Coversheet on evidence assessment by ATAGI using the GRADE framework for updated formulation COVID-19 vaccine in people aged 6 months and over

A summary of the use of the GRADE approach in the development of ATAGI and Australian Immunisation Handbook recommendations for a single dose of the updated formulation COVID-19 vaccine following a previous dose in the past 6–12 months compared with no updated formulation COVID-19 vaccine dose following a previous dose in the past 6–12 months in people aged 6 months and over

Background

- In early 2021, the Australian Technical Advisory Group on Immunisation (ATAGI) made recommendations on the COVID-19 vaccine rollout in Australia for adolescents and adults, including older adults.
- In January 2022, the rollout expanded to children aged 5–11 years and later extended to children under 5 years of age in August 2022.
- In 2023, bivalent COVID-19 vaccines for primary vaccination were approved. The ATAGI preferred these vaccines over the original vaccines for vaccination against COVID-19, and recommendations for further doses were revised based on risk conditions and COVID-19 epidemiology.
- The Therapeutics Good Administration (TGA) approved XBB.1.5 formulation COVID-19 vaccines in October 2023 and these vaccines are currently preferred over original and bivalent vaccines.
- Vaccination remains the most important measure to protect those at risk of severe disease from COVID-19. Currently, COVID-19 vaccines are recommended every 6–12 months for older adults and adults with severe immunocompromise due to their ongoing risk of severe COVID-19.
- The purpose of this GRADE was to investigate whether people aged 6 months and over should receive a single further dose of an updated formulation COVID-19 vaccine to protect from severe disease from COVID-19, and from this, to inform future recommendations for COVID-19 vaccination.

Research questions

1. Should people aged 6 months and over receive a single dose of the updated formulation COVID-19 vaccine following a previous dose in the past 6–12 months?

Table 1: Population, Intervention, Comparator, Outcomes (PICO) – A single dose of the updated formulation COVID-19 vaccine vs no COVID-19 vaccine dose, people aged 6 months and over

Population	People aged 6 months and over
Intervention	A single dose of an updated formulation COVID-19 vaccine following a previous dose between 6 and 12 months prior
Comparator	No dose of an updated formulation COVID-19 vaccine following a previous dose between 6 to 12 months prior
Outcomes	*Critical* • Vaccine effectiveness (VE) against COVID-19-related hospitalisation • VE against COVID-19-related death • VE against long COVID-19 • Serious adverse events (SAEs) (any and vaccine-related) • Adverse event of special interest (AESI): myocarditis (with or without pericarditis) occurring within 42 days from vaccination *Important* • Solicited local adverse events (AEs) • Solicited systemic AEs

Abbreviations: AE=adverse event; AESI=adverse event of special interest; SAE=serious adverse event; VE=vaccine effectiveness

Literature search

The literature search was completed on 12 January 2024 to identify all publications assessing the use of a dose of the updated formulation COVID-19 vaccine for PICO 1. The citations were included for review if they met the following criteria:

- *Study design:* Randomised controlled trial (RCT), observational study
- *Publication date:* Vaccine effectiveness (VE): 1 January 2023–13 February 2024; Safety: Phase 2/3 clinical trials published any time
- *Population:* Age 6 months and over
- *Intervention:* A single dose of updated formulation COVID-19 vaccine following a previous dose within the past 6–12 months
- *Comparator:* No dose of updated formulation COVID-19 vaccine following a previous dose within the past 6–12 months
- *Outcomes:* VE, safety

The literature search retrieved a total of 1897 (vaccine effectiveness [VE]) and 469 (myocarditis [MI]) unique citations, of which 4=VE, 1=MI, 7=safety met the pre-defined inclusion criteria for a single dose of the updated formulation COVID-19 vaccine vs no updated formulation COVID-19 vaccine dose following a previous dose within the past 6–12 months. The study characteristics and risk of bias (RoB) assessment of each individual study are presented in Appendix A (Tables A1 and A2). For detailed search strategy refer to Appendix B.

