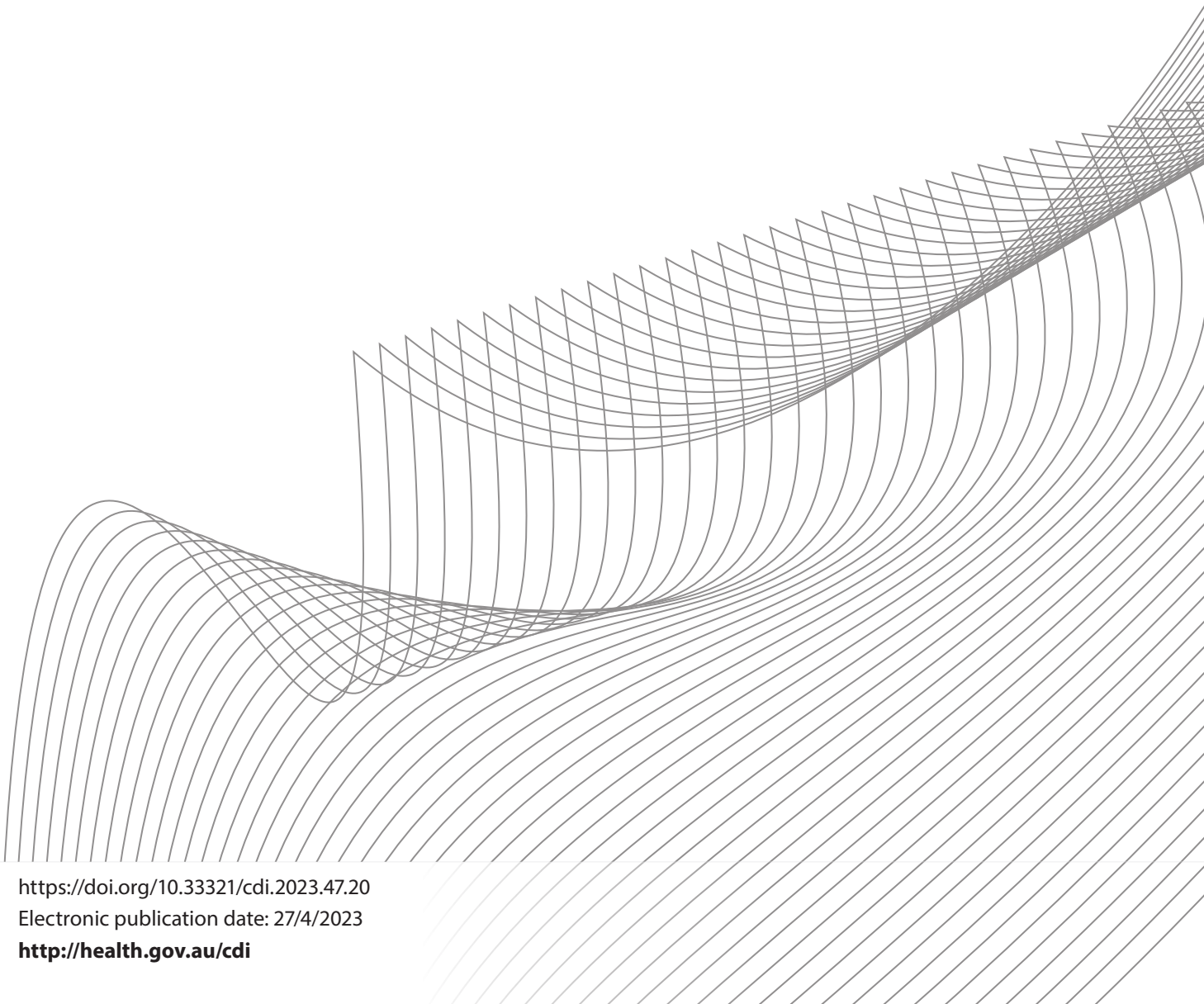
Australian Government
Department of Health and Aged Care

2023 · Volume 47

Communicable Diseases Intelligence

ATAGI Targeted Review 2021: the national COVID-19 vaccination program

Sanjay Jayasinghe, Cyra Patel, Lucy Armstrong, Clayton Chiu, Kristine Macartney, Katie Flanagan, Katherine Gibney, Michelle Giles, Nigel Crawford, Allen Cheng, Chris Blyth on behalf of ATAGI



https://doi.org/10.33321/cdi.2023.47.20
Electronic publication date: 27/4/2023
http://health.gov.au/cdi

Communicable Diseases Intelligence
ISSN: 2209-6051 Online

This journal is indexed by Index Medicus and Medline.

Communicable Diseases Network Australia
Communicable Diseases Intelligence contributes to the work of the Communicable Diseases Network Australia.
http://www.health.gov.au/cdna

Communicable Diseases Intelligence (CDI) is a peer-reviewed scientific journal published by the Office of Health Protection, Department of Health and Aged Care. The journal aims to disseminate information on the epidemiology, surveillance, prevention and control of communicable diseases of relevance to Australia.

Website
http://www.health.gov.au/cdi

Contacts
CDI is produced by the Office of Health Protection, Australian Government Department of Health and Aged Care, GPO Box 9848, (MDP 6) CANBERRA ACT 2601

Email:
cdi.editor@health.gov.au

Submit an Article
You are invited to submit your next communicable disease related article to the Communicable Diseases Intelligence (CDI) for consideration. More information regarding CDI can be found at: http://health.gov.au/cdi.

Further enquiries should be directed to:

cdi.editor@health.gov.au.

Review article

ATAGI Targeted Review 2021: the national COVID-19 vaccination program

Sanjay Jayasinghe, Cyra Patel, Lucy Armstrong, Clayton Chiu, Kristine Macartney, Katie Flanagan, Katherine Gibney, Michelle Giles, Nigel Crawford, Allen Cheng, Chris Blyth on behalf of ATAGI

Abstract

The overarching goal of the Australian coronavirus disease 2019 (COVID-19) vaccination program has been to protect all people in Australia from the harm caused by the novel coronavirus SARS-CoV-2. This review reflects on the role of the Australian Technical Advisory Group on Immunisation (ATAGI) in the national COVID-19 vaccination program, in terms of the initial programmatic and clinical recommendations in the evolving context of evidence relating to the disease and vaccines, epidemiology, and the program rollout. To fulfil the obligation to provide evidence-based advice to the Minister for Health and Aged Care on the safe, effective and equitable use of COVID-19 vaccines, ATAGI has worked closely with other agencies and committees such as the Therapeutic Goods Administration (TGA) and the Communicable Diseases Network Australia. ATAGI recommendations have sought to optimise the use of the available vaccine doses in achieving the objectives of preventing serious illness and death from COVID-19 while addressing any emerging safety signals following program commencement on 22 February 2021. As of mid-November 2021, the use of COVID-19 vaccines in children aged 5 to 11 years was being considered by the TGA and ATAGI; and emerging evidence, in areas such as use of heterologous vaccine schedules and co-administration with other vaccines, was under review. Despite unprecedented challenges which the delivery of mass COVID-19 vaccination presented to health systems globally, in Australia much was achieved in 2021 with over 90% coverage for primary doses in the vaccine-eligible population. Evaluation, using high quality data and assessment methods, of vaccination program outcomes—such as coverage, vaccine effectiveness and impact—is key to determine whether program objectives have been achieved and where gaps remain. Reflecting on the lessons learned so far would help further improve the national COVID-19 vaccination program and would also benefit programs for other routine vaccines and planning for future pandemics.

Introduction

This is the first of a series of targeted reviews from the Australian Technical Advisory Group on Immunisation (ATAGI) on the use of vaccines for the prevention and control of vaccine-preventable diseases. This review focuses on the national coronavirus disease 2019 (COVID-19) vaccination program, particularly the key considerations, including the relevant national and international contexts that underpinned ATAGI's recommendations.

The COVID-19 pandemic has caused substantial mortality and morbidity globally, disrupting health systems, economic activity and societal function since early 2020.[1] While non-pharmaceutical interventions were used initially with varying degrees of success, a core strategy to manage the acute phase of this pandemic has been population-wide COVID-19 vaccination.[2,3] COVID-19 vaccines have been developed and brought to market with unprecedented rapidity.[4]

The overarching goal of the Australian COVID-19 vaccination program has been to protect all people in Australia from the harm caused by the novel coronavirus SARS-CoV-2.[5] The program aims have been to reduce COVID-19-related

harm by preventing serious illness and death and, where possible, disease transmission; to ensure equity in vaccine access and uptake; to promote public and health professional trust and confidence in COVID-19 vaccines; and to maintain functioning of healthcare and other essential services.[5]

This review documents ATAGI's role in Australia's national COVID-19 vaccination program and key outcomes (as of November 2021), addressing:

- the initial programmatic and clinical recommendations for COVID-19 vaccine use made in the context of evolving information on COVID-19 vaccines (including prioritisation for vaccination considering initial limited vaccine supply);
- the response to safety concerns regarding COVID-19 vaccines;
- the challenges due to factors such as variant viral strains and constraints impacting on required scaling up of program delivery; and
- reflections and considerations relevant to future programmatic decision-making.

Aspects of COVID-19 vaccine program implementation that were outside ATAGI's remit are not covered in this review.

Initial planning and implementation of Australia's COVID-19 vaccination program

Governance of the COVID-19 vaccination program in Australia

The Australian Government's National COVID-19 Vaccine Taskforce led the rollout of the COVID-19 vaccination program with input from several agencies and advisory committees, including the Therapeutic Goods Administration (TGA), the COVID-19 Vaccines and Treatments Australia – Science and Industry Technical Advisory Group (SITAG), and ATAGI.[6,7] Other advisory committees established to inform the government's response to COVID-19 also had input into the COVID-19 vaccine rollout, including on Aboriginal and Torres Strait Islander populations,[8] culturally and linguistically diverse communities,[9] people with disabilities,[10] and aged care.[11]

The ATAGI terms of reference stipulated that the committee was to provide evidence-based advice to the Minister for Health and Aged Care on the safe, effective and equitable use of COVID-19 vaccines.[12] ATAGI has worked in close collaboration with other agencies and committees, notably with the TGA and the Communicable Diseases Network Australia (CDNA), and with invited experts from various clinical fields, including groups commissioned by the Department of Health and Aged Care to model COVID-19 vaccination strategies.

