COVID-19 Vaccination Screening Questions

Decision Support Guide - June 2021

The Pfizer and AstraZeneca Vaccine protocols contain further detailed information about specific risk factors, contraindications, vulnerable population groups including references to source material. This is developed as a supporting reference guide only. Vaccine protocols and other useful clinicians resources can be found on the COVID-19 vaccination information for healthcare workers webpage. The Australian Technical Advisory Group on Immunisation (ATAGI) provides clinical guidance and advice for COVID-19 vaccines approved in Australia. The expert technical group has provided clinical advice on a number of issues and are available here.

Question	Rationale		Actions recommended
Are you younger than 60 years of age?	There is a link b AstraZeneca vac new adverse ev thrombosis with thrombocytope (TTS). Although can cause disab death, with a fa about 19% of th	ccine and a rare ent called n nia syndrome very rare, TTS ility and even tal outcome in the cases	If for Pfizer vaccination, Vaccination is recommended to proceed. If for AstraZeneca vaccination, 1) Change to Pfizer Vaccination if available. 2) If Pfizer is contraindicated
	But for those ur age, the rate is estimated to be No biological or factors have be	e rate of TTS is about 1-2 per ated with ne AstraZeneca. nder 60 years of currently higher. other risk en identified	or not available, discuss risks and benefits for the individual as per below. If consumer wishes to proceed, then PROCEED with informed consent. Staff must respect a persons choice to decline vaccination.
	to AstraZeneca distributed as p	Centre for Risk ommunication erious harm due vaccines is	Risk benefit discussion, - At the current time, use of Comirnaty COVID-19 vaccine (Pfizer) is preferred over AstraZeneca COVID-19 vaccine in adults aged < 60 years who have not already received a first
	Age	Potential serious harm per 100,000	dose of AstraZeneca vaccine. - This is based both on the increased risk of complications
	20-29	1.1	from COVID-19 with increasing age (and thus increased benefit
	30-39	0.8	of vaccination), and the



Question	Rationale		Actions recommended
	40-49	0.5	potentially lower, but not zero,
	50-59	0.4	risk of TTS with increasing age People who have had their first
	60-69	0.2	dose of COVID-19 Vaccine
	This resource al above risk relations benefits of vaccing COVID-1 risks scenarios.	ive to potential ination in	AstraZeneca without any serious adverse effects can be given their second dose. This includes adults under 60 years of age. - If an individual cannot access the Pfizer vaccine for any reason, consideration should be given to their risk factors that might increase their exposure to COVID-19 in their workplace, environment or at home. - As one example, healthcare workers aged under 60 working in a COVID-19 ward with COVID-19 positive patients may benefit from vaccination to reduce their risk of severe disease should they contract COVID-19 in the course of their work.
Are you 60 years old or an older age?	in Australia, ATA that the benefit is favorable for	h from COVID- older age arly rising from In the context risk of COVID-19 AGI considers -to-risk balance use of ccine in all older s.	AstraZeneca is the preferred vaccine for patients greater than 60 years old. Due to constrained Pfizer vaccine supply, stock is being prioritised for the population most at risk of an TTS. Vaccination against COVID-19, with whichever vaccine is available, continues to be important in populations at high risk of COVID.

Question Rationale Actions recommended Do you have a past history of In most cases of TTS, these People who have had blood clots blood clots occurred in veins in cerebral venous sinus associated with low platelet levels thrombosis (CVST), heparin the brain (cerebral venous (TTS) after their first dose of COVIDinduced thrombocytopenia sinus thrombosis, CVST) and 19 Vaccine AstraZeneca should not (HIT), idiopathic splanchnic the abdomen (splanchnic vein be given their second dose. (mesenteric, portal, splenic) thrombosis) and in arteries, vein thrombosis or together with low levels of antiphospholipid syndrome blood platelets and sometimes See below links for further guidance with thrombosis? bleeding. Some people have antibodies ATAGI statement on which activate platelets (anti-AstraZeneca vaccine in response PF4 antibodies). These to new vaccine safety concerns antibodies have been detected Joint statement on COVID-19 in another disorder triggered AstraZeneca vaccine advice by the drug heparin, which has from ATAGI a similar presentation (heparin induced thrombocytopenia ATAGI statement for health care (HIT). HIT is an immuneproviders on suitability of mediated complication of COVID-19 vaccination in people treatment with heparin that with history of clotting affects platelet function. A HITconditions like mechanism is being ATAGI statement on COVID-19 investigated as a potential, but vaccination and a reported case unconfirmed, pathway to CVST post COVID-19 vaccination. of thrombosis **THANZ Vaccine** It is currently unknown if a Thrombocytopenia Working prior history of these **Group's Vaccine Induced** conditions will increase your risk of TTS/VIPIT post-**Prothrombotic Immune** vaccination with AstraZeneca, Thrombocytopenia (VIPIT) however these screening <u>Statement</u> questions have been implemented as a precaution. TTS is a still poorly understood and we are learning more about it daily and this advice will be updated as more information is available. **Standard Pre-Screening Questions** Do you currently have a fever Vaccinations in general are not **Delay** vaccination until well. (temperature >38.5°C) or are recommended for those who Refer to primary healthcare provider you feeling sick today? are currently unwell, especially and consider COVID-19 with fevers. testing/screening. If someone is unwell on the day of vaccination, consideration of if vaccination should proceed on the same day must be given. For example, in a patient who is currently on antibiotics