Four observational studies reporting short-term VE of a single dose of updated formulation COVID-19 vaccine against hospitalisation were identified: two among older adults and two among individuals of ages 18 years and above. These studies are from the Netherland, Denmark, and the United States of America. No publications for VE of a single dose of updated formulation COVID-19 vaccine against COVID-19-related death and long COVID were identified. The June 2023 COVID-19 vaccine safety report published by the Therapeutic Goods Administration (TGA) was included to report the rates of MI in Australian males and females after 'all dose' and 'second doses' of mRNA and protein subunit COVID-19 vaccines.

Adverse event profile safety outcome data were used from seven RCTs conducted in high- and middle-income countries. As data on adverse events of special interest (AESIs) were not available for the updated formulation COVID-19 vaccines, safety outcomes for the updated formulations were extrapolated from phase 3 clinical trials of the original and earlier formula COVID-19 vaccines (compared with placebo) in line with regulatory agencies, such as the TGA, which approved the updated formulation COVID-19 vaccines using this extrapolation method.

Inclusion criteria and rationale

Table 2: Rationale for PICO and inclusion criteria

PICO	Rationale
Study type Randomised controlled trial, observational study, meta-analysis	Vaccine effectiveness (VE) studies were preferred, particularly nationwide studies which included a large and diverse population. For safety outcomes, large population-based database-based studies were preferred. However, large clinical trial data was acceptable for inclusion if it met the other criteria.
Population People aged ≥6 months	People aged ≥6 months were the selected population as that is the age of lowest registration approved by TGA for COVID-19 vaccination in Australia. Currently, infants, children and adolescents are not routinely recommended a COVID-19 vaccine dose; however, to keep the PICO relevant for any future GRADEs or recommendations targeting any age group, a broad age group was selected proactively.
Intervention A single dose of an updated formulation COVID-19 vaccine following a dose between 6 and 12 months prior	Updated formulation vaccines (e.g. XBB.1.5-based formulation, JN.1-based formulation) are now preferred over other older formulation COVID-19 vaccines in Australia.
Comparator	This comparator was used as it was most relevant to the most recent ATAGI recommendations regarding further doses for COVID-19 vaccination.

No single dose of updated formulation COVID-19 vaccine following a previous dose between 6 and 12 months prior	
Outcomes	The outcomes stated in Table 1 (above) represent the severe COVID-19 disease outcomes which COVID-19 vaccination should protect at-risk individuals from. Less severe outcomes, such as VE against COVID-19 infection, were excluded as the recommendations prioritise protecting people from severe outcomes of COVID-19 and because most of the population has had exposure to COVID-19 through previous vaccination, natural infection or hybrid immunity.
	Ranking of importance discussed in many iterations with portfolio leads and the full ATAGI panel.
	General framework (depending on outcomes measured in studies available): *Critical* • VE against COVID-19-related hospitalisation • VE against COVID-19-related death* • Vaccine effectiveness against long COVID-19* • Serious adverse events (SAE): any or vaccine-related • Adverse event of special interest (AESI): myocarditis (with or without pericarditis) occurring within 42 days from vaccination *Important* • Solicited local adverse events (AEs) • Solicited systemic AEs * Note: some outcomes may be missing in GRADE projects due to no data from available included studies.

Abbreviations: AE=adverse event; AESI=adverse event of special interest; ATAGI=Australian Technical Advisory Group on Immunisation; SAE=serious adverse event; VE=vaccine effectiveness

Risk of bias assessment

Risk of Bias (RoB) assessment was carried out on all included studies by two assessors using ROB 2.0 and Risk of Bias In Non-randomised Studies - of Interventions (ROBINS-I) for randomised controlled trials and comparative observational studies, respectively. Refer to Appendix A for RoB and ROBINS-I rating of included studies.