A timeline of the key events of the COVID-19 vaccination program in Australia is shown in Figure 1.

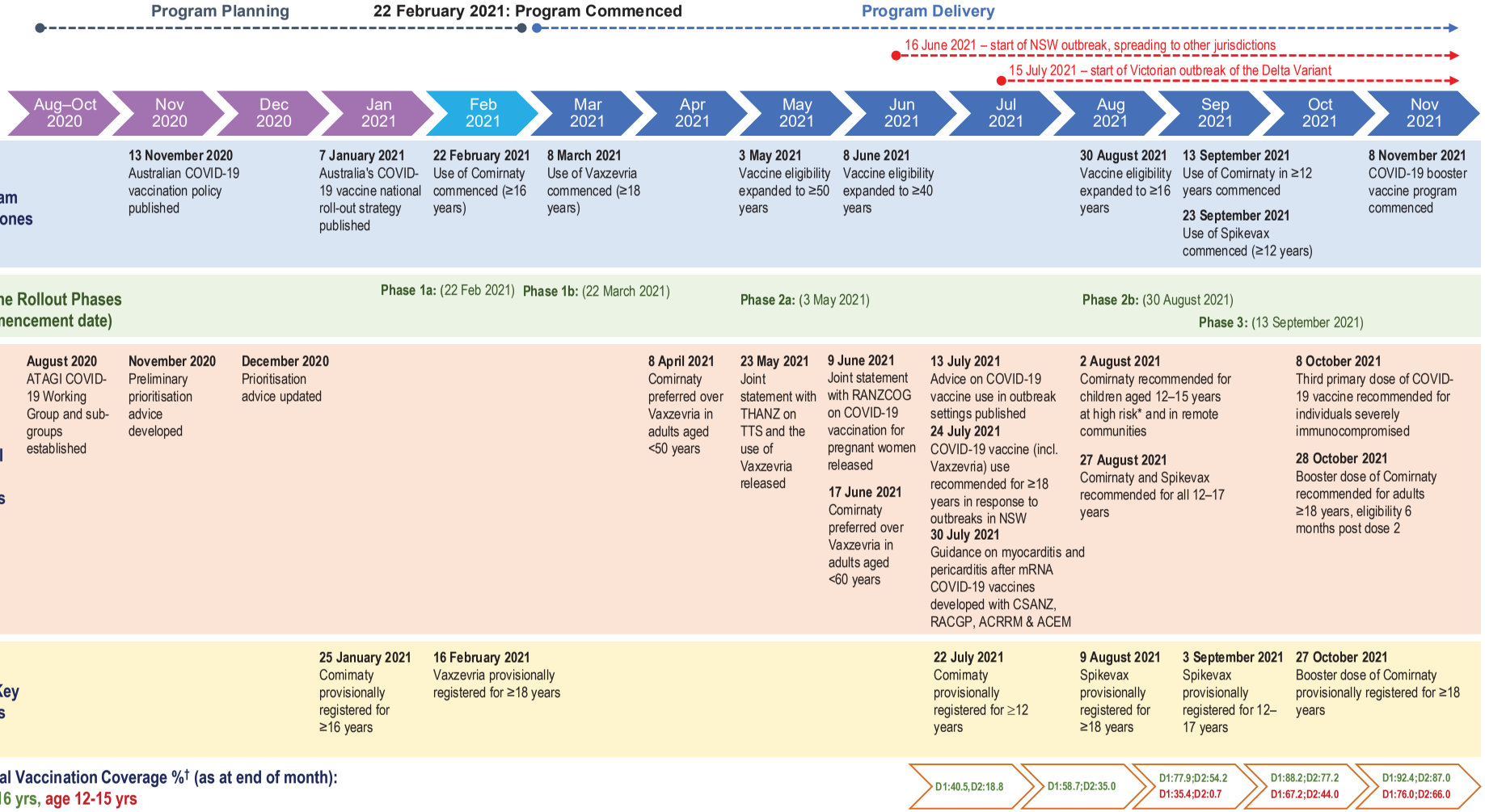
Prioritising the allocation of COVID-19 vaccines

Initial planning for the rollout of COVID-19 vaccines in Australia predominantly involved ATAGI identifying which population groups should be prioritised,[5] given the expected initial limited global and national supply of vaccines. Several COVID-19 vaccination allocation and prioritisation frameworks were consulted, particularly the WHO Strategic Advisory Group of Experts on Immunization (SAGE)[13] and the National Academy of Sciences[14] frameworks, both of which highlighted key ethical principles for equitable vaccine allocation. Recommendations about vaccine prioritisation were based on:

- epidemiological evidence on which population groups were at highest risk of exposure to SARS-CoV-2 or of becoming seriously ill or of dying from COVID-19;
- operational considerations, particularly vac-

Commun Dis Intell (2018) 2023;47 (https://doi.org/10.33321/cdi.2023.47.20) Epub 27/4/2023

Figure 1: The timeline of the Australian COVID-19 vaccination program



*people at high risk = Aboriginal and Torres Strait Islander people and people with underlying medical conditions that increase the risk of severe COVID-19 as listed here: https://www.health.gov.au/news/atagi-statement-regarding-vaccination-of-adolescents-aged-12-15-years

†Source: COVID-19 vaccination daily rollout update, Australian Government Department of Health

ATAGI: Australian Technical Advisory Group on Immunisation; NSW: New South Wales; TGA: Therapeutic Goods Administration; THANZ: Thrombosis and Haemostasis Society of Australia and New Zealand; RANZCOG: Royal Australian and New Zealand College of Obstetricians and Gynaecologists; CSANZ: Cardiac Society of Australia and New Zealand; RACGP: Royal Australian College of General Practitioners; ACRRM: Australian College of Remote and Rural Medicine; ACEM : Australasian College of Emergency Medicine

cine supply and distribution (as advised by the National COVID-19 Taskforce); and

- social and economic considerations such as protecting critical sectors (eg: health and other essential services).

Australia's strong pandemic response, using public health measures such as test-trace-isolate-quarantine (TTIQ) protocols and border measures, resulted in a substantially lower burden of COVID-19 in Australia in 2020 than was observed globally. The first wave of infections in Australia (between January and June 2020) was characterised by international importation of SARS-CoV-2 (63% of all confirmed cases during this period). Although outbreaks were limited in scale, some resulted in more widespread transmission, including across multiple states.[15] There were 7,489 confirmed cases to 9 June 2020, although serosurveys suggest SARS-CoV-2 transmission was likely higher.[16–18] The second period (10 June to 13 October 2020) was dominated by the large Victorian outbreak of 18,504 cases, with 99.6% of cases locally acquired. Over 2,000 cases occurred within residential aged care facilities.[19] Healthcare workers comprised a substantial proportion of cases (approximately 17.5%),[20] and were three times more likely to acquire infection than were non-healthcare workers.[21]

ATAGI recommendations in December 2020, regarding initial priority population groups for vaccination (Box 1), were made in the setting of no to minimal community transmission. It was anticipated that modifications may be required in response to emerging changes in epidemiology or to the evidence on vaccine efficacy and safety. ATAGI recommended that robust modelling be undertaken, examining a range of vaccination strategies on health outcomes under different scenarios and assumptions on vaccine characteristics, to guide the optimal COVID-19 vaccination rollout over time.[5]

ATAGI identified Aboriginal and Torres Strait Islander populations as a priority, noting that any vaccination strategy for this population must be developed in consultation with the National Aboriginal Advisory group and all other relevant stakeholders. A list of conditions associated with increased risk of COVID-19 severe disease and mortality was also developed in consultation with other specialist groups.

Box 1: ATAGI's recommendations in December 2020 for priority groups for COVID-19 vaccine allocation

First recipients of COVID-19 vaccines should include:

1. Staff at entry points to the country and in quarantine facilities; and

2. Healthcare workers at increased risk or likelihood of exposure to persons infected with SARS-CoV-2. This includes those in healthcare facilities, services, or settings where patients with COVID-19 or suspected COVID-19 may present and patients with confirmed COVID-19 are managed.

Subsequent populations for vaccination, in recommended order, include:

- Staff and residents of care facilities;
- Elderly adults aged 70 years and over; and
- Staff in remaining health care settings.

At the time, there was insufficient information to advise on the order of priority for the remaining populations below:

- Older adults aged 60–69 years;
- Aboriginal and Torres Strait Islander adults;
- Adults (< 60 years old) with underlying

medical conditions; and

- Other essential services personnel and settings with higher risks of transmission.

Registration of COVID-19 vaccines and commencement of the program

Comirnaty (Pfizer) was the first COVID-19 vaccine to be granted TGA provisional registration, on 25 January 2021, for use in individuals 16 years of age and older. Vaxzevria (AstraZeneca) was granted provisional registration on 16 February 2021, for use in individuals 18 years of age and older. ATAGI's clinical guidance for use of COVID-19 vaccines in Australia[22] was based on interim analyses of phase 2/3 trials and on emerging real-world evidence from countries which had already started to use the vaccines.[23–30] Supplementary statements for specific groups (such as pregnant women) and decision guides were published subsequently.[31]

The Australian national COVID-19 vaccination program commenced on 22 February 2021, in phases based on priority groups as determined by the Australian Government incorporating ATAGI advice (Figure 2). From March 2021, there was a steady supply of locally-manufactured Vaxzevria.

Challenges faced during the COVID-19 vaccination program in Australia

Over the course of the vaccination program various challenges arose, including changes in the local epidemiology of COVID-19, detection of safety signals, and emerging virus variants. The limited supply of COVID-19 vaccine, particularly Comirnaty, in the first six months of the program compounded these challenges.