Question	Rationale	Actions recommended
	treatment for an acute condition, it may be beneficial to wait till the course is complete and symptoms resolve prior to vaccinating.	
Have you had allergen immunotherapy (AIT) or venom immunotherapy (VIT) injections in the previous 48 hours?	Australasian Society of Clinical Immunology and Allergy (ASCIA) recommends that AIT or VIT injections should not be given within 48 hours of the COVID-19 vaccine injection. This avoids confusion about the cause of side effects or allergic reactions.	Delay vaccination for at least 48 hours
Have you had an injection of immunoglobulin, or received any blood products, or a whole blood transfusion in the last 24 hours?	Vaccination should occur on a different day (if possible) from regular infusion treatments, such as immunoglobulin (Ig) or immunosuppressant infusions. Individuals should seek advice from their specialist regarding	Immunoglobulins Delay vaccination for at least 24 hours
	timing of vaccine in relation to their immunoglobulin therapy.	
	For blood products, vaccinate if no other contraindications. Antibodies in blood products may interfere with the immune response to MMR, MMRV and varicella vaccines. As the COVID-19 vaccines are under enhanced surveillance, additional questions are being asked for efficacy surveillance and monitoring.	Vaccination is recommended to proceed.
Have you had the Pfizer COVID- 19 vaccine in the last 21 days OR the AstraZeneca COVID-19	Need to determine exact date of vaccination.	
vaccine in the last 28 days?	For all Pfizer COVID Vaccinations in the past 21 days.	Delay Vaccination until minimum 21 days has elapsed
	Therapeutic Goods Administration (TGA) and Australian Technical Advisory Group on Immunisation (ATAGI) recommendation is	

Question	Rationale	Actions recommended
	minimum time between Pfizer vaccine doses is 21 days.	
	For all AstraZeneca COVID Vaccinations in the past 28 days. TGA and ATAGI recommendation is minimum time between AstraZeneca vaccine doses is 28 days. Recommended second dose	Delay Vaccination until minimum 28 days has elapsed. Recommended second dose for AstraZeneca is 10- 12 weeks (allowing two-week range for booking flexibility).
	for AstraZeneca is 12 weeks.	
Have you received any other vaccine (e.g. flu, tetanus) in the last 7 days?	Need to determine exact date of vaccination.	Delay Vaccination until minimum 7 days has elapsed.
lust 7 days.	For all vaccines except COVID vaccinations in the past 7 days,	Shortening of this interval may be justified if adhering to the interval may result in non-adherence to the vaccination or if there is
	There is no known harm from administering the COVID-19 vaccinations with other vaccines. However, coadministration (or within 7 days) makes it difficult to determine the cause of any side effects or allergic reactions. The TGA and ATAGI recommend at least 7 days between any vaccination and COVID-19 vaccination.	an imminent need to administer either of these vaccines because of the prevailing local epidemiological situation.
Are you pregnant, think you might be pregnant, planning to fall pregnant?	The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and ATAGI recommend that	Pregnant Pregnant women should be routinely offered Pfizer mRNA vaccine (Cominarty).
	pregnant women are routinely offered Pfizer mRNA vaccine (Cominarty) at any stage of pregnancy. This is because the risk of severe outcomes from COVID-19 is significantly higher for pregnant women and their unborn baby.	See also 1) ATAGI COVID-19 vaccination decision aid for women who are pregnant, breastfeeding, or planning pregnancy

