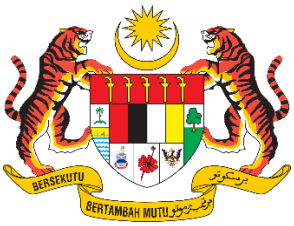
Annex 48b

Lampiran 1



CLINICAL GUIDELINES ON COVID-19 VACCINATION IN MALAYSIA

COVID-19 Vaccine AstraZeneca (ChAdOx1-S®[recombinant])

Ministry of Health, Malaysia

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Table of Content

1. Description of Treatment

COVID-19 Vaccine AstraZeneca (ChAdOx1-S®[recombinant])	
	Description
Indication	Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older
Type of vaccine	Adenovirus vector
Constituents	One dose (0.5 mL) contains $5x10^{10}$ viral particles of recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein. The product contains genetically modified organisms. Excipients: ● L-Histidine ● L-Histidine hydrochloride monohydrate ● Magnesium chloride hexahydrate ● Polysorbate 80 (E 433) ● Ethanol ● Sucrose ● Sodium chloride ● Disodium edetate (dihydrate) ● Water for injections This vaccine contains less than 1mmol sodium (23mg) per dose, i.e. essentially 'sodium free'.
Presentation	Slightly brown, clear to slightly opaque solution Discard if particulate matter or differences in the described appearance are observed Do not shake the vial.
Number of doses in each vial	10 doses
Dilution	Not applicable
Latex	No The vial has a rubber (bromobutyl) stopper, aluminium seal and a flip-off plastic cap. *Bromobutyl is a synthetic rubber*
Preservatives	No
Dosage	0.5ml
Number of doses required	2
Interval between doses	4 – 12 weeks (28 to 84 days)

Storage	**Unopened** vial: Store in a refrigerator (2 to 8°C). Do not freeze. Keep vials in outer carton to protect from light. **After first dose withdrawal**: Use the vial as soon as practically possible and within 6 hours (stored at 2°C to 25°C). Discard any unused vaccine.
Precautions for use	• Acute illness/infection • Patients with a history of Cerebral Venous Sinus Thrombosis or splanchnic vein thrombosis. Patients • with a history of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2). • Patients who have experienced major venous and/or arterial thrombosis occurring with thrombocytopenia following vaccination with any COVID-19 vaccine should not receive a second dose of COVID-19 vaccine AstraZeneca
Contraindications	• History of anaphylaxis to previous non COVID-19 vaccines, injectable medicines of multiple different drug classes, or substances possibly containing polysorbate or polyethylene glycol (PEG), idiopathic anaphylaxis. • Person with a previous history of severe allergic reactions to the vaccine (e.g. anaphylaxis, SCARs) after a previous dose or to any ingredient of the AstraZeneca COVID-19 vaccine • Allergic reaction of any severity within 72 hours after a previous dose or any known (diagnosed) allergy to any ingredient of the AstraZeneca COVID-19 vaccine • Pregnancy

2. Possible Adverse Drug Reactions

Very Common (≥1/10)	Local: injection site tenderness, injection site pain, injection site warmth, injection site pruritus, injection site bruising[a] General: headache, nausea, myalgia, arthralgia, fatigue, malaise, pyrexia[b], chills
Common (≥ 1/100 to <1/10)	Local: injection site swelling, injection site erythema, injection site induration General: vomiting, diarrhoea, influenza-like illness
Uncommon (≥ 1/1,000 to <1/100)	Local: rash, pruritus General: lymphadenopathy, decreased appetite, dizziness, abdominal pain, hyperhidrosis
Rare (≥ 1/10,000 to <1/1,000)	-
Very rare (<1/10,000)	Thrombosis in combination with thrombocytopenia *Very rare events of neuroinflammatory disorders have been reported following vaccination with COVID-19 Vaccine AstraZeneca. A causal relationship has not been established.*
Not known (cannot be estimated from available data)	Anaphylaxis, Hypersensitivity

[a] *injection site bruising includes injection site haematoma (uncommon, unsolicited adverse reaction)*
[b] *pyrexia includes feverishness (very common) and fever ≥38°C (common)*

3. Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT)

Unusual blood clots with low platelets are a very rare side effect of COVID-19 Vaccine AstraZeneca *(ChAdOx1-S®[recombinant]).*

People receiving the vaccine should be made aware of the possibility of this very rare incidence of blood clots seen with low platelets occurring mostly within 2 weeks of vaccination. This condition is called Vaccine–induced Immune Thrombotic Thrombocytopenia (VITT). So far, most of the reported cases of VITT have occurred in women under 60 years of age.