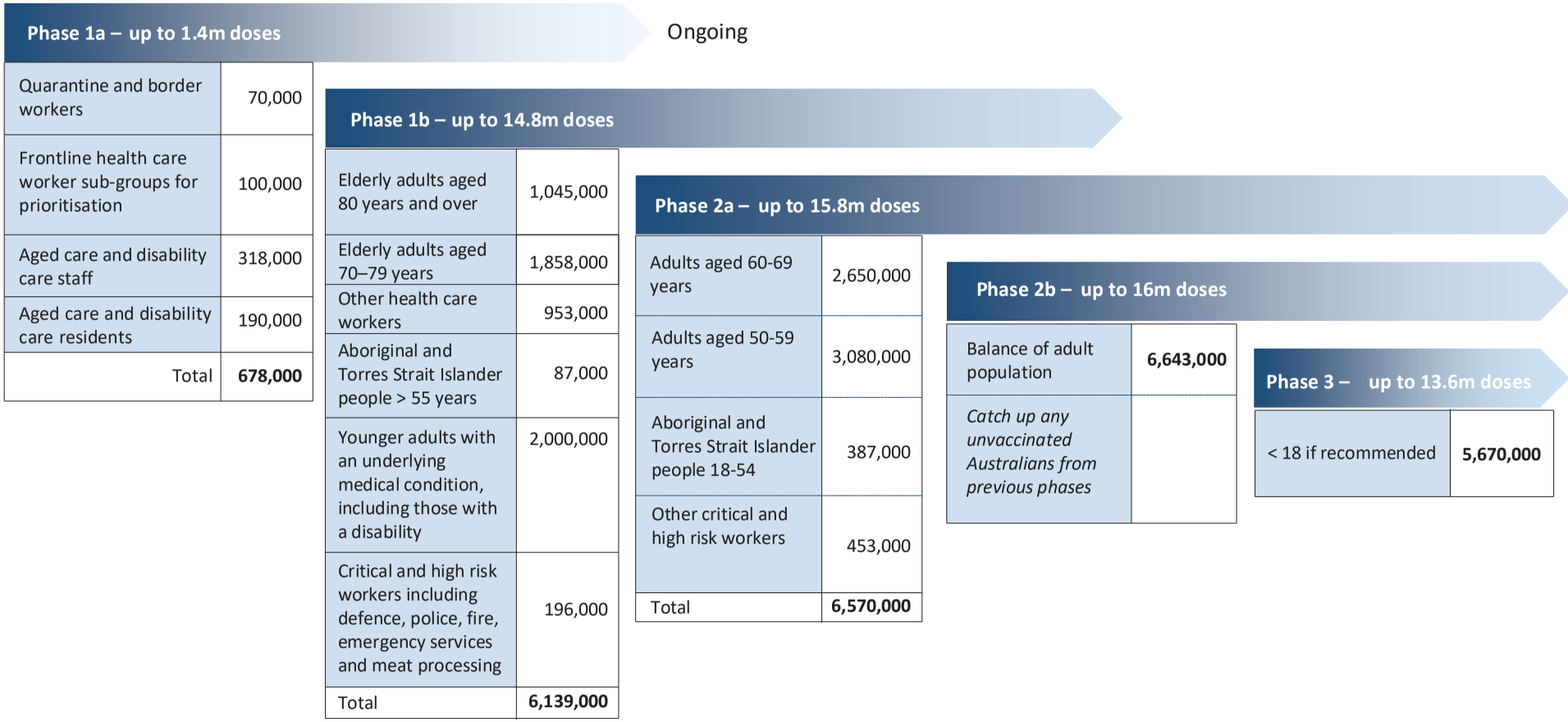
Thrombosis and thrombocytopenia syndrome (TTS) following Vaxzevria

A new clinical condition, thrombosis and thrombocytopenia syndrome (TTS) following Vaxzevria vaccination, emerged as a safety signal in March 2021. The European Medicines Agency (EMA) and their Pharmacovigilance Risk Assessment Committee (PRAC) reviewed thromboembolic events following COVID-19 vaccine receipt after a person in Austria was diagnosed with thrombosis at multiple anatomical sites and died ten days after vaccination.[32,33] ATAGI issued a statement on 19 March 2021, following the review of TTS data from Europe and the EMA preliminary assessment, highlighting that the benefits of vaccination using Vaxzevria outweighed any risk of side effects.[34,35] As a precautionary measure, on 25 March, ATAGI advised health care providers to defer vaccination with any COVID-19 vaccine in people with a confirmed medical history of cerebral venous sinus thrombosis (CVST) or heparin-induced thrombocytopenia (HIT).[36]

TGA received the first report of a local TTS case on 2 April 2021.[37] On 8 April 2021, ATAGI recommended that Comirnaty be preferred over Vaxzevria in adults aged under 50 years, for whom the risk of severe COVID-19 was lower, and the risk of TTS was considered higher, than for those in older age groups.[38] However, ATAGI also emphasised that Vaxzevria should be considered for adults under 50 years where the benefits outweighed the risks and where the person had made an informed decision. At the time, studies suggested an overall rate of TTS of approximately 4–6 per million occurring 4 to 20 days after the first dose of Vaxzevria, and in the United Kingdom (UK) overall mortality of 25%, with some variability seen in TTS rates across settings.[38] In the UK, the reported rate of TTS in those aged 50–59 years was 4 per million doses.[39] A resource was developed, comparing the benefits of vaccination with the risk of TTS in various epidemiologic scenarios, to guide informed decisions about receiving Vaxzevria.[40]

Commun Dis Intell (2018) 2023;47 (https://doi.org/10.33321/cdi.2023.47.20) Epub 27/4/2023

Figure 2: Phases of the COVID-19 vaccine national rollout strategy, as published at commencement of the national program[a,b]



a Figure reproduced from https://www.health.gov.au/sites/default/files/documents/2021/01/covid-19-vaccination-australia-s-covid-19-vaccine-national-roll-out-strategy.pdf.
b Numbers in the tables indicate the estimated size of eligible population groups in each phase.

ATAGI established weekly meetings from 28 April 2021 with the full ATAGI membership, to review emerging safety data on TTS from the TGA and from other countries (including liaising directly with international regulators and committees), and began publishing a weekly statement summarising deliberations. ATAGI published a joint statement with the Thrombosis and Haematosis Society of Australia and New Zealand (THANZ) on the use of Vaxzevria, including an expanded list of conditions for which Comirnaty was preferred.[41] The comprehensive review of emerging safety data led ATAGI to revise the age limit below which the preferred vaccine was Comirnaty, from 50 years to 60 years, on 17 June 2021.[42] At this stage, the incidence and severity of TTS following Vaxzevria vaccination, reported through national adverse event surveillance systems among people aged 50 to 59 years, was higher than that reported internationally and was also higher than the incidence initially estimated in Australia (increasing from 19 to 27 per million first doses of Vaxzevria).[42] Similar vaccine preferences, based on age and risk-assessment, had been issued in several other countries from March 2021 onwards.[43–45]

The occurrence of TTS adversely impacted the Australian public's confidence in COVID-19 vaccines, with cross-sectional surveys indicating that the proportion of the population willing to receive a COVID-19 vaccine had declined from 80% in February 2021 to 68% in April 2021.[46] Repeat surveys found increasing reluctance to receive Vaxzevria from April onwards, with the proportion of people stating that they were willing to receive Comirnaty but not Vaxzevria increasing from 28% in April to 30% in June, to 42% in July and to 47% in August.[47] These surveys were conducted at a time when there was low to moderate local transmission of SARS-CoV-2 but during which supply of Pfizer vaccine was limited.

Vaccine use in outbreak settings

In mid-June 2021, a large outbreak of the more transmissible SARS-CoV-2 Delta variant in Metropolitan Sydney began and soon spread to regional NSW and Melbourne. In response to increasing community-based transmission of SARS-CoV-2 in these settings, on 13 July ATAGI reasserted the importance of the benefits over risk of using Vaxzevria among younger adults aged 18–59 years in outbreak areas, and broadly where Comirnaty was not immediately accessible.[48] The recommended interval between Vaxzevria doses was also shortened from 12 weeks to 4–8 weeks, to more rapidly achieve two-dose protection based on higher vaccine effectiveness observed against the Delta variant with two doses than with one dose (Table 1). On 24 July, ATAGI reiterated that all individuals aged ≥ 18 years in Greater Sydney should strongly consider vaccination with any available vaccine, including Vaxzevria.[49] Flexibility in the interval between Comirnaty doses was recommended, as an interval of 6 weeks would allow limited vaccine supplies to be redirected to provide higher dose 1 uptake among affected areas to help mitigate against transmission.

Table 1: Estimates of vaccine effectiveness of Vaxzevria which ATAGI considered in developing advice supporting a shorter interval between doses in settings of outbreaks caused by the Delta variant[a]

Number of doses	Endpoint	VE[b] (95% CI)[c]
Two	Symptomatic laboratory-confirmed COVID-19	67% (61–72%)
	Hospitalisation	92% (75–97%)
One	Symptomatic laboratory-confirmed COVID-19	30% (24–35%)
	Hospitalisation	71% (51–83%)

a Based on the United Kingdom study (July 2021) by Stowe et al.[50]

b Vaccine effectiveness.

c 95% confidence interval.

Myocarditis and pericarditis after mRNA COVID-19 vaccines

In June 2021, an emerging safety signal of myocarditis and pericarditis following mRNA COVID-19 vaccines was detected, particularly among young adult males after their second dose of mRNA vaccines. In initial data from Israel, Europe, and the United States of America (USA), where mRNA vaccines were extensively used, the crude rates of myocarditis or pericarditis per million second doses of vaccines in people aged 12–29 years were 40.6 in males and 4.2 in females.[51] Following a comprehensive review, ATAGI and the Cardiac Society of Australia and New Zealand (CSANZ) jointly developed guidance on myocarditis and pericarditis after mRNA vaccines, published on 30 July 2021, recognising these conditions as a complication of COVID-19 mRNA vaccines, as well as from COVID-19 itself, and that the risk to benefit ratio remained overwhelmingly in favour of vaccination.[52] The statement included recommendations for subsequent COVID-19 vaccine doses in individuals who had this adverse event following immunisation. The joint statement was updated later with input from the Royal Australian College of General Practitioners (RACGP), the Australian College of Remote and Rural Medicine (ACRRM) and the Australasian College of Emergency Medicine (ACEM).

