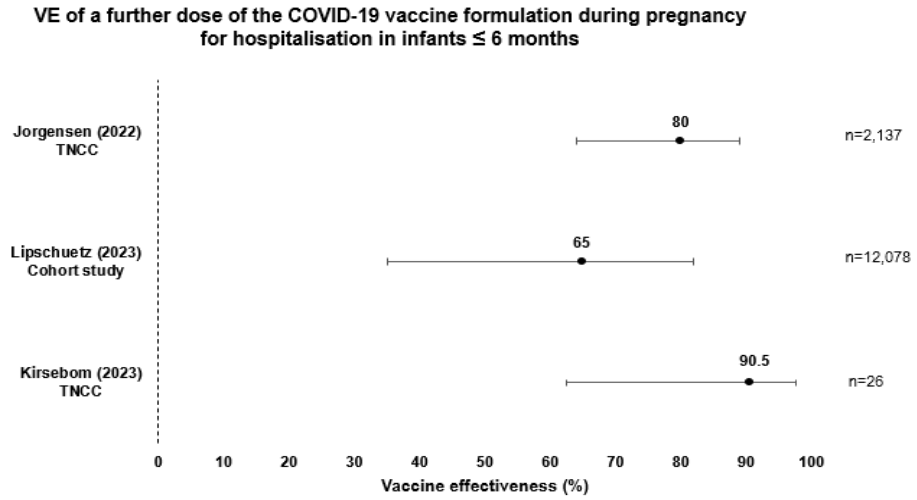
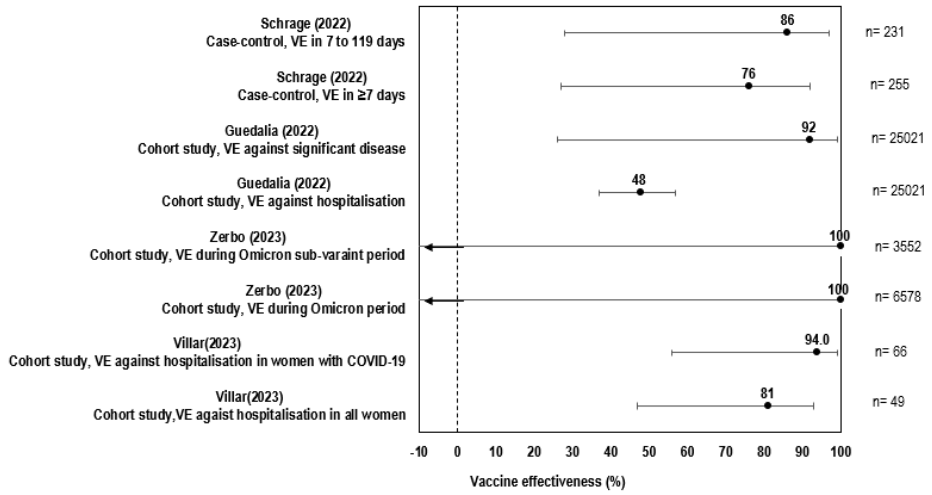
GRADE tables: Comparison of a further dose of the COVID-19 vaccine with no further dose of the COVID-19 vaccine during pregnancy in previously vaccinated pregnant women

NCIRS is conducting GRADE assessments in support of the Australian Technical Advisory Group on Immunisation (ATAGI) and making pilot results available on the Centre's website. Please read this material as a supplement to the Australian Immunisation Handbook COVID-19 chapter.

A further dose of the COVID-19 vaccine formulation compared with no further dose of the COVID-19 vaccine formulation during pregnancy in previously vaccinated pregnant women				
Patient or population: Infants ≤6 months and pregnant women **Intervention:** A further dose of the COVID-19 vaccine formulation received by previously vaccinated mother during pregnancy **Comparison:** No further dose of the COVID-19 vaccine formulation received by previously vaccinated mother during pregnancy				
Outcomes	**Impact**	**№ of participants (studies)**	**Certainty of the evidence (GRADE)**	**Interpretation**
CRITICAL OUTCOMES				
Vaccine effectiveness (VE) against COVID-19-related hospitalisation in infants aged ≤6 months		14,241 (3 non-randomised studies)[1-3]	⨁⨁◯◯ Low[a,b]	A further dose of the COVID-19 vaccine during pregnancy may result in a moderate reduction in hospitalisation among infants compared with no further dose during pregnancy.