Appendix A

Table A1: Risk of Bias assessment for comparative, observational studies using ROBINS-I

Study	Outcome	Confounding	Selection	Intervention classification	Deviations from intervention	Missing data	Measurement of outcomes	Selection of the reported results	Overall bias
van Werkhoven et al, 2024[1]	VE against COVID-19-related hospitalisation	Low	Moderate	Low	Low	Moderate	Moderate	Moderate	Moderate
Hansen et al, 2024[2]	VE against COVID-19-related hospitalisation	Low	Moderate	Low	Low	Low	Low	Low	Moderate
DeCuir et al, 2024[3]	VE against COVID-19-related hospitalisation	Low	Low	Low	Low	Low	Low	Low	Low
Tartof et al, 2024[4]	VE against COVID-19-related hospitalisation	Low	Moderate	Low	Low	Low	Low	Low	Moderate
TGA COVID-19 vaccine safety report, June 2023[15]	AESI: myocarditis (with or without pericarditis) occurring within 42 days from vaccination	Low	Moderate	Low	Low	Low	Low	Low	Moderate*

* The ROBINS-I assessment rated the TGA report as moderate RoB due to potential risk of bias in the domain of selection. This risk of bias domain for the AESI outcome in the GRADE summary of findings and evidence profile tables was not downgraded as the TGA report included nationwide data and is the largest and most appropriate study to use to evaluate this outcome.

Abbreviations: AESI=adverse event of special interest; ROBINS-I=Risk of Bias In Non-randomised Studies - of Interventions; TGA=Therapeutic Goods Administration; VE=vaccine effectiveness.

Table A2: Risk of bias assessment for randomised controlled trials using ROB 2.0

Study	Outcome	Domain 1: Risk of bias arising from the randomisation process	Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Domain 3: Missing outcome data	Domain 4: Risk of bias in measurement of the outcome	Domain 5: Risk of bias in selection of the reported result	Overall risk of bias
Munoz et al 2023[5]	Safety	Low	Low	Low	Low	Low	Low
Walter et al 2022[6]	Safety	Low	Low	Low	Low	Low	Low
Anderson et al 2022[7]	Safety	Low	Low	Low	Low	Low	Low
Creech et al 2022[8]	Safety	Low	Low	Low	Low	Low	Low
Frenck et al 2021[9]	Safety	Low	Low	Low	Low	Low	Low
Ali et al 2021[10]	Safety	Low	Low	Low	Low	Low	Low
Polack et al, 2020[11] Thomas et al 2021[12]	Safety	Low	Low	Low	Low	Low	Low
Baden et al, 2021[13] El Sahly et al 2021[14]	Safety	Low	Low	Low	Low	Low	Low

Appendix B: Search strategy

Vaccine effectiveness

MEDLINE: COVID-19 mRNA vaccines – outcomes including GP presentation, Hospitalisation, Death and Long COVID (as at 12.01.24)

Notes: Limited to PY=2023. Updated and corrected typo from search originally run on 22.12.23.

Database: MEDLINE(R) All including Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946-current>

Search strategy:

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1 exp COVID-19/ (251636)

2 ('2019 nCoV$' or 2019-nCoV$ or 2019nCoV$ or 'n CoV$' or n-CoV$ or nCoV$).tw. (3285)

3 ('covid 19' or covid-19 or covid19).tw. (340520)

4 exp SARS-CoV-2/ (163906)

5 ("Severe Acute Respiratory Syndrome Coronavirus 2" or "Severe Acute Respiratory Syndrome Coronavirus-2" or "SARS coronavirus 2" or "SARS coronavirus-2").tw. (34846)

6 ('SARS CoV2' or SARS-CoV2 or SARSCoV2 or SARS-CoV-2).tw. (117459)

7 1 or 2 or 3 or 4 or 5 or 6 (393288)

8 exp Immunization/ (213178)

9 exp Immunization Programs/ (16205)

10 exp Vaccines/ (283284)

11 (immuni$ or vaccin$).tw. (688952)

12 8 or 9 or 10 or 11 (790781)

13 7 and 12 (69024)

14 exp COVID-19 Vaccines/ (24750)

15 13 or 14 (69302)

EMBASE: COVID-19 mRNA vaccines – outcomes including GP presentation, Hospitalisation, Death and Long COVID (as at 12.01.24)

Notes: Limited to PY=2023.

