of AstraZeneca for Australians over 65 [SEC=OFFICIAL]

Good morning CHOs

For your info and to assist with any questions in pressers, please see below some TPs and 'if asked' questions on TGA's approval on AstraZeneca for Australians over 65.

TPs - TGA approval of AstraZeneca for Australians over 65

- The TGA has assessed the AstraZeneca vaccine to be safe and effective for all people over the age of 18.
- In the TGA's rigorous assessment of the AstraZeneca vaccine, we have not come across any evidence that indicates it is not safe or effective for people over the age of 65.
- The TGA has now approved two vaccines for used in Australia: Pfizer and AstraZeneca.
- Both are safe and will prevent serious illness.
- The experience and evidence from the rollout of both vaccines in the UK is that they have been very effective among older people.

If asked about the Provider Information Statement:

- The Provider Information statement is highly precautionary and highly cautious based on current clinical trial information.
- But we are absolutely confident this vaccine is safe will protect against COVID-19 among elderly people particularly against severe disease and our priority is to protect all older Australians as soon as possible.

Does this mean everyone over 65 should discuss with their GP whether they should or should not have this vaccine?

 No – that's not our advice – unless the patient is very frail, in which case any vaccination should be discussed with their GP.

Kind regards

Australian Health Protection Principal Committee (AHPPC)



of the Australian Health Ministers' Advisory Council (AHMAC)

Office of Health Protection | Australian Government Department of Health T: 02 6289 s22 | E: ahppc.secretariat@health.gov.au

A: MDP 140, GPO Box 9848, CANBERRA ACT 2601, Australia

I acknowledge the traditional custodians of the lands and waters where we live and work, and pay my respects to elders past and present.

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 From:
 \$22

 To:
 \$47F
 ; Christopher Blyth; Allen Cheng; \$47F
 @bigpond.com; \$47F

 \$47F
 ; \$47F
 \$47F

47F ;s47F @sydney.edu.au;s4/F

Cc: MURPHY, Brendan; KELLY, Paul; \$22 SCHOFIELD, Lisa; \$22

Subject: SITAG - Talking Points [SEC=OFFICIAL]

Date: Wednesday, 17 February 2021 2:02:14 PM

Attachments: image001.png

Hi All

As discussed at today's SITAG meeting, please find the below talking points:

TGA approval of AstraZeneca for Australians over 65

- The TGA has assessed the AstraZeneca vaccine to be safe and effective for all people over the age of 18.
- In the TGA's rigorous assessment of the AstraZeneca vaccine, we have not come across any evidence that indicates it is not safe or effective for people over the age of 65.
- The TGA has now approved two vaccines for use in Australia: Pfizer and AstraZeneca.
- Both are safe and will prevent serious illness.
- The experience and evidence from the rollout of both vaccines in the UK is that they have been very effective among older people.

If asked about the Provider Information Statement:

- The Provider Information Statement is highly precautionary and highly cautious based on current clinical trial information.
- But we are absolutely confident this vaccine is safe will protect against COVID-19 among elderly people – particularly against severe disease – and our priority is to protect all older Australians as soon as possible.

Does this mean everyone over 65 should discuss with their GP whether they should or should not have this vaccine?

• No – that's not our advice – unless the patient is very frail, in which case any vaccination should be discussed with their GP.

Kind Regards

s22

s22

Director, Engagement and Governance

Executive Officer

COVID-19 Vaccine Taskforce Division

Australian Government Department of Health

P: \$22 | Mob: \$22 | E: \$22 | @health.gov.au

From: \$22 @Health.gov.au>

Subject: FW: vaxquestions from CPMC [SEC=OFFICIAL]

Hi \$22

Re Paul's e-mail below, here are the TPs. I'm happy to pass on or did you want to respond?

s22

If asked about the Provider Information Statement:

- The Provider Information Statement is highly precautionary and highly cautious based on current clinical trial information.
- But we are absolutely confident this vaccine is safe will protect against COVID-19 among elderly people – particularly against severe disease – and our priority is to protect all older Australians as soon as possible.

s22





From: Allen Cheng

To: <u>KELLY, Paul; SKERRITT, John</u>

Subject: Twitter

Date: Tuesday, 13 July 2021 7:05:28 PM

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Just thinking of answering Jan Fran's thread - this ok? https://twitter.com/Jan Fran/status/1414784977464565772

I won't try to give you medical advice without knowing your personal circumstances, and I'm sorry that you've had a difficult time seeking advice.