Blood clots mainly occurred in veins in the brain (cerebral venous sinus thrombosis, CVST) and the abdomen (splanchnic vein thrombosis), though in some cases the arteries were involved too. Sometimes, bleeding can also be seen and therefore VITT should still be suspected if the timing fits the presentation.

COVID-19 is associated with a risk of hospitalization and death. The reported incidence of VITT is very rare, and the overall benefits of the vaccine in preventing COVID-19 outweigh the risks of side effects.

<u>Possible pathogenesis of VITT</u>:

- Rare development of thrombosis caused by uncontrolled platelet activation due to development of antibodies against PF4.
- Clinically mimics Heparin Induced Thrombocytopenia (HIT)

<u>Consider VITT in the following patients:</u>

Vaccine recipients should be advised to seek medical attention immediately if they **develop these symptoms** in the **4 days to 4 weeks after vaccination**:

- a new, severe headache which is not improving with pain killers or is getting worse
- a headache which seems worse when lying down or bending over
- an unusual headache that may be accompanied by:
    - blurring vision, feeling nauseous or vomiting
    - difficulty with your speech
    - weakness, drowsiness, or seizures (fits)
- new, unexplained bruising or bleeding
- shortness of breath, chest pain, leg swelling or persistent abdominal (stomach) pain

4. Diagnosis and Management of Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT)

1. **Recent** COVID Vaccination (<30 days)
2. New Onset **Warning Signs**:
- Severe persistent headache +/- visual change ; seizures
- Severe persistent abdominal pain
- Leg pain or swelling
- Chest pain and / or shortness of breath

YES to both

Screen for ViTT:
- Urgent FBC (+/- FBP)
- D-dimer / Fibriongen / Coagulation Profile
- Appropriate symptom-based Imaging

Thrombosis AND Platelet < 150

D-Dimer > 4000mcg/l
Fibrinogen: low / normal

POSSIBLE VITT

Send for Confirmatory Test **AND** Start Treatment Urgently

VITT Treatment:
IVIG (0.5-1g/kg x 2 days)
Steroids if platelets < 50 x 10^9/l
Avoid platelet transfusion,Heparin/LMWH, VKA
Start non cross-reacting anticoagulant : Fonda / DOACs
Consult Haematologist
Consider plasma exchange if platelet <30 (with plasma)

NOT VITT if:
NO recent vaccination (4-30 D)
NO Thrombosis
Platelet > 150 x 10^9/l
PF4 ELISA: Negative

Manage according to standard practice.

When in doubt:
Seek Expert Opinion

DON'T FORGET TO REPORT ALL CASES

5. Allergy Concern

The COVID-19 Vaccine AstraZeneca contains polysorbate 80. Individuals with an allergy to polysorbate 80 should not receive this vaccine.

Polysorbate and polyethylene glycol (PEG) are structurally related. PEG is not present in the COVID-19 Vaccine AstraZeneca. However, some people with PEG allergy may also be allergic to polysorbate 80 which is widely used in medicines particularly in biologics, and in processed foods. Individuals who have tolerated polysorbate-containing injections (e.g. influenza vaccine) are likely to tolerate the COVID-19 Vaccine AstraZeneca.

As of 14 April 2021, an estimated 21.2 million first doses and around 2.3 million second doses of the Oxford University/AstraZeneca vaccine had been administered in United Kingdom. Based on the update of Medicines and Healthcare products Regulatory Agency (MHRA) United Kingdom (from period 9 December 2020 to 14 April 2021), 145,994 spontaneous reports with a total 548,495 of adverse reactions to Oxford University/AstraZeneca vaccine were received. Of these, 627 reports had a fatal outcome.