COVID-19 vaccine use in pregnancy

At the beginning of the vaccine roll-out, the initial ATAGI position was that COVID-19 vaccine was not routinely recommended in pregnancy due particularly to lack of specific safety data. However, vaccination was recommended to be considered if the potential benefits of vaccination outweighed any potential harms such as in the presence of medical risk conditions for severe COVID-19 and being at high risk of exposure to SARS-CoV-2. In subsequent months, global surveillance data became available on COVID-19 use in large numbers of pregnant women; this surveillance data did not identify any significant safety concerns with mRNA COVID-19 vaccines given at any stage of pregnancy. There was also evidence of antibodies in cord blood and breastmilk, which may offer protection against SARS-Cov-2 to infants through passive immunity. Additionally, there was clear evidence that the risk of severe outcomes from COVID-19 was significantly higher for pregnant women and their unborn babies.

A review of these data was undertaken by ATAGI and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), with publication of a joint statement, in June 2021, recommending that pregnant women be routinely offered Comirnarty at any stage of pregnancy.

Expansion of the program to young adolescents

On 23 July 2021, TGA's provisional registration of Comirnaty was extended to include all people from 12 years of age (from age ≥ 16 years previously).[53] ATAGI initially recommended that Comirnaty be offered to children aged 12–15 years who had underlying medical conditions that increased their risk of COVID-19, who were Aboriginal and Torres Strait Islander children, or who lived in remote communities.[54] From 27 August 2021, ATAGI recommended Comirnaty for all individuals from 12 years of age.[55] Efficacy data for Comirnaty in the phase 3 trial, with over 2,000 participants aged 12–15 years, was 100% (95% CI: 78–100%). There was a good safety profile, similar to that in young adults, reported in the trial and also from safety surveillance overseas in countries which had already implemented an adolescent program.[29]

Spikevax (Moderna) was provisionally registered for use on 9 August 2021, initially for individuals aged ≥ 18 years,[56] and extended to 12–17 year olds on 4 September 2021.[57] The delivery of COVID-19 vaccine to adolescents via a school program was considered but was assessed as unfeasible, at the time, due to several potential implementation challenges such as limited workforce capacity; interference with routine school vaccination program; missing those children not in school; and school closures in states

with ongoing outbreaks. Therefore, the delivery of vaccination to adolescents occurred using the same settings as for adults. Uptake of COVID-19 vaccine in adolescents was swift, with 35% in the 12 to 15 years age group receiving the first dose in the first two weeks of the program (to 30 September 2021).[58]

ATAGI has continued to monitor the safety of Comirnaty and Spikevax in adolescents, including review of data in Australia and other countries on the occurrence of myocarditis/pericarditis in this age group. The emerging local data and international data on these adverse events across all age groups were reviewed in ATAGI weekly meetings to determine whether any changes in recommendations were warranted. Ongoing monitoring of COVID-19 epidemiology and emerging data on vaccine effectiveness evaluations were also reviewed as standard agenda items in weekly ATAGI meetings.

Challenges to scaling up program delivery

The scale of the program, constraints on workforce capacity, and distribution and access logistics were key challenges to delivering mass COVID-19 vaccination. The program was initially envisaged to be delivered primarily through the existing primary care system, particularly general practice (GP) clinics and Aboriginal and Torres Strait Islander Community Controlled Health sector services, supplemented by on-site delivery in aged care facilities and more broadly dedicated mass vaccination clinics established by state and territory health departments.[59] Once vaccines were locally available, mass vaccination hubs established by states and territories, in combination with GPs, successfully helped to build the program quickly.[60] Vaccination locations were also expanded to pharmacies, particularly when Spikevax became available in September 2021.

As vaccine supply improved, outreach clinics were used increasingly to address access barriers. Following relevant advice from ATAGI, mobile vaccination hubs and drive-through vaccination clinics were established.[61] By this stage of the program, new information on more flexible storage and handling requirements for COVID-19 vaccines, particularly regarding thermostability, became available;[62] this enabled easier cold chain management, assisting in transportation of vaccines. The program scaled up considerably from approximately August 2021: by the end of September 2021, more than 300,000 vaccine doses were being administered daily.[63] Vaccine uptake nationally reached 92.4% for at least one dose and 87.0% for two doses among people aged ≥ 16 years as of 30 November 2021.[64] Among adolescents aged 12–15 years, the coverage estimates at this time were 76% for dose 1 and 66% for dose 2.

Future directions for the COVID-19 vaccination program

Some of the key areas for consideration in the coming months are upscaling the booster vaccine program (as progressively more people become eligible), use of heterologous vaccine schedules, co-administration with other vaccines, and vaccination of children younger than 12 years, as well as consideration of new COVID-19 vaccines.

Booster doses and three-dose primary courses

Since July 2021, several countries commenced booster vaccination for older and at-risk individuals prior to the northern hemisphere winter season.[65,66] Observational study data (predominantly for Comirnaty, Spikevax and Vaxzevria) suggests that vaccine protection against severe outcomes of COVID-19 (i.e. hospitalisations, ICU admissions and deaths) following two doses of COVID-19 vaccine is maintained for at least six months including against the Delta variant.[67–70] There is, however, evidence that some severely immunocompromised people have a decreased immune response to COVID-19 vaccination[71–73] that translates to lower vaccine effectiveness.[74–80] A third primary dose of

COVID-19 vaccine in severely immunocompromised individuals was recommended by ATAGI on 8 October 2021.[81]

Following TGA provisional registration of the booster dose of Comirnaty for individuals aged ≥ 18 years, ATAGI supported the use of a single booster dose for those who had completed their primary COVID-19 vaccine course at least six months earlier. The program commenced on 8 November 2021[82] and, while open to all adults, the groups prioritised for vaccination in the early stages of the program would become eligible first.[83]

Use of mixed schedules

The evidence on the effectiveness of schedules using heterologous primary or booster COVID-19 vaccine doses is still evolving. Early evidence shows increased immunogenicity in mixed schedules when a first dose of Vaxzevria is followed by Comirnaty,[84] although some data suggest higher reactogenicity.[85] Some overseas countries permit heterologous schedules for booster doses,[86] while some preference the use of an mRNA vaccine to complete a schedule where Vaxzevria was the first dose.[87] These data are informing advice on use of a mixed primary schedule, such as those who have had a serious adverse reaction to their first dose of vaccine or returning travellers who have had a first dose of vaccine not available in Australia, and considerations for the use of booster doses.[22]

Co-administration of COVID-19 vaccines with other vaccines

Due to the absence of information on the safety and efficacy of COVID-19 vaccines with other vaccines, ATAGI initially recommended maintaining a 14-day interval between receipt of vaccines,[88] which was later reduced to seven days. However, overseas countries routinely permitted co-administration in all age groups.[89,90] Evidence indicates that co-administering Comirnaty, Vaxzevria and Novavax COVID-19 vaccine with influenza vaccine is safe and immunogenic.[91,92] Additional trials of co-administration with influenza[93,94] and pneumococcal vaccines[95] were underway at the time of writing this review. In October 2021, ATAGI revised its advice to permissive recommendation of concomitant administration of COVID-19 vaccines with any other vaccine due at the same time.

Vaccination of children aged < 12 years

As of mid-November 2021, the use of Comirnaty in children aged 5 to 11 years was under review by the TGA and ATAGI. Its use in this age group commenced in late 2021 in USA[96] using a smaller dose of 10 μg of mRNA (compared with 30 μg for people aged ≥ 12 years). A phase 3 clinical trial of approximately 2,000 children aged 5–11 yrs reported vaccine efficacy to be 90.7% (95% CI: 67.7–98.3%).[97] While initial data appear to support a good safety profile of Comirnaty in this age group, careful assessment of risks and benefits of vaccination is needed given the relatively lower burden of acute COVID-19 disease among young children and absence of data on myocarditis risk following vaccination in this age group. Trials of Spikevax and Vaxzevria in children < 12 years of age were underway at the time of writing this review.[98,99]

Evaluation of the COVID-19 vaccination program

Independent monitoring and evaluation are critical elements of immunisation programs that guide program implementation and ensure accountability and transparency.[100] Of note, ATAGI has been provided with regular information on program implementation, coverage and uptake, specifically in special risk groups as available. Evaluation of program outcomes such as coverage, vaccine effectiveness and the impact on the burden of COVID-19, based on high quality data and study methods including data linkage, is key to determine whether program goals have been achieved and where gaps remain. Ongoing monitoring of vaccine confidence and community experiences with accessing vaccines and barriers to uptake will assist in further improving coverage, particularly in

populations where hesitancy and access inequity have been experienced and who are priority populations for vaccination. Serological surveys will provide long-term validation of coverage and ongoing population susceptibility. A performance audit by the Australian National Audit Office (ANAO), that was underway at the time of writing this review, would examine the planning and the implementation of the entire national COVID-19 vaccination program including the governance arrangements established to manage the rollout.[101]

Reflections

COVID-19 and delivery of mass COVID-19 vaccination presented an unprecedented challenge for health systems globally. In Australia despite these challenges, much has been achieved thus far as of November 2021 with over 90% COVID-19 vaccine two-dose coverage in the vaccine-eligible population ≥ 12 years within reach. Achieving high uptake of vaccines among adults has been an ongoing challenge. The experience of delivering COVID-19 vaccines has also provided insights into how to effectively target, reach and communicate with adults about vaccination. New legislation mandating reporting of most vaccines to the Australian Immunisation Register[102] will lead to improved ascertainment of coverage of adulthood vaccines. Pharmacovigilance and vaccine safety surveillance systems have been rigorously tested emphasising the need to communicate carefully on benefits and risks. Collaborations across medical disciplines and with networks and leadership groups representing priority populations have been strengthened. The engagement with external policy settings and contexts has ongoing implications for workforce, training, models of vaccine delivery and COVID-19 control in the regional setting. The overall low level of COVID-19 disease in 2020 and 2021 in Australia, also meant that a number of other countries had priority with regards to vaccines that were a scare resource in early 2021 while the global access via the COVAX initiative remained a work in progress.