Question	Rationale	Actions recommended
	Global surveillance data from large numbers of pregnant women have not identified any significant safety concerns with mRNA COVID-19 vaccines given at any stage of pregnancy. Furthermore, there is also evidence of antibody in cord blood and breastmilk, which may offer protection to infants through passive immunity. Pregnant women are encouraged to discuss the decision in relation to timing of vaccination with their health professional. Source: Joint statement between RANZCOG and ATAGI about COVID-19 vaccination for pregnant women	
	Women who are planning pregnancy can receive COVID-19 vaccine. There are no theoretical concerns regarding the safety of COVID-19 vaccines in these groups.	Planning to fall pregnant. Vaccination is recommended to proceed.
Have you had an allergic reaction following a vaccination, or are you allergic to a COVID-19 vaccination ingredient? (see below) Pfizer-Comirnaty BNT162b2	Probing question to ascertain previous reactions to vaccines. Individuals with a history of allergy to vaccine (not a COVID-19 vaccine)	Vaccination is recommended to proceed. Patient to be monitored for 15 minutes.
 COVID-19 Vaccine ingredients: mRNA ALC-0315 Polyethylene Glycol (ALC-0159) (PEG), DSPC, 	The following individuals should be assessed for suitability for vaccination before being given a vaccine dose, if necessary, in consultation with an allergist/immunologist or specialist immunisation clinic:	Delay vaccination until appropriate review of the reaction has occurred. GP to refer patient to Public Health unit, a clinical immunology/ allergy specialist for assessment, before a dose is considered. If individuals in these categories are vaccinated, they may require vaccination in a

Question	Rationale	Actions recommended
 Cholesterol, Potassium chloride, Monobasic potassium phosphate, Sodium chloride, 	 people with immediate (within 4 hours) and generalised symptoms of a possible allergic reaction (e.g. urticaria/hives) to a previous dose of a COVID-19 vaccine 	facility with medical staff in attendance, and to be observed for 30 minutes following administration of a COVID-19 vaccine dose.
 Dibasic sodium phosphate dihydrate Sucrose water for injections. AstraZeneca (ChAdOx1-S) COVID-19 Vaccine ingredients: chAdOx1-S, histidine, histidine hydrochloride monohydrate, sodium chloride, magnesium chloride hexahydrate, disodium edetate (EDTA), sucrose, 	 people with a generalised allergic reaction (without anaphylaxis) to any component of the COVID-19 vaccine to be administered (e.g. PEG in Comirnaty or polysorbate 80 in COVID-19 Vaccine AstraZeneca) people with a prior history of anaphylaxis to previous vaccines and/or multiple drugs (injectable and/or oral) where ingredients such as PEG or polysorbate 80 may conceivably be the cause people with a known systemic mast cell activation disorder with raised mast cell tryptase that requires treatment. 	
 ethanol absolute, polysorbate 80 water for injections. 	There are two vaccines available in Australia. Each have different ingredients. If someone is allergic to one type of vaccine, they may be able to have another type of vaccine, without having an allergic reaction. Action is dependent on the severity of the reaction.	Note: Someone who is allergic to one type/brand of COVID-19 vaccine may be able to have another type/brand of COVID-19 vaccine without having further reactions. Please note: If an individual develops anaphylaxis or a severe allergic reaction after the first dose of a COVID-19 vaccine, an alternate brand should be considered for the second dose. If an alternate brand is used for the second dose, a third dose of COVID-19 vaccine does not need to be given.