Database: Embase <1974 to 2024 January 10>

Search strategy:

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1 exp coronavirus disease 2019/ (376952)

2 ('2019 nCoV$' or 2019-nCoV$ or 2019nCoV$ or 'n CoV$' or n-CoV$ or nCoV$).tw. (4204)

3 ('covid 19' or covid-19 or covid19).tw. (385826)

4 exp Severe acute respiratory syndrome coronavirus 2/ (107339)

5 ("Severe Acute Respiratory Syndrome Coronavirus 2" or "Severe Acute Respiratory Syndrome Coronavirus-2" or "SARS coronavirus 2" or "SARS coronavirus-2").tw. (35191)

6 ('SARS CoV2' or SARS-CoV2 or SARSCoV2 or SARS-CoV-2).tw. (137124)

7 1 or 2 or 3 or 4 or 5 or 6 (476085)

8 exp immunization/ (383919)

9 exp vaccine/ (422516)

10 (immuni$ or vaccin$).tw. (815430)

11 8 or 9 or 10 (967637)

12 7 and 11 (92572)

13 exp SARS-CoV-2 vaccine/ (43791)

14 12 or 13 (93531)

15 (Pfizer$ or BioNTech$ or Moderna$).tw. (51299)

16	(Pfizer$ or BioNTech$ or Moderna$).tw. (7507)
17	15 and 16 (3908)
18	exp mRNA Vaccines/ (5357)
19	((rna or mrna or (messenger adj1 rna)) adj3 vaccin$).tw. (9771)
20	18 or 19 (11796)
21	15 and 20 (9840)
22	exp BNT162 Vaccine/ (3726)
23	(BNT162b2$ or tozinameran$ or comirnaty$).tw. (5072)
24	exp 2019-nCoV Vaccine mRNA-1273/ (871)
25	(mRNA-1273$ or elasomeran$ or spikevax$).tw. (1914)
26	22 or 23 or 24 or 25 (6357)
27	17 or 21 or 26 (12024)
28	exp General Practice/ (78981)
29	exp General Practitioners/ (10969)
30	((general or family) adj3 (practice$ or practitioner$)).tw. (114841)
31	exp Hospitalization/ (297187)
32	hospital$.tw. (1667542)
33	exp Emergency Service, Hospital/ (101176)
34	(emergency adj2 (department$ or room$ or ward$ or attend$ or present$)).tw. (157709)
35	(urgent adj3 care).tw. (4607)
36	exp Mortality/ (425557)
37	exp Death/ (166561)
38	(mortalit$ or death$ or fatal$ or case-fatal$ or lethal$ or died).tw. (2228980)
39	exp Post-Acute COVID-19 Syndrome/ (2864)

16	14 and 15 (9113)
17	exp RNA vaccine/ (18585)
18	((rna or mrna or (messenger adj1 rna)) adj3 vaccin$).tw. (12584)
19	17 or 18 (22987)
20	14 and 19 (20145)
21	exp bnt 162 vaccine/ (318)
22	(BNT162b2$ or tozinameran$ or comirnaty$).tw. (7893)
23	exp elasomeran/ (6860)
24	(mRNA-1273$ or elasomeran$ or spikevax$).tw. (4360)
25	21 or 22 or 23 or 24 (12743)
26	16 or 20 or 25 (22409)
27	exp general practice/ (86008)
28	exp general practitioner/ (121026)
29	((general or family) adj3 (practice$ or practitioner$)).tw. (75797)
30	exp hospitalization/ (548126)
31	hospital$.tw. (2601504)
32	exp hospital emergency service/ (10271)
33	(emergency adj2 (department$ or room$ or ward$ or attend$ or present$)).tw. (249385)
34	(urgent adj3 care).tw. (7363)
35	exp mortality/ (1405595)
36	exp death/ (2046481)
37	(mortalit$ or death$ or fatal$ or case-fatal$ or lethal$ or died).tw. (3193274)
38	exp long COVID/ (6572)
39	"post COVID-19 syndrome".tw. (600)