I'd thought I'd talk you through the advice ATAGI provided today about vaccines for people in Sydney at the moment.

COVID is more severe in older people, so the benefit of vaccination is greater in older people. I'd strongly recommend older people in Sydney get the vaccine because they really don't want to get severe COVID.

This isn't to say that younger people don't benefit from being protected by vaccination. Young people generally don't die from COVID, but some end up in hospital, there is "long COVID", and we now know that vaccines do prevent transmission so there is a benefit to those around you.

ATAGI said today that people under 60 should re-consider the benefits and risks of earlier protection with AZ if they can't access Pfizer. The benefit of vaccination for people in Sydney is greater now there is an outbreak, compared to when it was just a theoretical future concern.

But we are still concerned about clotting ("TTS"), which is a rare but serious side effect. If you choose to get vaccinated, we want you make this decision with eyes wide open, so we recommend you talk to your GP or vaccine provider about this.

Some topics you may want to discuss - what is your risk of getting COVID? What are your personal circumstances - your medical history, do you live with elderly parents, what risk are you willing to take? What is "TTS" and what should you look out for if you get vaccinated?

If you choose to wait for Pfizer, I'd rather you did this as a fully informed decision. Hope this helps.

__

Allen Cheng, MB BS, FRACP, MPH, MBiostat, PhD **Director**

Infection Prevention and Healthcare Epidemiology Unit, Alfred Health

Professor of Infectious Diseases Epidemiology

School of Public Health and Preventive Medicine, Monash University

Infectious Diseases Physician

Department of Infectious Diseases, The Alfred and Central Clinical School, Monash

University

Monash University

553 St Kilda Road Melbourne VIC 3004

P: ^{s47l}

E: allen.cheng@monash.edu

Alfred Health

55 Commercial Road Melbourne VIC 3004

P: s47F E: s47F



From: SCHOFIELD, Lisa

To: MURPHY, Brendan; KELLY, Paul

Cc: STREET, Celia; \$22

Subject: FW: For info only - papers on vaccine effectiveness against symptomatic Delta and household transmission

[SEC=OFFICIAL]

Date: Sunday, 25 July 2021 1:11:39 PM

Brendan, Paul – FYI from \$22 below. L

From: \$22 @health.gov.au>

Sent: Friday, 23 July 2021 1:28 PM

To: SCHOFIELD, Lisa <Lisa.Schofield@health.gov.au>; PEISLEY, Hope

<Hope.Peisley@health.gov.au>; s22
@Health.gov.au>; JONES, Allison

<Allison.Jones@health.gov.au>

Cc: \$22 @health.gov.au>; \$22

@Health.gov.au>; \$22 @health.gov.au>; \$22

@health.gov.au>; \$22 @Health.gov.au>

Subject: For info only - papers on vaccine effectiveness against symptomatic Delta and household transmission [SEC=OFFICIAL]

Hi All,

In case useful wanted to provide some points from two papers this week:

1. Effectiveness of Pfizer and AZ vaccines on symptomatic COVID-19 caused by the Delta variant (UK dataset)

2. Effectiveness of two doses Pfizer vaccine on household transmission (Israel dataset)

Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant

Published NEJM 21 July 2021 (previously available in pre-print)

Data from over 19,000 vaccinated individuals in England was used to estimate the effectiveness of the Pfizer and AstraZeneca COVID-19 vaccines against symptomatic disease caused by the delta variant.

Key Points

- Effectiveness of two doses of the Pfizer vaccine was 88% among those with the delta variant and 93.7% among persons with the alpha variant.
- Effectiveness of two doses of the AstraZeneca vaccine was 67% among those with the delta variant and 74.5% among persons with the alpha variant.
- Effectiveness of one dose of a vaccine (Pfizer or AstraZeneca) was lower among persons with the delta variant (30.7%) than among those with the alpha variant (48.7%).
- These findings support efforts to maximise vaccine update with two doses among vulnerable populations.