There were 540 UK spontaneous adverse reactions associated with anaphylaxis or anaphylactoid reactions with one death reported. Other rare but severe allergic reactions observed by MHRA include Stevens Johnson Syndrome (5 cases), toxic epidermal necrolysis (1 case), and drug reactions eosinophilia with systemic symptoms (DRESS, 10 cases).

Non-life-threatening allergic reactions such as pruritus (5089 cases), urticaria (1454 cases), and angioedema (210 cases) were also reported.

6. Contraindications and Precautions When Considering *COVID-19 Vaccine AstraZeneca (ChAdOx1-S®[recombinant])*

Proceed with vaccination	Special precautions	Vaccination contraindicated
1. Prior history of allergic reaction (of any severity including anaphylaxis) to an identified food or venom or pet or environmental allergens/ medications/ latex 2. Bronchial asthma 3. Atopy (eczema, allergic rhinitis, allergic conjunctivitis) 4. Family history of allergies 5. Local reaction and non-allergic reactions to a previous dose of vaccine 6. Hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) e.g. aspirin, diclofenac acid, mefenamic acid, ibuprofen, naproxen, paracetamol 7. Chronic spontaneous urticaria 8. Angiotensin converting enzyme inhibitor (ACEi) induced angioedema 9. Severe cutaneous adverse drug reactions (SCARs) or other non-IgE mediated hypersensitivities to identified medications/agents 10. Patients receiving omalizumab, dupilumab or other specific biologics for allergic diseases	1. History of anaphylaxis to previous non COVID-19 vaccines 2. History of anaphylaxis to injectable medicines or substances possibly containing polysorbate or polyethylene glycol (PEG) 3. History of anaphylaxis to multiple different drug classes 4. History of idiopathic anaphylaxis	1. **Severe allergic reaction** (e.g. anaphylaxis, SCARs) after a previous dose or to any ingredient of the AstraZeneca COVID-19 vaccine 2. **Allergic reaction of any severity within 72 hours** after a previous dose or any known (diagnosed) allergy to any ingredient of the AstraZeneca COVID-19 vaccine
• Observe 15 to 30 minutes after vaccination	• Do not administer COVID-19 Vaccine AstraZeneca but consider other COVID-19 vaccine without polysorbate or PEG • Refer to hospital vaccination center	• Do not vaccinate with COVID-19 Vaccine AstraZeneca • Choose a different vaccine that is not contraindicated (if available) • Consider referral to allergists/immunologists if no other vaccines available

7. Frequently Asked Questions (FAQs)

About COVID-19 Vaccine AstraZeneca (ChAdOx1-S®[recombinant])	
What type of vaccine is it?	It is a non-replicating viral vector (ChAd)
What does it contain?	It is made from a weakened version of a common cold virus (known as an adenovirus) from chimpanzees, ChAdOx1-S (recombinant). It has been modified to contain genetic material shared by the **coronavirus**. It is not able to cause the illness.
Does the vaccine contain animal or human enzymes?	No. None of the excipients are of animal or human origin. In addition to ChAdOx1-S (recombinant), this product also contains the excipients L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80, ethanol, sucrose, sodium chloride, disodium edetate dihydrate and water for injection. These excipients are well established for pharmaceutical products.
How is the vaccine given?	It is administered intramuscularly, preferably into the deltoid region of the upper arm.
Can viral vector vaccines like COVID-19 Vaccine AstraZeneca interact with a person's DNA?	No, they cannot. The viral vector enters the body's cells and delivers the genetic code for the spike protein. The human cells then produce the spike protein but there are no changes to the human DNA.
How many doses does a person need?	Two doses. This is given at a minimum 28 days apart. There is evidence of better efficacy if the second dose is delayed to 6 - 12 weeks. WHO recommends an interval of 8 to 12 weeks between the two doses. However, an interval of 28 days may be observed when rapid protection is required (for example for those about to receive immunosuppressive treatment).