A further dose of the COVID-19 vaccine formulation compared with no further dose of the COVID-19 vaccine formulation during pregnancy in previously vaccinated pregnant women				
Patient or population: Infants ≤6 months and pregnant women **Intervention:** A further dose of the COVID-19 vaccine formulation received by previously vaccinated mother during pregnancy **Comparison:** No further dose of the COVID-19 vaccine formulation received by previously vaccinated mother during pregnancy				
Outcomes	**Impact**	**№ of participants (studies)**	**Certainty of the evidence (GRADE)**	**Interpretation**
VE against COVID-19-related hospitalisation in pregnant women	**VE of a further dose of the COVID-19 vaccine formulation during pregnancy for hospitalisation in pregnant women**  	35,580 (5 non-randomised studies)[2,4-7]	⨁⨁◯◯ Low[a,b]	A further dose of the COVID-19 vaccine during pregnancy may result in a large reduction in hospitalisation among pregnant women compared with no further dose during pregnancy.

A further dose of the COVID-19 vaccine formulation compared with no further dose of the COVID-19 vaccine formulation during pregnancy in previously vaccinated pregnant women				
Patient or population: Infants ≤6 months and pregnant women **Intervention:** A further dose of the COVID-19 vaccine formulation received by previously vaccinated mother during pregnancy **Comparison:** No further dose of the COVID-19 vaccine formulation received by previously vaccinated mother during pregnancy				
Outcomes	**Impact**	**№ of participants (studies)**	**Certainty of the evidence (GRADE)**	**Interpretation**
Explanations a. Overall risk of bias assessment was moderate for all studies, with potential risk of bias identified in one or more domains of: confounding and selection of the reported results. The largest study was low risk of bias in all domains except confounding, selection, and selection of the reported results, where risk of bias was moderate. b. Comparison group in few studies was unvaccinated women rather than women with the primary vaccination and no further dose during pregnancy. *Abbreviations*: N=number of participants; TNCC=test-negative case-control; VE=vaccine effectiveness				
GRADE Working Group grades of evidence *High certainty:* We are very confident that the true effect lies close to that of the estimate of the effect. *Moderate certainty:* We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. *Low certainty:* Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect. *Very low certainty:* We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.				

GRADE evidence profile

Evidence profile: A further dose of COVID-19 vaccine during pregnancy compared with no further dose of COVID-19 vaccine during pregnancy in previously vaccinated pregnant women

Certainty assessment							Impact	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
Vaccine effectiveness (VE) against COVID-19-related hospitalisation in pregnant women (follow-up: 10 months; assessed with: pregnant patients who received a further dose of COVID-19 vaccine and were admitted to hospital with COVID-19-like illness (CLI) or acute respiratory infection (ARI) and were tested for SARS-CoV-2 using polymerase chain reaction (PCR) and/or hospitalisations where COVID-19 was the primary reason for hospital admission)									
5	Non-randomised studies	Serious[a]	Not serious	Serious[b]	Not serious	None	VE against hospitalisation due to COVID-19 ranged from 48 to 100% in pregnant women after receiving further dose during pregnancy compared with those with no further dose during pregnancy. In studies where comparison group was unvaccinated women, VE against hospitalisation due to COVID-19 ranged from 76 to 100%.[2,5-7] Only one study compared VE in pregnant women after receiving further dose during pregnancy with those with no further dose during pregnancy and reported VE of 48% against hospitalisation and 92% (95% CI: 26–99) against significant disease.[4]	⨁⨁◯◯ Low[a,b]	CRITICAL
VE against COVID-19-related hospitalisation in infants aged ≤6 months (follow-up: 16 months; assessed with: pregnant patients who received a further dose of COVID-19 vaccine and gave birth to infants who were admitted to hospital with CLI or ARI and were tested for SARS-CoV-2 using PCR and/or hospitalisations where COVID-19 was the primary reason for hospital admission when the infant was aged ≤6 months)									
3	Non-randomised studies	Serious[a]	Not serious	Serious[b]	Not serious	None	VE against hospitalisation due to COVID-19 ranged from 65 to 90.5% during Omicron period among infants.[1-3] Of 3 studies, two were TNCC[1,2] and one cohort.[3] VE of TNCC ranged from 80 to 90.5%[1,2] and VE reported by cohort study was 65%[3] among infants.	⨁⨁◯◯ Low[a,b]	CRITICAL

Explanations

a. Overall risk of bias assessment was moderate for all studies, with potential risk of bias identified in one or more domains of: confounding, selection, and selection of the reported results. The largest study was low risk of bias in all domains except confounding and selection of the reported results, where risk of bias was moderate.
b. Comparison group in few studies was unvaccinated women rather than women with the primary vaccination and no further dose during pregnancy.