40 "post COVID-19 syndrome".tw. (478) 41 "post acute COVID-19 syndrome".tw. (206) 42 (("post acute" or "post-acute" or postacute) adj2 (COVID$ or "SARS CoV2" or SARS-CoV2 or SARSCoV2 or SARS-CoV-2)).tw. (678) 43 (post-acute adj1 sequelae adj2 (COVID$ or "SARS CoV2" or SARS-CoV2 or SARSCoV2 or SARS-CoV-2)).tw. (543) 44 PASC.tw. (699) 45 ("long COVID$" or long-COVID$ or longCOVID$).tw. (3721) 46 (("long term" or "long-term" or longterm) adj2 (COVID$ or "SARS CoV2" or SARS-CoV2 or SARSCoV2 or SARS-CoV-2)).tw. (482) 47 (("long haul$" or "long-haul$" or longhaul$) adj2 (COVID$ or "SARS CoV2" or SARS-CoV2 or SARSCoV2 or SARS-CoV-2)).tw. (122) 48 ((protract$ or extend$ or sustain$ or persist$ or prolong$ or continu$ or chronic$ or ongoing) adj2 (COVID$ or "SARS CoV2" or SARS-CoV2 or SARSCoV2 or SARS-CoV-2) adj2 (symptom$ or sequela$ or illness$ or syndrome$)).tw. (389) 49 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 (4053226) 50 27 and 49 (2923) 51 limit 50 to yr="2023" (926) 52 remove duplicates from 51 (923)	40 "post acute COVID-19 syndrome".tw. (255) 41 (("post acute" or "post-acute" or postacute) adj2 (COVID$ or "SARS CoV2" or SARS-CoV2 or SARSCoV2 or SARS-CoV-2)).tw. (880) 42 (post-acute adj1 sequelae adj2 (COVID$ or "SARS CoV2" or SARS-CoV2 or SARSCoV2 or SARS-CoV-2)).tw. (745) 43 PASC.tw. (990) 44 ("long COVID$" or long-COVID$ or longCOVID$).tw. (4775) 45 (("long term" or "long-term" or longterm) adj2 (COVID$ or "SARS CoV2" or SARS-CoV2 or SARSCoV2 or SARS-CoV-2)).tw. (577) 46 (("long haul$" or "long-haul$" or longhaul$) adj2 (COVID$ or "SARS CoV2" or SARS-CoV2 or SARSCoV2 or SARS-CoV-2)).tw. (171) 47 ((protract$ or extend$ or sustain$ or persist$ or prolong$ or continu$ or chronic$ or ongoing) adj2 (COVID$ or "SARS CoV2" or SARS-CoV2 or SARSCoV2 or SARS-CoV-2) adj2 (symptom$ or sequela$ or illness$ or syndrome$)).tw. (530) 48 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 (6019652) 49 26 and 48 (7269) 50 limit 49 to yr="2023" (2269) 51 remove duplicates from 50 (2240)
Cochrane Central Register of Controlled Trials Issue 1 of 12, January 2024: **COVID-19 mRNA vaccines – outcomes including GP presentation, Hospitalisation, Death and Long COVID (as at 12.01.24)** ID Search Hits #1 MeSH descriptor: [COVID-19] explode all trees 5024 #2 (2019 NEXT nCoV OR 2019nCoV OR "n CoV" OR nCoV):ti,ab,kw 403	

