

Literature screening report

COVID-19 vaccines approved in Switzerland Report (1)

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Abstract

This report provides a review of the **four** Swiss authorized COVID-19 vaccines: BNT162b2/COMIRNATY (Pfizer-BioNTech, USA), Spikevax/Moderna COVID-19 Vaccine/ mRNA-1273 (Moderna, USA), Janssen Covid-19 vaccine/ Ad26CoV2.S/ Johnson & Johnson (Janssen, USA), and Novavax/ NXV-CoV2373/ COVAVAX (USA, India)]. The current report provides the methodology and summarizes the latest data on COVID-19 vaccine-related literature from 01 November 2022 to 13 February 2023 in the form of an Excel document containing extracted data for each included study. The Excel document can be found in the supplementary material.





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Preamble

A large number of scientific publications become available on a daily basis, reflecting the rapid development of knowledge and progress of science on COVID-19 related issues. Leading authorities should base decisions or policies on this knowledge; hence they need to master the actual state of this knowledge. Due to the large number of publications shared daily, decision makers heavily depend on accurate summaries of these publications, in the different public health domains. Therefore, the authors of this report were mandated by the Swiss School of Public Health plus (SSPH+), upon request of the Federal Office of Public Health (FOPH), to inform the FOPH on recent findings from the literature.





Executive Summary

COVID-19 vaccines are crucial tools for reducing mortality, hospitalization and severe disease caused by the COVID-19 pandemic. As of February 2023, approximately 69% of the Swiss population has received their second dose of the COVID-19 vaccine, for which they are considered to be fully vaccinated (<u>1</u>). Despite studies having demonstrated the effectiveness of COVID-19 vaccines towards severe forms of SARS-CoV-2 infection, there are knowledge gaps around the duration of protection of first-generations vaccines against the ever-changing new variants. In Switzerland, four COVID-19 vaccines (Pfizer/BioNTech, Moderna, Janssen, and Novavax) have been authorized for use in the adult population. Furthermore, the Moderna Omicron adapted bivalent vaccine was also approved to be used in adults on 29 August 2022 (<u>2</u>), followed by the Pfizer Omicron adapted bivalent vaccine from 10 October 2022 (<u>3</u>). As for the pediatric population, children aged 5 to 11 can be vaccinated with the Pfizer/BioNTech vaccine and those aged 12 to 17 can be vaccinated with the Pfizer/BioNTech or Moderna vaccines.

This report monitors the literature on COVID-19 vaccine for Swiss approved vaccines with a special focus on effectiveness and transmission against the Omicron variant and its subvariants, safety and adverse events, and long-COVID. Previous reports can be accessed on the <u>Swiss Federal Office of Public Health</u> website alongside the previous <u>Data Extraction</u> <u>Table</u> from October 2022.

Please note that this report is published monthly. The next report will be published at the end of March 2023.

This month's report contains updates on COVID-19 vaccines (BNT162b2, mRNA-1273, and Ad26.COV2.S) effectiveness against infection and hospitalization and/or death, the effectiveness of bivalent boosters (BNT162b2 and mRNA-1273), the effectiveness for the BA.4/BA.5 subvariants, and the vaccine effectiveness in immunocompromised, elderly adults, and pregnant women. In addition, updates on the risk of myocarditis and pericarditis, and the effectiveness against transmission are included.





Methodology

To produce a report with the most up-to-date information on the effectiveness of COVID-19 vaccination and their safety and reported adverse events, a rapid systematic review adhering to the PRISMA guidelines was conducted. Literature published since 01 November 2022 up to 13 February 2023 were included in this report. This time period was chosen since the previous report monitoring the literature on COVID-19 vaccine for Swiss approved vaccines, included studies up to 31 October 2022. The previous report can be accessed on the <u>Swiss</u> <u>Federal Office of Public Health</u> website alongside the previous <u>Data Extraction Table</u> from October 2022.

Literature and Information Search

To identify potentially relevant studies, we searched for the literature published since 01 November 2022 up to 13 February 2023 in the following electronic databases: Medline (PubMed), Embase, MedRxiv & BioRxiv, Cochrane Library, SSRN. In addition, the grey literature such as data produced by government agencies, academic institutions, and press releases were screened and hand searched. A design strategy composed of text words (e.g., coronavirus disease), MeSH terms or Emtree terms (e.g., covid-19 vaccine), Boolean terms (e.g., AND, OR) and truncations (e.g., immune*) to electronically identify studies related to SARS-CoV-2 vaccines effectiveness and/or safety was utilized.

Eligibility of Studies

Eligible studies were those reporting any data about efficacy and/or effectiveness (e.g., prevention of SARS-CoV-2 infection), booster doses, duration of protection, variants, and safety (e.g., adverse events) of COVID-19 vaccines approved in Switzerland. No language restriction was used but the studies were limited by publication date (01 November 2022 to 13 February 2023). Any study design using mathematical modelling was excluded. Emphasis was made to include studies focusing on the Omicron variant and its subvariants.