Abbreviations: CI=confidence interval; N=number of participants; TNCC=test-negative case-control; VE=vaccine effectiveness.

ATAGI Evidence to decision framework for a further dose of the COVID-19 vaccine formulation compared with no dose of the COVID-19 vaccine formulation during pregnancy in previously vaccinated pregnant women

PICO Question	
Population	Infants ≤6 months and pregnant women
Intervention	Further dose of the COVID-19 vaccine formulation received by previously vaccinated mother during pregnancy
Comparison	No further dose of the COVID-19 vaccine formulation received by previously vaccinated mother during pregnancy
Main outcomes	*Critical* • Vaccine effectiveness (VE) of a further dose in pregnancy against COVID-19-related hospitalisation in infants aged ≤6 months • VE of a further dose in pregnancy against COVID-19-related hospitalisation in pregnant women
Setting	Argentina, Brazil, Canada, Egypt, England, France, Indonesia, Israel, Italy, Japan, Mexico, Nigeria, North Macedonia, Pakistan, Spain, Switzerland, Türkiye (Turkey), the UK, Uruguay and the USA.

ASSESSMENT					
Problem *Is the problem a priority?*					
Don't know	Varies	No	Probably no	Probably yes	Yes

- In Australia, COVID-19 vaccine recommendations for pregnant women are the same as the general population. Unvaccinated pregnant women are recommended to get primary course of COVID-19 vaccination, but further doses are not recommended in already vaccinated pregnant women as risk of severe disease is low in otherwise healthy pregnant women.[8-12]
- Recommendations for a further dose in people with severe immunocompromise are the same for pregnant and non-pregnant women.
- Reducing the risk of severe illness from COVID-19 remains a priority for high-risk groups; however, both pregnant women and infants aged <6 months have lower disease severity from COVID-19 during omicron period compared with the previous variants.[8-12]
- Studies have reported lower rates of preterm birth, and moreover, the number of stillbirths, neonatal infections and neonatal deaths remained low during omicron period in vaccinated pregnant women.[8-10]
- Studies reported no difference in disease severity between pregnant women receiving further dose during pregnancy compared with vaccinated pregnant women with no further dose during pregnancy with COVID-19 infection and lower rates of stillbirth.[10]
- Infants aged <1 year have highest threshold for hospital admission, but severity of COVID-19 infection is lower compared with the previous waves.[13] Fever is the most common symptom among COVID-19-positive infants presenting for hospitalisation with consistent/shorter median length of stay (1–2 days).[11,12]

Desirable effects

How substantial are the desirable anticipated effects?

Don't know	Varies	Large	Moderate	Small	Trivial

- COVID-19 vaccine significantly reduced the risk of severe COVID-19 disease, especially in high-risk groups and, therefore, vaccinated pregnant women and infants <6 months of age are not routinely recommended to receive further dose during pregnancy as the risk of severe COVID-19 disease is low in them.
- Since the onset of the pandemic, the incidence of severe illness has declined due to high COVID-19 vaccination coverage, hybrid immunity and with changes in dominant variants. Desirable effects of further doses are more prominent in high-risk cohorts, such as individuals aged ≥75 years, those with comorbidities and immunocompromised conditions and those in disability or aged care, compared with healthy individuals.
- Three studies reported VE of a further dose in pregnancy against COVID-19-related hospitalisation among infants <6 months, and concluded that a further dose of COVID-19 vaccine during pregnancy protected against COVID-19-related hospitalisation in infants for the first six months; VE ranged from 65 to 90.5% during the Omicron period among infants.[1-3] However, it was difficult to identify whether those infants were hospitalised because of severe disease or because they have a low threshold for hospitalisation due to fever, etc.[1-3]
- Five studies reported VE of a further dose of COVID-19 vaccine during pregnancy against COVID-19-related hospitalisation in previously vaccinated women. The results suggested that a further dose of COVID-19 vaccine during pregnancy protected against COVID-19-related hospitalisation in pregnant women; VE ranged from 48 to 100% during the Omicron period.[2,4-7] It was difficult to determine the severity of disease in these studies, and the comparison group was unvaccinated women (not the ideal comparator) in most of the studies.[2,4-7]
- The transmission of SARS-CoV-2 antibodies from vaccinated mothers to their fetuses varies due to several factors, such as the timing of vaccination, vaccine type, maternal immune response, and placental function. While many studies show effective transfer of IgG antibodies, especially with mRNA vaccines administered in the second or early third trimester, conflicting results arise due to differences in study design, population, and measurement methods. Despite these variations, maternal vaccination during pregnancy is widely regarded as beneficial for providing passive immunity to newborns.[14,15-17] However, as the severity of disease is considerably low among infants, vaccinating pregnant women with a further dose seems less desirable.