Question	Rationale	Actions recommended
Do you have any allergies, particularly anaphylaxis to anything or carry or have been prescribed an adrenaline autoinjector (EpiPen)?	Individuals with a history of allergy; anaphylaxis to food, drugs, venom or latex; or allergic conditions, including asthma, atopic dermatitis (eczema) or allergic rhinitis (hay fever) can receive any COVID-19 vaccine.	Vaccination is recommended to proceed. Patient to be monitored for 15 minutes.
	Individuals with a known systemic mast cell activation disorder with raised mast cell tryptase that requires treatment.	Mast cell activation disorder Recommend delaying vaccination administration until individual is assessed for suitability for vaccination if necessary in consultation with an allergist/immunologist or specialist immunisation clinic: If people in these categories are vaccinated, they may require vaccination in a facility with medical staff in attendance, and to be observed for 30 minutes following administration of a COVID-19 vaccine dose.
	For individuals who have had a previous severe reaction, including anaphylaxis, to any component of a COVID-19 vaccine (e.g. PEG in Comirnaty or polysorbate 80 in COVID-19 Vaccine AstraZeneca) consultation with an immunology/allergy specialist is recommended.	Previous severe reaction to COVID-19 Vaccine components. Delay vaccination until appropriate review of the reaction has occurred. GP to refer patient to Public Health unit, a clinical immunology/ allergy specialist for assessment, before a dose is considered. If people in these categories are vaccinated, they may require vaccination in a facility with medical staff in attendance, and to be observed for 30 minutes following administration of a COVID-19 vaccine dose.
Are you younger than 18 years of age?	Age needs to be clarified and specific advice followed dependent on actual age	

Question	Rationale	Actions recommended
	If under 16 years old	If under 16 years old
	The COVID-19 vaccines available in Australia are not indicated for people less than 16 years old.	<u>Cancel</u> vaccination
	If under 18 years old, but at least 16 years old.	If under 18 years old, but at least 16 years old.
	Currently, the AstraZeneca vaccine is only indicated for people older than 18 years.	Delay vaccination if in an AstraZeneca only location. Individual to contact closest Pfizer hub to see if eligible for vaccination.
	Individual may be eligible for the Pfizer vaccine if at least 16 years old.	
Do you have a mast cell disorder?	People with a known systemic mast cell activation disorder with raised mast cell tryptase (that requires treatment) should be assessed for suitability for vaccination before being given a vaccine dose.	Delay vaccination until appropriate review of disorder has occurred. If individuals in these categories are vaccinated, they may require vaccination in a facility with medical staff in attendance, and to be observed for 30 minutes following administration of a COVID-19
	GP to refer patient to Public Health unit, a clinical immunology/ allergy specialist for assessment, before a dose is considered.	vaccine dose.
Do you have a condition or take medication or treatment that weakens your immune system	Conditions/disease which lowers immunity include leukaemia, cancer, HIV, SCID.	Vaccination is recommended to proceed.
(immunocompromised)?	If any spleen diseases, disorders or have had surgery to remove your spleen? People with an absent or dysfunctional	Soc also following swiders
	spleen are at increased risk of severe bacterial infections, especially invasive	See also following guidance, 1) ATAGI – COVID-19
	pneumococcal disease. As the COVID-19 vaccines are under enhanced surveillance, additional questions are being	vaccination decision guide for people with immunocompromise

Question	Rationale	Actions recommended
	asked for efficacy & safety surveillance and monitoring. Treatments which lowers immunity can include oral steroid medicines such as cortisone and prednisone, disease-modifying anti-rheumatic drugs (DMARDs), radiotherapy, or chemotherapy.	2) ATAGI – COVID-19 provider guide for patients with immunocompromise
	The efficacy of the COVID-19 vaccines may be lower in immunosuppressed individuals. However, neither vaccine is a live-attenuated vaccine and is safe for people with immune system disorders such as allergy, primary or secondary immunodeficiency or autoimmune conditions, who are not considered to be at greater risk of vaccine allergy compared to the general population. The current vaccines does not contain any live SARS-CoV-2 virus. They cannot give you COVID-19. Concerned individuals should contact their GP/134COVID for further assessment of risk and benefits.	
Do you have a past history of Guillain-Barre syndrome?	In people with a history of GBS, the condition may recur after receiving influenza vaccine. As the COVID-19 vaccines are under enhanced surveillance, additional questions are being asked for efficacy & safety surveillance and monitoring. Vaccinate if no other contraindications and Guillain-Barre syndrome was NOT	Vaccination is recommended to proceed.

Question	Rationale	Actions recommended
	associated with previous COVID-19 vaccine.	
Do you have a bleeding disorder, or take any blood thinning medication (anticoagulants)?	Intramuscular injection may lead to haematomas in people with haemostasis disorders. • If the individual receives medication/treatment to reduce bleeding, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. • Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination.	Vaccination is recommended to proceed. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. Ensure individual is informed about risk of haematoma from the injection.
Have you ever fainted after having a vaccination?	Consider administering vaccine supine (lying down) if appropriate.	Vaccination is recommended to proceed.
Have you had COVID-19 before?	We currently do not know how effective the vaccine will be in individuals who have previously suffered from COVID-19. As the COVID-19 vaccines are under enhanced surveillance, additional questions are being asked for efficacy & safety surveillance and monitoring.	Vaccination is recommended to proceed.