On the other hand, the initial reliance of Australia's program on Vaxzevria as the main vaccine brand, and the unexpected safety issues associated with its use, limited the ability to rapidly scale up vaccine delivery, particularly in the first six months of the program. Some elements of the national rollout plan, including adherence to the initial prioritisation framework, were not well achieved, with low uptake among the Aboriginal and Torres Strait Islander population, the disability sector and aged-care facilities early in the program. Balancing ATAGI's key role in comprehensive review of emerging data, being transparent with the public about emerging safety signals, and maintaining confidence in vaccination proved to be a significant challenge. On reflection, alternative language and communication strategies, particularly with communities at highest risk, may have conveyed the information effectively but with less impact on vaccine confidence. The need for continual assessment and improvement of program performance and agility in responding to challenges was reflected in the renewed COVID-19 vaccination plan, Operation COVID Shield.[103] Documenting the lessons learned, and using the insights to drive changes in the governance and implementation of vaccine programs, can potentially improve the uptake of COVID-19 vaccines, other routine vaccines, and vaccines required in future pandemics.

Author details

Sanjay Jayasinghe[1,2]

Cyra Patel[1,3]

Lucy Armstrong[1]

Clayton Chiu[1,2]

Kristine Macartney[1,2,4]

Katie Flanagan[4,5,6,7]

Katherine Gibney[4,8,9]

Michelle Giles[4,10,11]

Nigel Crawford[4,12,13]

Allen C Cheng[4,14]

Christopher C Blyth[4,15,16]

1. National Centre for Immunisation Research and Surveillance, Children's Hospital at Westmead, Sydney, New South Wales, Australia

2. Discipline of Child and Adolescent Health, Faculty of Medicine and Health, University of Sydney, Sydney, New South Wales, Australia

3. National Centre for Epidemiology and Population Health, Australian National University, Canberra, Australian Capital Territory, Australia

4. Australian Technical Advisory Group on Immunisation, Department of Health and Aged Care, Australian Government, Canberra, Australian Capital Territory, Australia

5. Tasmanian Vaccine Trial Centre, Launceston General Hospital, Tasmania, Australia

6. School of Medicine, University of Tasmania, Tasmania, Australia

7. School of Health & Biomedical Science, Royal Melbourne Institute of Technology, Melbourne, Victoria, Australia

8. Victorian Infectious Diseases Service, The Royal Melbourne Hospital, Melbourne, Victoria, Australia

9. The Peter Doherty Institute for infection and Immunity, Melbourne, Victoria, Australia

10. Department of Obstetrics and Gynaecology, Monash University, Melbourne, Victoria, Australia

11. Department of Infectious Diseases, University of Melbourne, Melbourne, Victoria, Australia

12. Immunisation Services, Royal Children's Hospital, Melbourne, Victoria, Australia

13. Infection and Immunity, Murdoch Children's Research Institute and Department Paediatrics, University of Melbourne, Victoria, Australia

14. Monash Infectious Diseases, Monash Health and School of Clinical Sciences, Monash University, Melbourne, Victoria, Australia

15. Wesfarmers Centre of Vaccines and Infectious Diseases, Telethon Kids Institute and School of Medicine, University of Western Australia, Perth, Western Australia, Australia

16. Department of Infectious Diseases, Perth Children's Hospital and PathWest Laboratory Medicine, Perth, Western Australia, Australia

Corresponding author

Sanjay Jayasinghe

National Centre for Immunisation Research and Surveillance, Children's Hospital at Westmead, Sydney, New South Wales, Australia

Email: sanjay.jayasinghe@health.nsw.gov.au

References

1. International Labour Organisation (ILO), Foods and Agricultural Organisation (FAO), International Fund For Agricultural Development (IFAD), World Health Organization (WHO). Impact of COVID-19 on people's livelihoods, their health and our food systems. [Internet.] Geneva: WHO; 13 October 2020. [Accessed on 27 September 2021.] Available from: https://www.who.int/news/item/13-10-2020-impact-of-covid-19-on-people%27s-livelihoods-their-health-and-our-food-systems.

2. Emanuel EJ, Persad G, Kern A, Buchanan A, Fabre C, Halliday D et al. An ethical framework for global vaccine allocation. *Science*. 2020;369(6509):1309–12. doi: https://doi.org/10.1126/science.abe2803.

3. Australian Government Department of Health and Aged Care. Government response to the COVID-19 outbreak. [Internet.] Canberra: Australian Government Department of Health and Aged Care; 2021. [Accessed on 20 September 2021.] Available from: https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/government-response-to-the-covid-19-outbreak.

4. Vanderslott S, Dadonaite B, Roser M. Vaccintation: Vaccine Innovation. [Online resource.] Oxford: University of Oxford, Our World In Data; 2021. [Accessed on 27 October 2021.] Available from: https://ourworldindata.org/vaccination#vaccine-innovation.

5. Australian Technical Advisory Group on Immunisation (ATAGI). *Preliminary advice on general principles to guide the prioritisation of target populations in a COVID-19 vaccination program in Australia*. Canberra: Australian Government Department of Health and Aged Care, ATAGI; November 2020. Available from: https://www.health.gov.au/sites/default/files/documents/2020/11/atagi-preliminary-advice-on-general-principles-to-guide-the-prioritisation-of-target-populations-in-a-covid-19-vaccination-program-in-australia_0.pdf.

6. Australian Government Department of Health and Aged Care. The COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group. Meetings. [Webpage.] Canberra: Australian Government Department of Health and Aged Care; 2021. [Accessed on 29 November 2021.] Available from: https://www.health.gov.au/committees-and-groups/the-covid-19-vaccines-and-treatments-for-australia-science-and-industry-technical-advisory-group#meetings.

7. Australian Government Department of Health and Aged Care. *Australia's COVID-19 Vaccine and Treatment Strategy*. Canberra: Australian Government Department of Health and Aged Care; 18 August 2020. [Accessed on 29 November 2021.] Available from: https://www.health.gov.au/sites/default/files/documents/2020/08/australia-s-covid-19-vaccine-and-treatment-strategy.pdf.

8. Australian Government Department of Health and Aged Care. Aboriginal and Torres Strait Islander Advisory Group on COVID-19. [Internet.] Canberra: Australian Government Department of Health and Aged Care; 17 August 2021. [Accessed on 20 September 2021.] Available from: https://www.health.gov.au/committees-and-groups/aboriginal-and-torres-strait-islander-advisory-group-on-covid-19.

9. Australian Government Department of Health and Aged Care. Culturally and Linguistically Di-

verse Communities COVID-19 Health Advisory Group. [Internet.] Canberra: Australian Government Department of Health and Aged Care; 2021. [Accessed on 20 September 2021.] Available from: https://www.health.gov.au/committees-and-groups/culturally-and-linguistically-diverse-communities-covid-19-health-advisory-group.

10. Australian Government Department of Health and Aged Care. Advisory Committee for the COVID-19 Response for People with Disability. [Internet.] Canberra: Australian Government Department of Health and Aged Care; 2021. [Accessed on 20 September 2021.] Available from: https://www.health.gov.au/committees-and-groups/advisory-committee-for-the-covid-19-response-for-people-with-disability.

11. Australian Government Department of Health and Aged Care. Aged Care Advisory Group. [Internet.] Canberra: Australian Government Department of Health and Aged Care; 20 September 2021. [Accessed on 20 September 2021.] Available from: https://www.health.gov.au/committees-and-groups/aged-care-advisory-group.

12. Australian Government Department of Health and Aged Care. Australian Technical Advisory Group on Immunisation (ATAGI) COVID-19 Working Group. [Internet.] Canberra: Australian Government Department of Health and Aged Care; 2021. [Accessed on 20 September 2021.] Available from: https://www.health.gov.au/committees-and-groups/australian-technical-advisory-group-on-immunisation-atagi-covid-19-working-group.

13. WHO. *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*. Geneva: WHO; 13 September 2020. Available from: https://www.who.int/publications/i/item/who-sage-values-framework-for-the-allocation-and-prioritization-of-covid-19-vaccination.

14. National Academies of Sciences Engineering and Medicine. *Framework for Equitable Allocation of COVID-19 Vaccine*. Washington, DC: The National Academies Press; 2020. [Accessed on 20 September 2021.] Available from: https://www.nap.edu/read/25917/chapter/1.

15. New South Wales State Government. *Report. Special Commission of Inquiry into the Ruby Princess*. Sydney: New South Wales State Government; 14 August 2020. [Accessed on 20 September 2021.] Available from: https://apo.org.au/sites/default/files/resource-files/2020-08/apo-nid307566.pdf.

16. Gidding HF, Machalek DA, Hendry AJ, Quinn HE, Vette K, Beard FH et al. Seroprevalence of SARS-CoV-2-specific antibodies in Sydney after the first epidemic wave of 2020. *Med J Aust*. 2021;214(4):179–85. doi: https://doi.org/10.5694/mja2.50940.

17. Coatsworth N, Myles PS, Mann GJ, Cockburn IA, Forbes AB, Gardiner EE et al. Prevalence of asymptomatic SARS-CoV-2 infection in elective surgical patients in Australia: a prospective surveillance study. *ANZ J Surg*. 2021;91(1–2):27–32. doi: https://doi.org/10.1111/ans.16564.

18. Hicks SM, Pohl K, Neeman T, McNamara HA, Parsons KM, He JS et al. A dual-antigen enzyme-linked immunosorbent assay allows the assessment of severe acute respiratory syndrome coronavirus 2 antibody seroprevalence in a low-transmission setting. *J Infect Dis*. 2021;223(1):10–4. doi: https://doi.org/10.1093/infdis/jiaa623.