Undesirable effects

How substantial are the undesirable anticipated effects?

Don't know	Varies	Large	Moderate	Small	Trivial

- This GRADE did not evaluate outcomes related to safety and adverse events. However, the adverse event profile of pregnant women is similar to that of non-pregnant women following vaccination with an original mRNA COVID-19 vaccine.[18] Pregnant women are slightly more likely to report injection site pain, and less likely to report generalised symptoms such as fever or tiredness.[18,19]
- There are limited data available currently on the safety of the updated strain COVID-19 vaccines in pregnancy, although no additional concerns exist compared with the original mRNA vaccines.[19]
- Accumulated real-world evidence from other countries has shown that COVID-19 vaccines are safe in pregnancy. A living systematic review and meta-analysis of 177 studies reported that COVID-19 vaccination may result in minimal to no important differences compared with no vaccination in all maternal and infant safety outcomes from 26 fewer to 17 more events per 1,000 pregnant persons, and 13 fewer to 9 more events per 1,000 neonates, respectively.[19]
- Review of studies after a further dose of COVID-19 vaccine in pregnant people found their safety profile was comparable with that of published reports after primary COVID-19 vaccination in pregnant people.[20] Further dose of the SARS-CoV-2 vaccination during pregnancy was not associated with adverse obstetrical outcomes and foetal outcomes when compared with unvaccinated or twice-vaccinated women.[10,20,21]
- The World Health Organization also acknowledges the safety of further doses in pregnancy, particularly for women at high risk due to underlying health conditions or high exposure (e.g. healthcare workers). Further doses are especially encouraged for those who received the initial vaccine more than several months ago, given waning immunity and the risk from new COVID-19 variants.[22]
- In Australia, there are no safety concerns of further dose during pregnancy but as the threshold of severe disease is low in otherwise healthy women and infants aged <6 months, pregnant women are not routinely recommended to receive a further dose if previously vaccinated.[23]

- With respect to myocarditis and pericarditis, these conditions have been reported in vaccine recipients very rarely overall, with a higher incidence in males and adolescents. Reports of myocarditis after a further dose beyond the primary course of any type of COVID-19 vaccine are very rare, occurring in less than 1 in every 100,000 doses administered.[24] International study evaluating risk of severe adverse events of COVID-19 vaccine in pregnant women reported that further dose of COVID-19 vaccine in pregnancy was not associated with increased risk for thrombocytopenia, myocarditis, venous thromboembolism, ischaemic stroke, or other serious adverse events within 21 or 42 days after booster vaccination.[25]

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

Don't know	Varies	Favours comparison	Probably favours comparison	Does not favour either comparison or intervention	Probably favours intervention	Favours intervention

- The balance of effects does not favour either the comparator (no further dose during pregnancy) or the intervention (a further dose during pregnancy). The anticipated desirable effects were small, as were the anticipated undesirable effects.
- The three studies used in this GRADE for infant outcomes showed that VE ranged from 65 to 90.5% during the Omicron period among infants aged ≤6 months.[1-3] However, the certainty of evidence for this outcome was low. Additionally, it was difficult to identify whether those infants were hospitalised because of severe disease or because they have a low threshold for hospitalisation due to fever, etc.[1-3]
- The five studies used in this GRADE for maternal outcomes showed that VE ranged from 48 to 100% during the Omicron period among pregnant women.[4-7] However, the certainty of evidence for this outcome was low. Additionally, it was difficult to determine the severity of disease in these studies. [5-7] The comparator of unvaccinated women may have overestimated the effects of a further COVID-19 vaccine against COVID-19-related hospitalisation in pregnant women.