#3	("covid 19" OR "covid-19" OR covid19):ti,ab,kw	17989
#4	MeSH descriptor: [SARS-CoV-2] 1 tree(s) exploded	0
#5	("Severe Acute Respiratory Syndrome Coronavirus 2" OR "Severe Acute Respiratory Syndrome Coronavirus-2" OR "SARS coronavirus 2" OR "SARS coronavirus-2"):ti,ab,kw	2082
#6	("SARS CoV2" OR "SARS-CoV2" OR SARSCoV2 OR "SARS-CoV-2"):ti,ab,kw	840
#7	#1 OR #2 OR #3 OR #4 OR #5 OR #6	18265
#8	MeSH descriptor: [Immunization] explode all trees	6981
#9	MeSH descriptor: [Immunization Programs] explode all trees	307
#10	MeSH descriptor: [Vaccines] explode all trees	16164
#11	(vaccin* OR immunis* OR immuniz*):ti,ab,kw	34224
#12	#8 OR #9 OR #10 OR #11	34419
#13	#7 AND #12	2895
#14	MeSH descriptor: [COVID-19 Vaccines] explode all trees	501
#15	#13 OR #14	2895
#16	(Pfizer* OR BioNTech* OR Moderna*):ti,ab,kw	3276
#17	#15 AND #16	206
#18	MeSH descriptor: [mRNA Vaccines] explode all trees	122
#19	((rna OR mrna OR (messenger NEAR/1 rna)) NEAR/3 vaccin*):ti,ab,kw	597
#20	#18 OR #19	633
#21	#15 AND #20	475
#22	MeSH descriptor: [BNT162 Vaccine] explode all trees	83
#23	(BNT162b2* OR tozinameran* OR comirnaty*):ti,ab,kw	301
#24	MeSH descriptor: [2019-nCoV Vaccine mRNA-1273] explode all trees	41
#25	(mRNA-1273* OR elasomeran* OR spikevax*):ti,ab,kw	164

#26 #22 OR #23 OR #24 OR #25 393 #27 #17 OR #21 OR #26 665 #28 MeSH descriptor: [General Practice] explode all trees 3051 #29 MeSH descriptor: [General Practitioners] explode all trees 498 #30 ((general OR family) NEAR/3 (practice* OR practitioner*)):ti,ab,kw 15722 #31 MeSH descriptor: [Hospitalization] explode all trees 22793 #32 hospital*:ti,ab,kw 239043 #33 MeSH descriptor: [Emergency Service, Hospital] explode all trees 3369 #34 (emergency NEAR/2 (department* OR room* OR ward* OR attend* OR present*)):ti,ab,kw 16920 #35 (urgent NEAR/3 care):ti,ab,kw 612 #36 MeSH descriptor: [Mortality] explode all trees 21899 #37 MeSH descriptor: [Death] explode all trees 8082 #38 (mortalit* OR death* OR fatal* OR case-fatal* OR lethal* OR died):ti,ab,kw 185901 #39 MeSH descriptor: [Post-Acute COVID-19 Syndrome] explode all trees 87 #40 "post COVID-19 syndrome":ti,ab,kw 62 #41 "post acute COVID-19 syndrome":ti,ab,kw 114 #42 (("post acute" OR "post-acute" or postacute) NEAR/2 (COVID* OR "SARS CoV2" OR "SARS-CoV2" OR SARSCoV2 or "SARS-CoV-2")):ti,ab,kw 141 #43 (post-acute NEAR/1 sequelae NEAR/2 (COVID* OR "SARS CoV2" OR SARS-CoV2 OR SARSCoV2 OR SARS-CoV-2)):ti,ab,kw27 #44 PASC:ti,ab,kw 59 #45 ((long NEAR/1 COVID*) OR long-COVID* OR longCOVID*):ti,ab,kw 369 #46 (("long term" OR "long-term" OR longterm) NEAR/2 (COVID* OR "SARS CoV2" OR SARS-CoV2 OR SARSCoV2 OR SARS-CoV-2)):ti,ab,kw 22	

#47 ((long NEAR/1 haul*) OR long-haul* OR longhaul*):ti,ab,kw NEAR/2 (COVID* OR "SARS CoV2" OR SARS-CoV2 OR SARSCoV2 OR SARS-CoV-2):ti,ab,kw 14 #48 ((protract* OR extend* OR sustain* OR persist* OR prolong* OR continu* OR chronic* OR ongoing) NEAR/2 (COVID* OR "SARS CoV2" OR SARS-CoV2 OR SARSCoV2 OR SARS-CoV-2) NEAR/2 (symptom* OR sequela* OR illness* OR syndrome*)):ti,ab,kw 49 #49 #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 391969 #50 #27 AND #49 116 #51 #50 with Cochrane Library publication date Between Jan 2023 and Dec 2023 24 DSR – 0 CENTRAL – 24	