19. Viray P, Low Z, Sinnappu R, Harvey PA, Brown S. Residential aged care facility COVID-19

outbreaks and magnitude of spread among residents: observations from a Victorian residential in-reach service. *Intern Med J*. 2021;51(1):99–101. doi: https://doi.org/10.1111/imj.15143.

20. Victoria State Government Department of Health and Human Services (DHHS). Coronavirus update for Victoria - 31 October 2020. [Internet.] Melbourne: Victoria State Government, DHHS; 31 October 2020. Available from: https://www.dhhs.vic.gov.au/coronavirus-update-victoria-31-october-2020.

21. Quigley AL, Stone H, Nguyen PY, Chughtai AA, MacIntyre CR. Estimating the burden of COVID-19 on the Australian healthcare workers and health system during the first six months of the pandemic. *Intern J Nurs Stud*. 2021;114:103811. doi: https://doi.org/10.1016/j.ijnurstu.2020.103811.

22. Australian Government Department of Health and Aged Care. COVID-19 vaccination – ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021. [Online resource.] Canberra: Australian Government Department of Health and Aged Care; 2021. [Accessed on 20 September 2021.] Available from: https://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021.

23. Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. *N Engl J Med*. 2020;383(27):2603–15. doi: https://doi.org/10.1056/NEJMoa2034577.

24. Voysey M, Clemens SAC, Madhi SA, Weckx LY, Folegatti PM, Aley PK et al. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. *Lancet*. 2021;397(10269):99–111. doi: https://doi.org/10.1016/S0140-6736(20)32661-1.

25. Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R et al. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. *N Engl J Med*. 2020;384(5):403–16. doi: https://doi.org/10.1056/NEJMoa2035389.

26. ModernaTX Inc, Biomedical Advanced Research and Development Authority, National Institute of Allergy and Infectious Diseases. A study to evaluate efficacy, safety, and immunogenicity of mRNA- 1273 vaccine in adults aged 18 years and older to prevent COVID-19. ClinicalTrials.gov identifier: NCT04470427. [Webpage.] Bethesda: United States National Library of Medicine; 31 July 2020. [Accessed on 12 August 2021.] Available from: https://clinicaltrials.gov/ct2/show/NCT04470427.

27. Ramasamy MN, Minassian AM, Ewer KJ, Flaxman AL, Folegatti PM, Owens DR et al. Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomised, controlled, phase 2/3 trial. *Lancet*. 2020;396(10267):1979–93. doi: https://doi.org/10.1016/S0140-6736(20)32466-1.

28. European Medicines Agency (EMA). *COVID-19 Vaccine AstraZeneca: Product Information as approved by the CHMP on 29 January 2021, pending endorsement by the European Commission*. Amsterdam: EMA; 29 January 2021. [Accessed on 26 April 2021.] Available from: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-astrazeneca-product-information-approved-chmp-29-january-2021-pending-endorsement_en.pdf.

29. Frenck RW, Klein NP, Kitchin N, Gurtman A, Absalon J, Lockhart S et al. Safety, immunogenicity, and efficacy of the BNT162b2 Covid-19 vaccine in adolescents. *N Engl J Med*. 2021;385(3):239–50. doi: https://doi.org/10.1056/NEJMoa2107456.

30. Ali K, Berman G, Zhou H, Deng W, Faughnan V, Coronado-Voges M et al. Evaluation of mRNA-1273 SARS-CoV-2 vaccine in adolescents. *N Eng J Med*. 2021;385(24):2241–51. doi: https://doi.org/10.1056/NEJMoa2109522.

31. ATAGI. COVID-19 vaccination – Provider resources: Guidance to help people make informed decisions. [Webpage.] Canberra: Australian Government Department of Health and Aged Care, ATAGI; 2021. [Accessed on 1 Octover 2021.] Available from: https://www.health.gov.au/resources/collections/covid-19-vaccination-provider-resources#guidance-to-help-people-make-informed-decisions.

32. EMA. COVID-19 Vaccine AstraZeneca: PRAC investigating cases of thromboembolic events - vaccine's benefits currently still outweigh risks - Update. [Internet.] Amsterdam: EMA; 11 March 2021. [Accessed on 13 October 2021.] Available from: https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-prac-investigating-cases-thromboembolic-events-vaccines-benefits.

33. EMA. COVID-19 Vaccine AstraZeneca: PRAC preliminary view suggests no specific issue with batch used in Austria. [Internet.] Amsterdam: EMA; 10 March 2021. [Accessed on 13 October 2021.] Available from: https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-prac-preliminary-view-suggests-no-specific-issue-batch-used-austria.

34. ATAGI. ATAGI statement and clinical guidance on AstraZeneca COVID-19 vaccine following European Medicines Agency (EMA) safety review. [Internet.] Canberra: Australian Government Department of Health and Aged Care, ATAGI; 19 March 2021. Available from: https://www.health.gov.au/news/atagi-statement-and-clinical-guidance-on-astrazeneca-covid-19-vaccine-following-european-medicines-agency-ema-safety-review.

35. EMA. COVID-19 Vaccine AstraZeneca: benefits still outweigh the risks despite possible link to rare blood clots with low blood platelets. [Internet.] Amsterdam: EMA; 18 March 2021. [Accessed on 28 September 2021.] Available from: https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-benefits-still-outweigh-risks-despite-possible-link-rare-blood-clots.

36. ATAGI. ATAGI statement for health care providers on suitability of COVID-19 vaccination in people with history of clotting conditions. [Internet.] Canberra: Australian Government Department of Health and Aged Care, ATAGI; 25 March 2021. [Accessed on 27 September 2021.] Available from: https://www.health.gov.au/news/atagi-statement-for-health-care-providers-on-suitability-of-covid-19-vaccination-in-people-with-history-of-clotting-conditions.

37. Therapeutic Goods Administration (TGA). Specific clotting condition reported after COVID-19 vaccination. [Internet.] Canberra: Australian Government Department of Health and Aged Care, TGA; 2 April 2021. [Accessed on 13 October 2021.] Available from: https://www.tga.gov.au/media-release/specific-clotting-condition-reported-after-covid-19-vaccination.

38. ATAGI. ATAGI statement on AstraZeneca vaccine in response to new vaccine safety concerns. [Internet.] Canberra: Australian Government Department of Health and Aged Care, ATAGI; 8 April 2021. [Accessed on 25 September 2021.] Available from: https://www.health.gov.au/news/

atagi-statement-on-astrazeneca-vaccine-in-response-to-new-vaccine-safety-concerns.

39. Winton Centre for Risk and Evidence Communication (Winton Centre). *Communicating the potential benefits and harms of the Astra-Zeneca COVID-19 vaccine*. Cambridge: University of Cambridge, Winton Centre; 2021. [Accessed on 13 October 2021.] Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/976877/CovidStats_07-04-21-final.pdf.

40. Australian Government Department of Health and Aged Care. *Weighing up the potential benefits against risk of harm from COVID-19 Vaccine AstraZeneca: Information for health care providers to help consumers make informed decisions*. Canberra: Australian Government Department of Health and Aged Care; 29 June 2021. [Accessed on 25 September 2021.] Available from: https://www.health.gov.au/sites/default/files/documents/2021/06/covid-19-vaccination-weighing-up-the-potential-benefits-against-risk-of-harm-from-covid-19-vaccine-astrazeneca_2.pdf.

41. ATAGI, Thrombosis and Haemostasis Society of Australia and New Zealand (THANZ). A joint statement from ATAGI and THANZ on Thrombosis with Thrombocytopenia Syndrome (TTS) and the use of COVID-19 Vaccine AstraZeneca.[Internet.] Canberra: Australian Government Department of Health and Aged Care, ATAGI, THANZ; 23 May 2021. [Accessed on 13 October 2021.] Available from: https://www.health.gov.au/news/joint-statement-from-atagi-and-thanz-on-thrombosis-with-thrombocytopenia-syndrome-tts-and-the-use-of-covid-19-vaccine-astrazeneca.

42. ATAGI. ATAGI statement on revised recommendations on the use of COVID-19 Vaccine AstraZeneca, 17 June 2021. [Internet.] Canberra: Australian Government Department of Health and Aged Care, ATAGI; 17 June 2021. [Accessed on 26 September 2021.] Available from: https://www.health.gov.au/news/atagi-statement-on-revised-recommendations-on-the-use-of-covid-19-vaccine-astrazeneca-17-june-2021.

43. Joint Committee on Vaccination and Immunisation (JCVI). JCVI statement on use of the AstraZeneca COVID-19 vaccine: 7 April 2021. [Internet.] London: Unted Kingdom Government, Department of Health and Social Care; 7 April 2021. [Accessed on 18 November 2021.] Available from: https://www.gov.uk/government/publications/use-of-the-astrazeneca-covid-19-vaccine-jcvi-statement/jcvi-statement-on-use-of-the-astrazeneca-covid-19-vaccine-7-april-2021.

44. National Advisory Committee on Immunization (NACI). Archived 8: NACI rapid response: Recommended use of AstraZeneca COVID-19 vaccine in younger adults [2021-03-29]. [Internet.] Ottawa: Government of Canada, Health Canada, NACI; 29 March 2021. [Accessed on 18 November 2021.] Available from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-recommended-use-astrazeneca-covid-19-vaccine-younger-adults.html.

45. European Centre for Disease Prevention and Control (ECDC). *Overview of EU/EEA country recommendations on COVID-19 vaccination with Vaxzevria, and a scoping review of evidence to guide decision-making. 18 May 2021*. Solna: ECDC; 18 May 2021. [Accessed on 18 November 2021.] Available from: https://www.ecdc.europa.eu/sites/default/files/documents/Overview%20EU%20EEA%20country%20recommendations%20on%20COVID-19%20vaccination%20Vaxzevria%20and%20scoping%20review%20of%20evidence.pdf.

46. Australian Government Department of Health and Aged Care. Sentiment Towards COVID-19

Vaccine Research. Canberra: Australian Government Department of Health and Aged Care; April 2021. [Accessed on 15 November 2021.] Available from: https://www.health.gov.au/sites/default/files/documents/2021/08/foi-request-2398-release-documents-covid-19-vaccine-market-research-sentiment-towards-covid-19-vaccine-research-april-2021-part-1.pdf.