What if the second dose of COVID-19 Vaccine AstraZeneca is administered at less than the recommended interval?	There is no evidence of efficacy of doses given before 24 days. However there is also no safety and efficacy date in relation to repeating vaccination in this situation (giving a total of 3 doses). Therefore, a further dose is not required. A dose is considered valid when given between day 24 and 27 from the first dose.
What if the second dose of COVID-19 vaccine is administered longer than the recommended interval?	If the interval between doses is longer than the recommended interval, the second dose should still be given. The course does not need to be restarted.
Booster doses	At present, there is no evidence for additional boosters after the 2-dose series.
Vaccine Safety	
Is it true that this vaccine causes blood clotting issues?	There are reports of an exceedingly rare condition Thrombosis with Thrombocytopenia Syndrome (TTS) involving blood clots and unusual bleeding after getting the AstraZeneca vaccine. This is being carefully reviewed but the risk factors for this condition are not yet clear. Data from the UK suggest around 4 people develop this condition for every million doses of COVID-19 Vaccine AstraZeneca doses given. Although this condition remains extremely rare, the incidence seems to be slightly higher in younger people and tends to occur between 4 days and 2 weeks after the first dose vaccination. It is important to note that this condition can also occur naturally, and clotting problems are a common complication of COVID-19 infection itself. The odds of getting blood clot is 100 times greater in COVID-19 infection as compared to the risk after vaccination. An increased risk has not yet been seen with other COVID-19 vaccines but this is being carefully monitored.

Can the COVID-19 Vaccine AstraZeneca be given to immunocompromised hosts or patients receiving immunosuppressive therapy, with its live adenovirus vector?	Yes. This adenovirus does not replicate and is considered safe in immunocompromised individuals. *However, do note that the efficacy may be lower in immunocompromised individuals.*
What should we look for after vaccination with the COVID-19 Vaccine AstraZeneca?	Vaccine recipients should be advised to seek medical attention immediately if they **develop these symptoms** in the 4 days to 4 weeks after vaccination: • a new, severe headache which is not ameliorated by analgesic or is getting worse • a headache which seems worse when lying down or bending over • an unusual headache that may be accompanied by: – blurred vision, nausea, and vomiting – difficulty with your speech – weakness, drowsiness, or seizures • new, unexplained petechiae, ecchymosis or bleeding • shortness of breath, chest pain, leg swelling or persistent abdominal pain
Should someone with a history of a thrombotic event be given COVID-19 Vaccine AstraZeneca?	VITT is likely an immune-mediated mechanism. There is no reason to believe that individuals with a history of clots or of certain thrombophilic conditions would be at increased risk of this exceedingly rare condition. However, as a precaution, people with a confirmed medical history of cerebral venous sinus thrombosis (CVST) or a splanchnic vein thrombosis (SVT) or a confirmed medical history of heparin induced thrombocytopenia should not be given the COVID-19 Vaccine AstraZeneca and be given an alternate vaccine. There is no evidence that pregnant women, postpartum women or women on contraceptives are at higher risk of the specific condition of thrombosis in combination with thrombocytopaenia after the AstraZeneca vaccine. There have been no confirmed cases reported in pregnant women to date.