Additional information

- Study design was a test-negative case-control design to estimate the effectiveness of vaccination against symptomatic disease. Compared vaccination status in persons with symptomatic COVID-19 with vaccination status in persons who reported symptoms but had a negative test. The proportion of persons with cases caused by the delta variant relative to the main circulating virus (the alpha variant) was estimated according to vaccination status.
- The study compared vaccination status in persons with symptomatic Covid-19 with vaccination status in persons who reported symptoms but had a negative test. This approach helps to control for biases related to health-seeking behavior, access to

<u>Vaccination with BNT162b2 reduces transmission of SARS-CoV-2 to household contacts in</u> Israel

Pre-print form published 16 July 2021

The authors used two models to estimate vaccine effectiveness against susceptibility to infection and infectiousness given infection in household settings.

Key points

- The overall vaccine effectiveness against transmission was 88.5%.
- Vaccine effectiveness against susceptibility to infection was 80-88%
- For breakthrough infections among vaccinated individuals, the vaccine effectiveness against infectiousness was 41-79%
- These findings indicate vaccination with two doses of Pfizer COVID-19 vaccine provides substantial protection against susceptibility to infection and slightly lower protection against infectiousness given infection, thereby reducing transmission of SARS-CoV-2 to household contacts.

Additional information

- Data was used from Maccabi Healthcare Services centralized database, which captures all data on members' demographics and healthcare-related interactions
- The full dataset, covering the period from June 15, 2020 to March 24, 2021, included information on 2,305,704 individuals from 1,275,015 households.
- There were 191,138 detected infections caused by SARSCoV-2 (8.3% of the total population), with 4,141 infections following the second dose of the vaccine and 73,582 infections in unvaccinated individuals

Kind regards,

s22

s22

A/g Director

Science and Analysis

Science and Investment Branch

National COVID Vaccine Taskforce

T: \$22 @health.gov.au

Location: Scarborough House L8

GPO Box 9848, Canberra ACT 2601, Australia

We acknowledge the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: PEISLEY, Hope

To: MURPHY, Brendan; KELLY, Paul; KIDD, Michael; SKERRITT, John

Cc: SCHOFIELD, Lisa; ATAGI COVID19 WG; \$22

Subject: FYI: Additional data 27July: AZD1222 (AstraZeneca COVID19 vaccine) [SEC=OFFICIAL]

Date: Tuesday, 27 July 2021 9:46:35 AM

FYI -

Hope Peisley

Assistant Secretary

Program, Policy and ATAGI Branch

National COVID Vaccine Taskforce

T: 02 6289 7367 | M **S22** | E:hope.peisley@health.gov.au EO: **S22** | E: **S22** @health.gov.au

Location: Scarborough House Level 8 GPO Box 9848. Canberra ACT 2601. Australia

We acknowledge the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: S47F @astrazeneca.com

Sent: Tuesday, 27 July 2021 9:33 AM

To: ATAGI COVID19 WG <ATAGI.COVID19WG@health.gov.au> **Cc:** \$47F

@astrazeneca.com>: \$47F

@astrazeneca.com>; PEISLEY, Hope <Hope.Peisley@health.gov.au>; \$22

@health.gov.au>

Subject: Additional data 27July: AZD1222 (AstraZeneca COVID19 vaccine) [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear \$22 and \$22

There continues to be a significant amount of data being released around COVID-19 vaccines, particularly in the real world setting and around variants of concern.

I keeping with our commitment to continue to share scientific information, please see below links several additional data releases. Please note that these are both in pre-print, and as such not yet peer-reviewed publications.

Would greatly appreciate if you could share these with the ATAGI COVID-19 working group.