47. Essential Report. Essential Report: Preference towards COVID-19 vaccines (summary of results published 3 August 2021). Melbourne: Esential Media Communications; 3 August 2021. [Accessed on 13 October 2021.] Available from: https://essentialvision.com.au/preference-towards-covid-19-vaccines-4.

48. ATAGI. ATAGI statement on use of COVID-19 vaccines in an outbreak setting. [Internet.] Canberra: Australian Government Department of Health and Aged Care, ATAGI; 13 July 2021. [Accessed on 13 October 2021.] Available from: https://www.health.gov.au/news/atagi-statement-on-use-of-covid-19-vaccines-in-an-outbreak-setting.

49. ATAGI. ATAGI Statement, Response to NSW COVID-19 outbreak 24th July 2021. [Internet.] Canberra: Australian Government Department of Health and Aged Care, ATAGI; 24 July 2021. [Accessed on 13 October 2021.] Available from: https://www.health.gov.au/news/atagi-statement-response-to-nsw-covid-19-outbreak-24th-july-2021.

50. Stowe J, Andrews N, Gower C, Gallagher E, Utsi L, Simmons R et al. *Effectiveness of COVID-19 vaccines against hospital admission with the Delta (B.1.617.2) variant*. [Preprint.] The Global Health Network; 2021. Available from: https://media.tghn.org/articles/Effectiveness_of_COVID-19_vaccines_against_hospital_admission_with_the_Delta_B._G6gnnqJ.pdf.

51. Gargano JW, Wallace M, Hadler SC, Langley G, Su JR, Oster ME et al. Use of mRNA COVID-19 vaccine after reports of myocarditis among vaccine recipients: update from the Advisory Committee on Immunization Practices - United States, June 2021. *MMWR Morb Mortal Wkly Rep*. 2021;70(27):977–82. doi: https://doi.org/10.15585/mmwr.mm7027e2.

52. ATAGI, Cardiac Society of Australia and New Zealand (CSANZ). *COVID-19 vaccination – Guidance on Myocarditis and Pericarditis after mRNA COVID-19 vaccines*. Canberra: Australian Government Department of Health and Aged Care, ATAGI, CSANZ; 30 July 2021. [Accessed on 27 September 2021.] Available from: https://www.health.gov.au/resources/publications/covid-19-vaccination-guidance-on-myocarditis-and-pericarditis-after-mrna-covid-19-vaccines.

53. TGA. TGA Provisional Approval of Pfizer-BioNTech COVID-19 vaccine to include 12–15 years age group. [Internet.] Canberra: Australian Government Department of Health and Aged Care, TGA; 23 July 2021. [Accessed on 13 October 2021.] Available from: https://www.tga.gov.au/tga-provisional-approval-pfizer-biontech-covid-19-vaccine-include-12-15-years-age-group.

54. ATAGI. ATAGI statement regarding vaccination of adolescents aged 12–15 years. [Internet.] Canberra: Australian Government Department of Health and Aged Care, ATAGI; 2 August 2021. [Accessed on 25 September 2021.] Available from: https://www.health.gov.au/news/atagi-statement-regarding-vaccination-of-adolescents-aged-12-15-years.

55. ATAGI. ATAGI recommendations on the use of COVID-19 vaccines in all young adolescents in Australia. Canberra: Australian Government Department of Health and Aged Care, ATAGI; 27 August 2021. [Accessed on 27 September 2021.] Available from: https://www.health.gov.au/news/

atagi-recommendations-on-the-use-of-covid-19-vaccines-in-all-young-adolescents-in-australia.

56. TGA. TGA provisionally approves Moderna's COVID-19 vaccine. [Internet.] Canberra: Australian Government Department of Health and Aged Care, TGA; 9 August 2021. [Accessed on 13 October 2021.] Available from: https://www.tga.gov.au/media-release/tga-provisionally-approves-modernas-covid-19-vaccine.

57. TGA. TGA Provisional Approval of Moderna COVID-19 vaccine to include 12-17 years age group. [Internet.] Canberra: Australian Government Department of Health and Aged Care, TGA; 4 September 2021. [Accessed on 13 October 2021.] Available from: https://www.tga.gov.au/media-release/tga-provisional-approval-moderna-covid-19-vaccine-include-12-17-years-age-group.

58. Australian Government Department of Health and Aged Care. *COVID-19 vaccine rollout update – 30 September 2021*. Canberra: Australian Government Department of Health and Aged Care; 30 September 2021. Available from: https://www.health.gov.au/resources/publications/covid-19-vaccine-rollout-update-30-september-2021.

59. Australian Government Department of Health and Aged Care. *COVID-19 vaccination – Australian COVID-19 Vaccination Policy*. Canberra: Australian Government Department of Health and Aged Care; 13 November 2020. Available from: https://www.health.gov.au/resources/publications/covid-19-vaccination-australian-covid-19-vaccination-policy.

60. Australian Government Department of Health and Aged Care. *COVID-19 vaccine rollout update – 31 July 2021*. Canberra: Australian Government Department of Health and Aged Care; 31 July 2021. Available from: https://www.health.gov.au/resources/publications/covid-19-vaccine-rollout-update-31-july-2021.

61. ATAGI. ATAGI statement on considerations for establishing drive-through COVID-19 vaccination clinic sites. [Internet.] Canberra: Australian Government Depatment of Health and Aged Care, ATAGI; 9 August 2021. [Accessed on 28 September 2021.] Available from: https://www.health.gov.au/news/atagi-statement-on-considerations-for-establishing-drive-through-covid-19-vaccination-clinic-sites.

62. Therapeutic Goods Administration (TGA). TGA approves more flexible storage conditions for Pfizer-BioNTech COVID-19 vaccine. [Internet.] Canberra: Australian Government Department of Health and Aged Care, TGA; 24 May 2021. [Accessed on 28 September 2021.] Available from: https://www.tga.gov.au/behind-news/tga-approves-more-flexible-storage-conditions-pfizer-biontech-covid-19-vaccine.

63. Australian Government Department of Health and Aged Care. COVID-19 vaccination daily rollout update. [Website.] Canberra: Australian Government Department of Health and Aged Care; 2021. [Accessed on 28 September 2021.] Available from: https://www.health.gov.au/resources/collections/covid-19-vaccination-daily-rollout-update.

64. Australian Government Department of Health and Aged Care. *COVID-19 vaccine rollout update – 30 November 2021*. Canberra: Australian Government Department of Health and Aged Care; 30 November 2021. [Accessed on 5 December 2021.] Available from: https://www.health.gov.au/sites/default/files/documents/2021/11/covid-19-vaccine-rollout-update-30-november-2021.pdf.

65. Centers for Disease Control (CDC). CDC Statement on ACIP Booster Recommendations. [Internet.] Atlanta: United States Department of Health and Human Services, CDC; 24 September 2021. Available from: https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations-.html.

66. JCVI. Independent report: Joint Committee on Vaccination and Immunisation (JCVI) advice on third primary dose vaccination. [Internet.] London: Unted Kingdom Government, Department of Health and Social Care; 1 September 2021. [Accessed on 28 September 2021.] Available from: https://www.gov.uk/government/publications/third-primary-covid-19-vaccine-dose-for-people-who-are-immunosuppressed-jcvi-advice/joint-committee-on-vaccination-and-immunisation-jcvi-advice-on-third-primary-dose-vaccination.

67. Andrews N, Tessier E, Stowe J, Gower G, Kirsebom F, Simmons R et al. Duration of protection against mild and severe disease by COVID-19 vaccines. *N Engl J Med*. 2022;386(4):340–50. doi: https://doi.org/10.1056/NEJMoa2115481.

68. de Gier B, Kooijman M, Kemmeren J, de Keizer N, Dongelmans D, van Iersel SCJL et al. COVID-19 vaccine effectiveness against hospitalizations and ICU admissions in the Netherlands, April–August 2021. *medRxiv*. 2021. doi: https://doi.org/10.1101/2021.09.15.21263613.

69. Tartof SY, Slezak JM, Fischer H, Hong V, Ackerson BK, Ranasinghe ON et al. Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study. *Lancet*. 2021;398(10309):1407–16. doi: https://doi.org/10.1016/S0140-6736(21)02183-8.

70. Self WH, Tenforde MW, Rhoads JP, Gaglani M, Ginde AA, Douin DJ et al. Comparative effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) vaccines in preventing COVID-19 hospitalizations among adults without immunocompromising conditions — United States, March–August 2021. *MMWR Morb Mortal Wkly Rep*. 2021;70(38):1337–43. doi: https://doi.org/10.15585/mmwr.mm7038e1.

71. Hadjadj J, Planas D, Ouedrani A, Buffier S, Delage L, Nguyen Y et al. Immunogenicity of BNT162b2 vaccine against the Alpha and Delta variants in immunocompromised patients with systemic inflammatory diseases. *Ann Rheum Dis*. 2022. doi: https://doi.org/10.1136/annrheumdis-2021-221508.

72. Haidar G, Agha M, Bilderback A, Lukanski A, Linstrum K, Troyan R et al. Prospective evaluation of coronavirus disease 2019 (COVID-19) vaccine responses across a broad spectrum of immunocompromising conditions: the COVID-19 Vaccination in the Immunocompromised Study (COVicS). *Clin Infect Dis*. 2022;75(1):e630–44. doi: https://doi.org/10.1093/cid/ciac103.

73. Kearns P, Siebert S, Willicombe M, Gaskell C, Kirkham A, Pirrie S et al. Examining the immunological effects of COVID-19 vaccination in patients with conditions potentially leading to diminished immune response capacity – the OCTAVE trial. [Internet.] Amsterdam: Elsevier, SSRN; 23 August 2021. Available from: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3910058.

74. Caillard S, Chavarot N, Bertrand D, Kamar N, Taunat O, Moal V et al. Occurrence of severe COVID-19 in vaccinated transplant patients. *Kidney Int*. 2021;100(2):477–9. doi: https://doi.org/10.1016/j.kint.2021.05.011.