Can I get this vaccine if I have low platelet count?	There is no evidence indicating patients with low platelet count are more prone for bleeding from the available trials to date. However, you are encouraged to discuss the potential risks with your treating physician / haematologist.
Does the COVID-19 Vaccine AstraZeneca Vaccine interfere with antiplatelet or anticoagulant?	There is no data to date, to show interaction between antiplatelet or/and anticoagulant with the vaccine.
Can adults under the age of 60 years be vaccinated with the COVID-19 Vaccine AstraZeneca?	VITT happens more commonly in young patients, whilst the benefit of vaccination is dramatically increases with age. Thus, vaccination of those under 60 will need to take into account the benefit of vaccination versus the risk of VITT. (refer Appendix 1)
Are there other unique adverse effects with the COVID-19 Vaccine AstraZeneca?	There have been reports of very rare events of demyelinating disorders following vaccination. A causal relationship has not been established.
COVID-19 Prevention	
Does COVID-19 Vaccine AstraZeneca prevent COVID-19?	This vaccine is effective in preventing infection. In a pooled analysis of 4 randomized controlled trials, the overall vaccine effectiveness was 66.7% (95% CI 57.4–74.0). In the same study it was found that there is better efficacy with dose intervals between 6 -12 weeks, and is supported with immunogenicity findings. Real-world data also supports vaccine effectiveness (among the elderly) against COVID-19- associated hospitalization following the first dose.
Does the vaccine work against variants?	The COVID-19 Vaccine AstraZeneca has shown efficacy against the B.1.1.7 variant of SARS-CoV-2 despite a reduced neutralisation activity in vitro. Preliminary findings show a marked reduction in protection against mild-moderate disease due to the B1.351 variant. Current indirect evidence is compatible with protection against severe COVID-19; however, this remains to be demonstrated in ongoing clinical trials and post-implementation evaluations.

Pregnancy and breastfeeding	
Can women who are pregnant be vaccinated?	Currently contraindicated for pregnancy until more data is made available
Can breastfeeding mothers be vaccinated?	Breastfeeding individuals were excluded from the Phase III trials for COVID-19 vaccines available at present and thus, there is currently no data on the safety and efficacy of COVID-19 vaccines in lactating individuals or the effects of COVID-19 vaccines on the breastfed infant or milk production.

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Estimation of potential benefits and harms of COVID-19 Vaccine AstraZeneca based on EMA age based risk stratification calculated to COVID-19 Malaysia (1 Jan – 23 April, 2021)

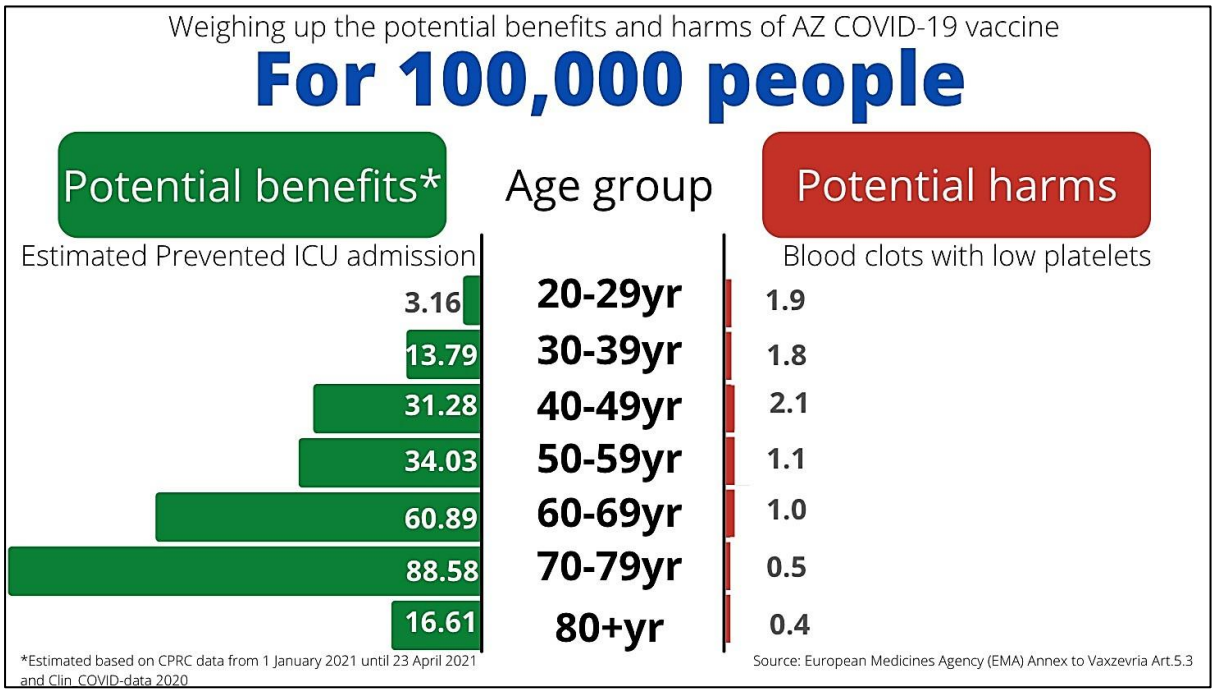

Figure 1: Illustrates the potential harms and benefits estimation by age category for risk of unusual blood clots with low platelets and prevention of ICU admission due to COVID-19.