- 1.) Viral infection and Transmission in a large well-traced outbreak caused by the Delta SARS-CoV-2 variant. Li et al. Preprint [Link to Preprint] Posted July 23, 2021. Research led by Guangdong Provincial Center for Disease Control and Prevention
- 2.) Thromboembolic Events and Thrombosis With Thrombocytopenia After COVID-19 Infection and Vaccination in Catalonia, Spain. Burn et al. Preprint [Link to Preprint] Posted 20 Jul, 2021. Research led by Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol) & funded by the European Medicines Agency
- 3.) Real World Data Demonstrating Increased Reactogenicity in Adults Receiving Heterologous Compared to Homologous Prime-Boost COVID-19 Vaccination: March-May 2021, England. Powell et al. Preprint [Link to Preprint] Posted 13 Jul 2021 Research led by Public Health England

- 4.) Pfizer-BioNTech and Oxford AstraZeneca COVID-19 vaccine effectiveness and immune response among individuals in clinical risk groups. Whitaker et al. Preprint [Link to Preprint] Posted 12 Jul, 2021. Research led by Public Health England
- 5.) Efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine against SARS-CoV-2 lineages circulating in Brazil; an exploratory analysis of a randomised controlled trial. Clemens et al. Preprint under consideration at a Nature Portfolio Journal [Link to Preprint] Posted 12 Jul, 2021. Research led by Oxford University
- **6.)** Reduced sensitivity of SARS-CoV-2 variant Delta to antibody neutralization. Planas *et al.* Nature (2021). https://doi.org/10.1038/s41586-021-03777-9 [Link to Publication] Published: 08 July 2021. Research led by Institut Pasteur
- 7.) Effectiveness of COVID-19 vaccines against variants of concern, Canada. Nasreen et al. Preprint [Link to Preprint] Originally Posted July 03, 2021. Research led by University of Toronto (on behalf of the Canadian Immunization Research Network (CIRN) Provincial Collaborative Network (PCN) Investigators)
- 8.) Clinicogenomic analysis of breakthrough infections by SARS CoV2 variants after ChAdOx1 nCoV- 19 vaccination in healthcare workers. Kale *et al.* Preprint [Link to Preprint] Posted July 03, 2021. *Research led by Institute of Liver and Biliary Sciences, India*
- 9.) Effectiveness of COVID-19 vaccines against variants of concern, Canada. Nasreen et al. Preprint [Link to Preprint] Posted July 03, 2021. Research led by University of Toronto (on behalf of the Canadian Immunization Research Network (CIRN) Provincial Collaborative Network (PCN) Investigators)
- 10.) T-cell mediated immunity after AZD1222 vaccination: A polyfunctional spike-specific Th1 response with a diverse TCR repertoire. Swanson et al. Preprint [Link to Preprint] Posted on June 23, 2021. Research led by NIH, Oxford University, Southampton University and AstraZeneca
- **11.)** Reduced neutralization of SARS-CoV-2 B.1.617 variants by vaccine and convalescent serum. Liu et al. Cell (2021), doi: https://doi.org/10.1016/j.cell.2021.06.020 [Link to Publication] Accepted 11th of June, 2021. Research led by University of Oxford

As always, if any questions please do not hesitate to reach out.

Kind regards

s47F

s47F

Senior Medical Director

AstraZeneca Australia

International I Australia and New Zealand 66 Talavera Road, Macquarie Park NSW 2113 T: s47F

1.547

s47F @astrazeneca.com

Please consider the environment before printing this e-mail

From: KELLY, Paul

To: POWER, Travis; DAVIS, Steph

Cc: \$22 LANCASTER, Megan; PATERSON, Carolyn; STREET, Celia; \$22

Subject: Re: WHO meeting notes: 6 December [SEC=OFFICIAL]

Date: Monday, 6 December 2021 8:33:01 PM

A true reflection of the meeting thanks Travis

Paul

Sent from Workspace ONE Boxer

On December 6, 2021 at 20:01:36 GMT+11, POWER, Travis <Travis.POWER@Health.gov.au> wrote:

Paul, Steph

Meeting record below. Let me know if you have any suggested changes. I've kept the focus on Omicron, not the discussion on vaccine hesitancy.

Others – for info, subject to changes from PK or SD Travis

WHO - Australia discussion on Omicron

6 December 2021, 7pm AEDT

Attendees:

WHO: Margaret Harris, spokesperson for emergencies team, Australia: Paul Kelly CMO Steph Davis DCMO, Travis Power AS International Strategies

Key discussion:

CMO noted the challenges presented by Omicron, particularly at a tricky time Australia was looking to reopen international borders.