Certainty of evidence

What is the overall certainty of the evidence of effects?

No included studies	Very low	Low	Moderate	High

- The overall certainty of evidence is low. For both GRADED outcomes the certainty of evidence is low.
- The evidence was downgraded to moderate due to indirectness as the comparison group was unvaccinated pregnant women, which was not reflective of the population of interest (women with primary vaccination but no further dose during pregnancy).
- The evidence was further downgraded to low due to serious risk of bias, with potential risk of bias identified in one or more domains of: confounding, selection, and selection of the reported results.

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

Important uncertainty	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

- Pregnant women likely value protection against COVID-19-related hospitalisation for themselves and their infants. However, with no changes in the current recommendations, pregnant women will value the option of considering vaccination based on risk–benefit assessment and shared decision-making with their healthcare providers.

Acceptability

Is the intervention acceptable to key stakeholders?

Don't know	Varies	No	Probably no	Probably yes	Yes

- With less severity of disease in both pregnant women and infants, previously vaccinated women will probably not accept any change in the current recommendations.[9,12,26] Pregnant women will likely prefer the option of considering vaccination (current guideline) based on risk–benefit assessment and shared decision-making with their healthcare providers.
- Even during the early stages of pandemic, a national online survey conducted between August 2021–2022 in Australia, reported around 1 in 10 pregnant women (and just over 1 in 13 postnatal women) reported vaccine hesitancy, and hesitancy was higher in the latter 3-month period.[27]
- For other medical and healthcare stakeholders, changing the recommendation without showcasing desirable consequences of a further dose during pregnancy will likely lead to confusion around guidelines, and increase the probability of lowering acceptability.

Equity

What would be the impact on health inequities?

Don't know	Varies	Increased	Probably increased	Probably no impact	Probably reduced	Reduced

- There is no expected impact on health inequities as the recommendation remains same. Vaccine supply remains adequate to be available to all those who would consider vaccination during pregnancy.
- In Australia vaccine recommendations for pregnant women are the same as the general population including both Indigenous and non-Indigenous Australians.
- A population-based, cohort study of all pregnant women who gave birth in Victoria, Australia between 1 July 2021 and 30 June 2022, also reported that maternal age, smoking, parity and Indigenous status were the key factors associated with delayed and sustained lower coverage, even in a population with background maternal influenza and pertussis coverage of 70.6% and 81.8%, respectively.[28]

Feasibility

Is the intervention feasible to implement?

Don't know	Varies	No	Probably no	Probably yes	Yes

Implementing a further dose recommendation during pregnancy should be feasible as the vaccine delivery system is already in use, including through primary care and pharmacist vaccination. However, as the recommendation remains unchanged, there is no expected impact on feasibility.

ATAGI recommendation

ATAGI continues to recommend that unvaccinated pregnant women receive a single primary dose during pregnancy. For women who are previously vaccinated, recommendations are the same as for non-pregnant people. Unless a woman is otherwise eligible, a dose of COVID-19 vaccine is not routinely recommended in pregnancy. A further dose can be considered for pregnant women based on individual preference and the presence of risk conditions for severe illness.

Justification and considerations

Additional considerations

- Unvaccinated pregnant women are at higher risk of severe illness from COVID-19 than pregnant women who are vaccinated.[29] However, emerging data is supporting no severe disease in otherwise healthy pregnant women who were previously vaccinated and in infants of age <6 months.[12,13,18,26,30]
- While infants aged <1 year have highest threshold for hospital admission, severity of COVID-19 infection is lower compared with the previous waves.[13] Fever, not severity of COVID-19 symptoms, is the most common presenting symptom among COVID-19 positive infants for hospitalisation with consistent/shorter median length of stay (1–2 days).[11,12]
- ATAGI has considered the low severity of disease in these populations and continue to support the current recommendations: that unvaccinated pregnant women should receive a primary dose of COVID-19 vaccine, and vaccinated pregnant women should discuss with their healthcare provider whether to have a further dose during their pregnancy, based on an individual risk-benefit assessment.

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