Other questions which may arise but are not formally asked in the pre-screening document.

Question	Rationale	Action
Can I Have my FluVax?	The dose of influenza vaccine can be given in any sequential order in relation to the 2 doses of a COVID-19 vaccine, as long as the minimum 14-day interval is observed. An influenza vaccine dose can be administered between dose 1 and dose 2 of Comirnaty or COVID-19 Vaccine AstraZeneca if sufficiently spaced apart to allow for minimal intervals between vaccines. This is particularly applicable to the COVID-19 Vaccine AstraZeneca for which the 2 doses are recommended to be given 10-12 weeks apart. The effect on immune response to the COVID-19 vaccine of intercalating a dose of influenza vaccine between the 2 doses is currently not known.	If ≤ 14 days between vaccinations, Delay vaccination and patient to be re-booked. If > 14 days between vaccinations, Vaccination is recommended to proceed. Routine scheduling and co- administration of an influenza vaccine with a COVID-19 vaccine on the same day is not recommended. The preferred minimum interval between a dose of seasonal influenza vaccine and a dose of Comirnaty (Pfizer) or COVID-19 Vaccine AstraZeneca is 14 days.
Have you transitioned through a declared COVID-19 hotspot or travelled overseas in past 14 days?	Increased risk of COVID-19 infection.	Delay vaccination and advise patient to follow any relevant state public health directives. Exception- If the patient is a phase 1a recipient who has received an invitation to be vaccinated by a HHS - this could include pilots, airline workers, marine pilots, aeromedical staff who are in perpetual quarantine due to their profession.
Have you had, or do you have, any of the following symptoms today: fever (greater than 38.5°C), cough, sore throat, shortness of breath, runny nose, fatigue, diarrhoea, vomiting or nausea, loss of smell or taste?	Symptoms of COVID-19	<u>Delay</u> vaccination and patient to be referred to COVID-19 testing clinic.
Do you live with someone who has a disease which lowers immunity (for example,	Household members are the most likely sources of vaccine-preventable diseases among	Vaccination is recommended to proceed.

Question	Rationale	Action
leukaemia, cancer, HIV), or live with someone who is having treatment which lowers immunity (for example, oral steroid medicines such as cortisone and prednisone, disease modifying anti-rheumatic drugs (DMARDs) radiotherapy, chemotherapy)?	people who are immunocompromised. People who are immunocompromised are often unable to be vaccinated, especially with live viral vaccines. As the COVID-19 vaccines are under enhanced surveillance, additional questions are being asked for efficacy & safety surveillance and monitoring.	Patient should be advised that despite the vaccine being effective there is still a chance they could still contract COVID-19. It is currently unknown if the vaccine reduces transmission of the virus.
Are you older than 85 years?	Relevant for Pfizer and AstraZeneca vaccines. Insufficient number of participants in vaccine studies to conclusively determine the efficacy in this subgroup. The decision to immunise an elderly patient should be decided on a case-by-case basis	Vaccination is recommended to proceed.
Have you had a COVID-19 vaccination before? If so, please specify.	This question is to ascertain if the individual has had a previous dose of the vaccine before and if it was the same brand as they are going to receive on the day. At present, Comirnaty and COVID-19 Vaccine AstraZeneca are not considered interchangeable. The two-dose course should be completed with the same vaccine. There are no data yet on the efficacy of mixed schedules.	Vaccination can proceed if the same brand and no contraindications. If different brand, recommend assessment by doctor or nurse to determine best strategy- this could result in a delay of vaccination if appropriate brand not available.
Are you breastfeeding?	Women who are breastfeeding can receive COVID-19 vaccine. There are no theoretical concerns regarding the safety of COVID-19 vaccines in these groups.	Vaccination is recommended to proceed.
Are vaccines suitable for elderly patients?	Broadly YES . See below guidance, 1) TGA advice on Pfizer-BioNTech COVID-19	See Guidance.

Question	Rationale	Action
	vaccine in elderly patients 2) COVID-19 vaccination decision guide for frail older people, including those in residential aged care facilities	

16 June 2021