75. Wadei HM, Gonwa TA, Leoni JC, Shah SZ, Aslam N, Speicher LL. COVID-19 infection in solid organ transplant recipients after SARS-CoV-2 vaccination. *Am J Transplant*. 2021;21(10):3496–9. doi: https://doi.org/10.1111/ajt.16618.

76. Whitaker H.J, Tsang RSM, Byford R, Andrews NJ, Sherlock J, Pillai PS et al. Pfizer-BioNTech and Oxford AstraZeneca COVID-19 vaccine effectiveness and immune response among individuals in clinical risk groups. *J Infect*. 2022. doi: https://doi.org/10.1016/j.jinf.2021.12.044.

77. Young-Xu Y, Korves C, Roberts J, Powell EI, Zwain GM, Smith J et al. Coverage and estimated effectiveness of mRNA SARS-CoV-2 vaccines among US veterans. *JAMA Netw Open*. 2021;4(10):e2128391. doi: https://doi.org/10.1001/jamanetworkopen.2021.28391.

78. Khan N, Mahmud N. Effectiveness of SARS-CoV-2 vaccination in a Veterans Affairs cohort of patients with inflammatory bowel disease with diverse exposure to immunosuppressive medications. *Gastroenterology*. 2021;161(3):827–36. doi: https://doi.org/10.1053/j.gastro.2021.05.044.

79. Chemaitelly H, AlMukdad S, Joy JP, Ayoub HH, Yassine HM, Benslimane FM et al. SARS-CoV-2 vaccine effectiveness in immunosuppressed kidney transplant recipients. *medRxiv*. 2021. doi: https://doi.org/10.1101/2021.08.07.21261578.

80. Aslam S, Adler E, Mekeel K, Little SJ. Clinical effectiveness of COVID-19 vaccination in solid organ transplant recipients. *Transpl Infect Dis*. 2021;23(5):e13705. doi: https://doi.org/10.1111/tid.13705.

81. ATAGI. *Recommendations on the use of a 3rd primary dose of COVID-19 vaccine in individuals who are severely immunocompromised. Version 1.0 7 October 2021*. Canberra: Australian Government Department of Health and Aged Care, ATAGI; 7 October 2021. [Accessed on 27 October 2021.] Available from: https://www.health.gov.au/sites/default/files/documents/2021/10/atagi-recommendations-on-the-use-of-a-third-primary-dose-of-covid-19-vaccine-in-individuals-who-are-severely-immunocompromised_1.pdf.

82. Australian Government Department of Health and Aged Care, Minister for Health and Aged Care. Start of COVID-19 booster vaccination program. [Internet.] Canberra: Australian Government Department of Health and Aged Care; 8 November 2021. [Accessed on 18 November 2021.] Available from: https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/start-of-covid-19-booster-vaccination-program.

83. ATAGI. *Australian Technical Advisory Group on Immunisation (ATAGI) recommendations on the use of a booster dose of COVID-19 vaccine*. Canberra: Australian Government Department of Health and Aged Care, ATAGI; 27 October 2021. [Accessed on 18 November 2021.] Available from: https://www.health.gov.au/sites/default/files/documents/2021/10/atagi-recommendations-on-the-use-of-a-booster-dose-of-covid-19-vaccine.pdf.

84. Callaway E. Mix-and-match COVID vaccines trigger potent immune response. *Nature*. 2021;593(7860):491. doi: https://doi.org/10.1038/d41586-021-01359-3.

85. Shaw RH, Stuart A, Greenland M, Liu X, Nguyen Van-Tam JS, Snape MD et al. Heterologous prime-boost COVID-19 vaccination: initial reactogenicity data. The *Lancet*. 2021;397(10289):2043–6. doi: https://doi.org/10.1016/S0140-6736(21)01115-6.

86. CDC. Interim clinical considerations for use of COVID-19 vaccines currently approved or authorized in the United States: interchangeability of COVID-19 vaccine products. [Internet.] Atlanta: United States Department of Health and Human Services, CDC: 2021. [Accessed on 27 October 2021.] Available from: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Interchangeability.

87. NACI. Archive 22: Recommendations on the use of COVID-19 vaccines [2021-10-22]. [Internet.] Ottawa: Government of Canada, Health Canada, NACI; 22 October 2021. [Accessed on 27 October 2021.] Available from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html.

88. ATAGI. *Statement on the administration of seasonal influenza vaccines in 2021 – updated June 2021*. Canberra: Australian Government Department of Health and Aged Care, ATAGI; June 2021. [Accessed on 27 October 2021.] Available from: https://www.health.gov.au/sites/default/files/documents/2021/06/atagi-advice-on-seasonal-influenza-vaccines-in-2021.pdf.

89. CDC. Interim clinical considerations for use of COVID-19 vaccines currently approved or authorized in the United States : coadministration of COVID-19 vaccines with other vaccines. [Internet.] Atlanta: United States Department of Health and Human Services, CDC: 2021. [Accessed on 27 October 2021.] Available from: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Coadministration.

90. Public Health England. *COVID-19 – SARS-CoV-2*. London: United Kingdom Government; 2021. [Accessed on 27 October 2021.] Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1018444/Greenbook_chapter_14a_16Sept21.pdf.

91. Toback S, Galiza E, Cosgrove C, Galloway J, Goodman AL, Swift PA et al. Safety, immunogenicity, and efficacy of a COVID-19 vaccine (NVX-CoV2373) co-administered with seasonal influenza vaccines: an exploratory substudy of a randomised, observer-blinded, placebo-controlled, phase 3 trial. *Lancet Respir Med*. 2022;10(2)167–79. doi: https://doi.org/10.1016/S2213-2600(21)00409-4.

92. Lazarus R, Baos S, Cappel-Porter H, Carson-Stevens A, Clout M, Culliford L et al. Safety and immunogenicity of concomitant administration of COVID-19 vaccines (ChAdOx1 or BNT162b2) with seasonal influenza vaccines in adults in the UK (ComFluCOV): a multicentre, randomised, controlled, phase 4 trial. *Lancet*. 2021;398(10318):2277–87. doi: https://doi.org/10.1016/S0140-6736(21)02329-1.

93. Janssen Vaccines & Prevention BV. A study of Ad26.COV2.S and influenza vaccines in healthy adults. ClinicalTrials.gov identifier: NCT05091307. [Webpage.] Bethesda: United States National Library of Medicine; 25 October 2021. [Accessed on 27 October 2021.] Available from: https://clinicaltrials.gov/ct2/show/NCT05091307.

94. Sanofi Pasteur. Study of a quadrivalent high-dose influenza vaccine and a Moderna COVID-19 vaccine administered either concomitantly or singly in participants 65 years of age and older previously vaccinated with a 2-dose schedule of Moderna COVID-19 vaccine. ClinicalTrials.gov identifier: NCT04969276. [Webpage.] Bethesda: United States National Library of Medicine; 20

July 2021. [Accessed on 27 October 2021.] Available from: https://clinicaltrials.gov/ct2/show/NCT04969276.

95. Pfizer. Safety and immunogenicity study of 20vPnC when coadministered with a booster dose of BNT162b2. ClinicalTrials.gov identifier: NCT04887948. [Webpage.] Bethesda: United States National Library of Medicine; 14 May 2021. [Accessed on 27 October 2021.] Available from: https://clinicaltrials.gov/ct2/show/ NCT04887948.

96. United States Food and Drug Administration (FDA). FDA News Release: FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age. [Internet.] Silver Spring: United States Department of Health and Human Services, FDA; 29 October 2021. [Accessed on 18 November 2021.] Available from: https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age.

97. Walter EB, Talaat KR, Sabharwal C, Gurtman A, Lockhart S, Paulsen GC et al. Evaluation of the BNT162b2 Covid-19 vaccine in children 5 to 11 years of age. *N Engl J Med*. 2022;386(1)35–46. doi: https://doi.org/10.1056/NEJMoa2116298.

98. ModernaTX Inc. A study to evaluate safety and effectiveness of mRNA-1273 COVID-19 vaccine in healthy children between 6 months of age and less than 12 years of age. ClinicalTrials.gov identifier: NCT04796896. [Webpage.] Bethesda: United States National Library of Medicine; 15 March 2021. [Accessed on 1 October 2021.] Available from: https://clinicaltrials.gov/ct2/show/NCT04796896.

99. University of Oxford. Oxford COVID-19 vaccine study in children - FAQs. [Internet.] Oxford: University of Oxford; 2021. [Accessed on 1 October 2021.] Available from: https://covid19vaccinetrial.co.uk/faqs-childrens-trial.

100. Cherian T, Hwang A, Mantel C, Veira C, Malvolti S, MacDonald N et al. Global Vaccine Action Plan lessons learned III: monitoring and evaluation/accountability framework. *Vaccine*. 2020;38(33):5379–83. doi: https://doi.org/10.1016/j.vaccine.2020.05.028.

101. Australian National Audit Office (ANAO). Australia's COVID-19 Vaccine Rollout. [Webpage.] Canberra: ANAO; 2022. [Accessed on 25 January 2022.] Available from: https://www.anao.gov.au/work/performance-audit/australia-covid-19-vaccine-rollout.

102. Parliament of Australia: House of Representatives. BILLS – Australia Immunisation Register Amendment (Reporting) Bill 2020 – Second Reading. [Hansard transcript.] Canberra: Parliament of Australia; 3 December 2020. Available from: https://www.aph.gov.au/Parliamentary_Business/Hansard/Hansard_Display?bid=chamber/hansardr/11b18738-de56-4d82-82f6-2c10fddd6b2b/&sid=0019.

103. Australian Government Operation COVID Shield. *Op COVID Shield: National COVID Vaccine Campaign Plan. 3 August 2021*. Canberra: Australian Government; 3 August 2021. [Accessed on 18 November 2021.] Available from: https://www.health.gov.au/sites/default/files/documents/2021/08/op-covid-shield-national-covid-vaccine-campaign-plan.pdf.