Safety

MEDLINE: COVID-19 mRNA vaccines and myocarditis/pericarditis (as at 17.01.24) **Notes: No date limits applied.** Database: MEDLINE(R) All including Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946-current> Search Strategy: --- 1 exp COVID-19/ (251975) 2 ('2019 nCoV$' or 2019-nCoV$ or 2019nCoV$ or 'n CoV$' or n-CoV$ or nCoV$).tw. (3286) 3 ('covid 19' or covid-19 or covid19).tw. (340977) 4 exp SARS-CoV-2/ (164026) 5 ("Severe Acute Respiratory Syndrome Coronavirus 2" or "Severe Acute Respiratory Syndrome Coronavirus-2" or "SARS coronavirus 2" or "SARS coronavirus-2").tw. (34892)	**EMBASE: COVID-19 mRNA vaccines and myocarditis/pericarditis (as at 17.01.24)** **Notes: No date limits applied.** Database: Embase <1974 to 2024 January 12> Search Strategy: --- 1 exp coronavirus disease 2019/ (378282) 2 ('2019 nCoV$' or 2019-nCoV$ or 2019nCoV$ or 'n CoV$' or n-CoV$ or nCoV$).tw. (4226) 3 ('covid 19' or covid-19 or covid19).tw. (387325) 4 exp Severe acute respiratory syndrome coronavirus 2/ (107712) 5 ("Severe Acute Respiratory Syndrome Coronavirus 2" or "Severe Acute Respiratory Syndrome Coronavirus-2" or "SARS coronavirus 2" or "SARS coronavirus-2").tw. (35286) 6 ('SARS CoV2' or SARS-CoV2 or SARSCoV2 or SARS-CoV-2).tw. (137604)

6 ('SARS CoV2' or SARS-CoV2 or SARSCoV2 or SARS-CoV-2).tw. (117633)	7 1 or 2 or 3 or 4 or 5 or 6 (478042)
7 1 or 2 or 3 or 4 or 5 or 6 (393829)	8 exp immunization/ (384990)
8 exp Immunization/ (213247)	9 exp vaccine/ (423578)
9 exp Immunization Programs/ (16206)	10 (immuni$ or vaccin$).tw. (817289)
10 exp Vaccines/ (283376)	11 8 or 9 or 10 (969829)
11 (immuni$ or vaccin$).tw. (689388)	12 7 and 11 (92999)
12 8 or 9 or 10 or 11 (791243)	13 exp SARS-CoV-2 vaccine/ (44012)
13 7 and 12 (69138)	14 12 or 13 (93964)
14 exp COVID-19 Vaccines/ (24780)	15 (Pfizer$ or BioNTech$ or Moderna$).tw. (51376)
15 13 or 14 (69416)	16 14 and 15 (9173)
16 (Pfizer$ or BioNTech$ or Moderna$).tw. (7508)	17 exp RNA vaccine/ (18697)
17 15 and 16 (3909)	18 ((rna or mrna or (messenger adj1 rna)) adj3 vaccin$).tw. (12652)
18 exp mRNA Vaccines/ (5361)	19 17 or 18 (23120)
19 ((rna or mrna or (messenger adj1 rna)) adj3 vaccin$).tw. (9785)	20 14 and 19 (20252)
20 18 or 19 (11813)	21 exp bnt 162 vaccine/ (322)
21 15 and 20 (9857)	22 (BNT162b2$ or tozinameran$ or comirnaty$).tw. (7942)
22 exp BNT162 Vaccine/ (3728)	23 exp elasomeran/ (6913)
23 (BNT162b2$ or tozinameran$ or comirnaty$).tw. (5076)	24 (mRNA-1273$ or elasomeran$ or spikevax$).tw. (4387)
24 exp 2019-nCoV Vaccine mRNA-1273/ (871)	25 21 or 22 or 23 or 24 (12824)
25 (mRNA-1273$ or elasomeran$ or spikevax$).tw. (1914)	26 16 or 20 or 25 (22539)
26 22 or 23 or 24 or 25 (6361)	27 exp myocarditis/ (40755)
27 17 or 21 or 26 (12042)	28 myocardi$.tw. (621658)
28 exp Myocarditis/ (17460)	29 exp pericarditis/ (24169)
29 myocardi$.tw. (440133)	30 pericardi$.tw. (68236)