Harris noted Omicron now in more than 45 countries, with significant community spread. Evidence that it has been in southern Africa as far back as September, meaning travel restrictions are likely to have limited effect given the elapsed time. Severity of disease not clear and won't be for a few weeks (similar to the ancestry strain from Wuhan which took time to understand severity). Concern about the variant driven by:

- number and type of variations in proteins;
- spike in epi curve in South Africa;
- increase in hospitalisation rate, including among younger populations (PK noted advice from Sth Africa workshop last week suggested many hospitalisations may have been due to testing following admittance for other conditions such as malaria); and
- apparent reinfection rate is high.

Harris cautioned against extrapolating data and findings from South Africa to Australia. Populations are too different, particularly the age profiles. Little

evidence available vet of severity in older populations or the risk of immuneescape. Harris mentioned a meeting later today (6 December) with vaccinologists on issue of vaccine efficacy and escape. That meeting will consider if changes are needed to booster programs – ie is a different vaccine needed to stimulate different antibodies? Harris noted that the variant is servings as important reminder (particularly in Europe), of the continued need for public health measures (masks, etc).

CMO flagged that Australia now has virus growing in Westmead, and Australia will engage closely with other nations to share information found. CMO also flagged a largish-outbreak in SW Sydney (a largely double vaxxed community) associated with a school. Cases now spreading through associated communities.

Broad discussion followed of challenges with vaccine hesitancy and nonpharmaceutical public health measures. Australia has seen very high vaccine rates, particularly in outbreak jurisdictions, though notable exceptions in some communities, including indigenous communities. Global vaccine hesitancy largely linked to trust in Government. Australia has been fortunate to be able to address many of the concerns preventing uptake of vaccines or prevent spread (such as working from home, support for those who experience vaccine side-effects, etc).

[SEC=OFFICIAL] All agreed to stay in touch, particularly over coming weeks as further information

From: Raina MacIntyre
To: KELLY, Paul

Subject: Re: Vaccine procurement strategy [SEC=OFFICIAL]

Date: Monday, 14 December 2020 6:40:54 AM **Attachments:** image005.png

image005.png image006.png image011.png image012.png

image012.png image017.png image018.png

Dear Paul s47C



Regards Raina

Professor Raina MacIntyre

Head | Biosecurity Research Program | Kirby Institute | UNSW Medicine Professor of Global Biosecurity & NHMRC Principal Research Fellow



Kirby Institute \$47F

Tel: s47F Cell, Whatsapp & Signal: s47F | f: s47F | skype: s47F

e: s47F @unsw.edu.au | w: kirby.unsw.edu.au







I'm proud to work at the Kirby Institute, where my colleagues and I are fast-tracking solutions to COVID-19. You can support this life-saving research today https://alumni.unsw.edu.au/aiving/fb/KirbyInstitute





From: "MURPHY, Brendan" < Brendan. Murphy@health.gov.au>

Date: Saturday, 12 December 2020 at 9:50 pm

To: Raina MacIntyre <r.macintyre@unsw edu.au>, Kristine MCartney <s47F >, "KELLY, Paul" <Paul.Kelly@health.gov.au>

Subject: Re: Vaccine procurement strategy [SEC=OFFICIAL]

Thanks Raina

Brendan Murphy Secretary Department of Health +61 2 6289 522

On 12 December 2020 at 6:47:57 pm AEDT, Raina MacIntyre s47F wrote:

@unsw.edu.au>

Dear Brendan s47C

Raina

Professor Raina MacIntyre

Head | <u>Biosecurity Research Program</u> | Kirby Institute | UNSW Medicine Professor of Global Biosecurity & NHMRC Principal Research Fellow



Kirby Institute \$47F

Tel: s47F Cell, Whatsapp & Signal: s47F | f:

skype: s47F

e: s47F @unsw.edu.au | w: kirby.unsw.edu.au







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From: "MURPHY, Brendan" < Brendan. Murphy@health.gov.au>

Date: Friday, 11 December 2020 at 9:21 am

To: Raina MacIntyre s47F @unsw.edu.au>, Kristine MCartney

s47F

Subject: Re: Vaccine procurement strategy [SEC=OFFICIAL]

Thanks Raina

We are continuing to explore the mRNA vaccine field.