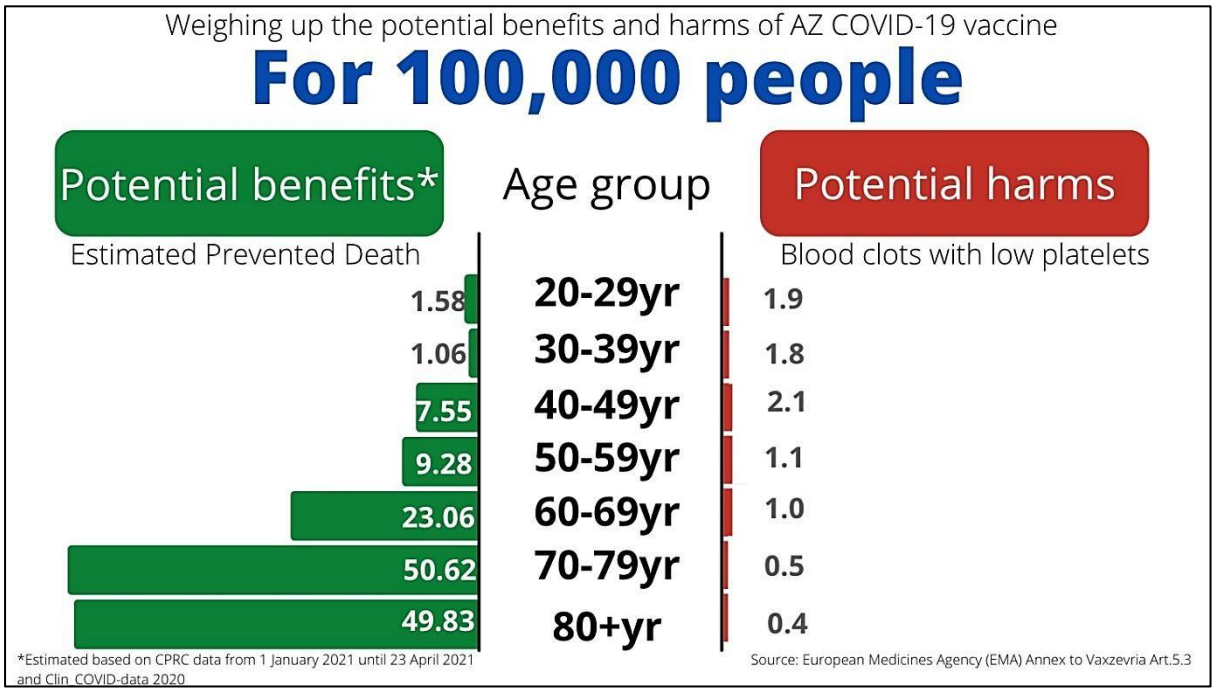

Figure 2: Illustrates the potential harms and benefits estimation by age category for risk of unusual blood clots with low platelets and prevention of death due to COVID-19.

All vaccines have rare adverse events.

Rare unusual blood clots in the brain (CVST) and abdomen, which are associated with low platelets (Vaccine–induced Immune Thrombotic Thrombocytopenia, VITT) has been reported for 1 in 100,000 people who received the vaccine.

Preliminary analysis shows that the risk of blood clots with low platelets appears to be inversely related after age 40 years; the older the age group, the higher the benefit against ICU admission and death from COVID-19.

For instance, 40-49 year old group has the benefit of preventing approximately 31 ICU admissions per 100,000 people. In comparison, the benefit increases by about 2 folds for the age group of 60-69 years.

The benefit/risk balance is more finely balanced in the younger adults compared to older adults

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