30 exp Pericarditis/ (12601)

31 pericardi$.tw. (49021)

32 myopericardi$.tw. (928)

33 28 or 29 or 30 or 31 or 32 (488555)

34 27 and 33 (793)

31 myopericardi$.tw. (1440)

32 27 or 28 or 29 or 30 or 31 (695443)

33 26 and 32 (1549)

Cochrane Library Central Register of Controlled Trials (CENTRAL) - Issue 1 of 12, January 2024: COVID-19 mRNA vaccines and myocarditis/pericarditis (as at 17.01.24)

Notes: No date limits applied.

ID Search Hits

#1 MeSH descriptor: [COVID-19] explode all trees 5024

#2 (2019 NEXT nCoV OR 2019nCoV OR "n CoV" OR nCoV):ti,ab,kw 404

#3 ("covid 19" OR "covid-19" OR covid19):ti,ab,kw 17999

#4 MeSH descriptor: [SARS-CoV-2] 1 tree(s) exploded 0

#5 ("Severe Acute Respiratory Syndrome Coronavirus 2" OR "Severe Acute Respiratory Syndrome Coronavirus-2" OR "SARS coronavirus 2" OR "SARS coronavirus-2"):ti,ab,kw 2082

#6 ("SARS CoV2" OR "SARS-CoV2" OR SARSCoV2 OR "SARS-CoV-2"):ti,ab,kw 840

#7 #1 OR #2 OR #3 OR #4 OR #5 OR #6 18275

#8 MeSH descriptor: [Immunization] explode all trees 6981

#9 MeSH descriptor: [Immunization Programs] explode all trees 307

#10 MeSH descriptor: [Vaccines] explode all trees 16164

#11 (vaccin* OR immunis* OR immuniz*):ti,ab,kw 34229

#12 #8 OR #9 OR #10 OR #11 34424

#13 #7 AND #12 2896

#14 MeSH descriptor: [COVID-19 Vaccines] explode all trees 501

#15	#13 OR #14	2896
#16	(Pfizer* OR BioNTech* OR Moderna*):ti,ab,kw	3277
#17	#15 AND #16	206
#18	MeSH descriptor: [mRNA Vaccines] explode all trees	122
#19	((rna OR mrna OR (messenger NEAR/1 rna)) NEAR/3 vaccin*):ti,ab,kw	597
#20	#18 OR #19	633
#21	#15 AND #20	475
#22	MeSH descriptor: [BNT162 Vaccine] explode all trees	83
#23	(BNT162b2* OR tozinameran* OR comirnaty*):ti,ab,kw	301
#24	MeSH descriptor: [2019-nCoV Vaccine mRNA-1273] explode all trees	41
#25	(mRNA-1273* OR elasomeran* OR spikevax*):ti,ab,kw	164
#26	#22 OR #23 OR #24 OR #25	393
#27	#17 OR #21 OR #26	665
#28	MeSH descriptor: [Myocarditis] explode all trees	169
#29	myocardi*:ti,ab,kw	52213
#30	MeSH descriptor: [Pericarditis] explode all trees	111
#31	pericardi*:ti,ab,kw	2039
#32	myopericardi*:ti,ab,kw	13
#33	#28 OR #29 OR #30 OR #31 OR #32	53904
#34	#27 AND #33	7

References

Should people aged 6 months and above receive a single dose of the updated formulation COVID-19 vaccine following a previous dose within the past 6–12 months?

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