Brendan Murphy

Secretary Department of Health +61 2 6289 s22

On 11 December 2020 at 7:41:45 am AEDT, Raina MacIntyre

<s47F @unsw.edu.au> wrote:

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Brendan, Kristine, s47C



s47C

Regards

Raina

Professor Raina MacIntyre

Head | Biosecurity Research Program | Kirby Institute | UNSW Medicine Professor of Global Biosecurity & NHMRC Principal Research Fellow



Kirby Institute \$47F

Tel: s47F

Cell, Whatsapp & Signal: +847F

| **f:** s47F

skype: s47F

e: s47F

@unsw.edu.au | w: kirby.unsw.edu.au







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[SEC=OFFICIAL]

[SEC=OFFICIAL]

From: WOOD, Mary
To: KELLY, Paul

Cc: s22 LUM, Gary; HARPER, Emily; s22 DAVIS, Steph

Subject: TPs for you to talk to Min Colbeck on vaccine effectiveness [SEC=OFFICIAL]

Date: Tuesday, 8 February 2022 5:28:17 PM

Attachments: image001.png

Hi Paul

The team has put together some pithy (and sobering) news on efficacy of vaccines against Omicron (thanks everyone).

Please let us know if you need any additional detail (sources, caveats etc).

Thanks,

Mary

Mary Wood

First Assistant Secretary

Office of Health Protection and Response | Chief Medical Officer Group

Australian Government Department of Health

P: 02 6289 s22 M: s22 | E: Mary.Wood@health.gov.au

Location: Scarborough Building 4.East.116 GPO Box 9848, Canberra ACT 2601, Australia

Executive Assistant – \$22 | P: \$22 | | E \$22 | @health.gov.au

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: DAVIS, Steph <Steph.Davis@health.gov.au>

Sent: Tuesday, 8 February 2022 3:59 PM

To: WOOD, Mary <Mary.WOOD@Health.gov.au>

Cc: \$22 @health.gov.au>; LUM, Gary <Gary.Lum@health.gov.au>;

HARPER, Emily < Emily. HARPER@Health.gov.au>

Subject: Words on vaccine effectiveness - for clearance [SEC=OFFICIAL]

Hi Mary,

Please see TPs/words below on vaccine effectiveness against Omicron for Minister Colbeck's office (as requested yesterday in WhatsApp by Paul). Unsure if they are still needed for this task or if he referred directly to the ATAGI website, however we need to have these up our sleeve regardless.

Many thanks to the team for pulling the bulk of this together. The delay is mine and my apologies for this.

We will update when the next ATAGI statement comes through on boosters to ensure that this aligns.

Cheers

Steph

• The Omicron variant shows significant immune escape compared with prior variants of COVID-19. This means that previous infection from COVID-19, or vaccine is less effective in preventing infection with Omicron.

- In its <u>publication of 3 February 2021</u>, the Australian Technical Advisory Group on Immunisation (ATAGI) noted that two doses of vaccine do not provide significant protection against infection with Omicron. Specifically, vaccine effectiveness against infection with Omicron ranges from 36 – 88% in the early weeks after receiving the second dose of vaccine, decreasing to 0-34% by about 4 months, and 0-10% by 6
- A booster with either Pfizer or Moderna vaccine improves protection against infection with Omicron, although this decreases over time. Studies demonstrate effectiveness of 54-76% in the early weeks after receiving a booster, decreasing to around 25-40% after 15 weeks.
- Vaccines remain more effective against severe disease from Omicron.
- After 2 doses, vaccines are between 25-57% effective in preventing hospitalisation, increasing to 88-90% in the immediate weeks following a booster dose.
- eeks د Omicron vari • Early evidence shows that vaccine effectiveness against the newer BA.2 a sub variant of Omicron is similar to the original Omicron variant

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