Risk of Bias (Quality) Assessment

For the quality assessment, we created a customizable checklist based on the STROBE and ROBINS-E checklist/tool including 7 domains (2 questions on Generalizability and 5 questions on Risk of Bias) and 13 questions on the overall reporting quality. A traffic light system was used to classify studies as High, Mid-, or Low Confidence where green is 'High Confidence' (study is complete, comprehensive, and adequately reports methods, biases, and results), yellow is 'Mid-confidence' (study is comprehensive but moderately reports methods, biases, and results), and red is 'Low Confidence' (study is incomplete and does not adequately report methods, biases, and results. In addition, we evaluated the quality of the reporting by classifying studies into two categories: Good or Poor. A more detailed explanation including the criteria for classification and the questions used to assess and determine the final quality assessment can be in Supplementary Material 1.





Data Abstraction and Analysis

We extracted data from eligible studies, which include, but are not limited to, vaccine effectiveness as well as safety and adverse events. We categorized the data into different sections: vaccine effectiveness, safety and adverse events, transmission, and long COVID. We analyzed the data based on the vaccine type, vaccine doses (primary schedule and booster doses), and topics (e.g., effectiveness, duration of protection, variants, safety, and heterologous vaccines). Information extracted from studies included study characteristics, population characteristics, intervention details, variants, and results. The variables covering the study characteristics are 'Author', 'Title/ URL', 'Publication Date', 'Journal', 'Peerreviewed?', 'Sponsor/ Funding', 'Country', 'Study Timeframe', 'Study Design', and 'Sample size/ number of participants'. The variables for population characteristics are 'Subgroup/ Demographic', 'Immune Status', 'Age interval', 'Age group', and 'Prior Infection'. The variables for intervention details are 'Effect size', 'Vaccine Schedule', 'Vaccine Platform', 'Vaccine Type', 'Infection Variant', 'Exposure', 'Outcome', 'Time since Most Recent Dose', 'Duration of Interval', and 'Variant'. As for the variables for results, the variables 'Vaccine Effectiveness (95% CI)', and 'Results (OR, HR, RR, IRR)' were included in the table. In addition to those variables, the table includes a variable for notes/comments.

Synthesis of Information

The information was summarized in the form of an Excel table containing key data on the variables of interest cited above.



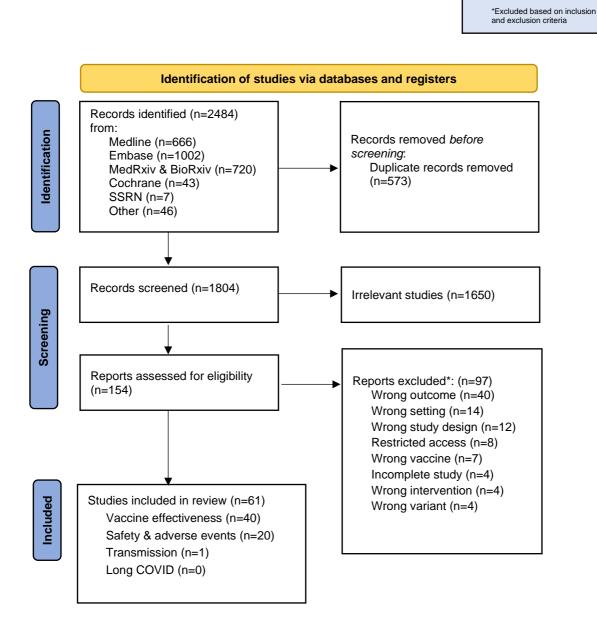


Legend:

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Results

Figure 1. PRISMA Flowchart of included studies





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Summary of Results

A total of 61 studies were identified from our selected databases, of which 573 studies were identified as duplicates and were discarded. Our team screened a total of 1804 studies for potential relevance and excluded 1650 for not meeting the eligibility criteria and being irrelevant. Overall 154 studies were reviewed of which 97 were excluded for reporting on the wrong outcome (n=40), using the wrong study setting (n=14), using the wrong study design (n=12), having restricted access (n=8), analyzing the wrong vaccine brand (n=7), being incomplete (n=4), reporting on the wrong intervention (n=4), and reporting on the wrong variant (n=4). A total of 61 studies were included, of which 40 reported on vaccine effectiveness, 20 on safety and adverse events, 1 on transmission, and 0 on long-COVID.

Summary of Quality Assessment Results

	Number of Studies (n=61)			
Assessment	Vaccine effectiveness	Safety & Adverse Events	Transmission	Long-COVID
High Confidence + Good	0	3	0	0
High Confidence + Poor	0	0	0	0
Mid-confidence + Good	37	17	1	0
Mid-confidence + Poor	0	0	0	0
Low confidence + Good	1	0	0	0
Low confidence + Poor	2	0	0	0

Table 1. Quality Assessment of Included Studies*

*Traffic light system is only based on the (High, Mid-, and Low) assessment of studies. The overall reporting quality (Good or Poor) is independent and is not represented by the traffic light system.



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Vaccine Effectiveness

Effectiveness against infection

Overall 24 studies reported on infection (including asymptomatic and symptomatic infections, and outpatients) (4-27). Table 2 provides a list of the studies and their quality assessment.

Table 2. Studies on Effectiveness against Infection

Study	Quality Assessment	
Six-Month Follow-up after a Fourth BNT162b2 Vaccine	Mid-confidence + Good	
Effectiveness of primary series and booster vaccination against SARS-CoV-2 infection and hospitalisation among adolescents aged 12–17 years in Singapore: a national cohort study	Mid-confidence + Good	
Comparative effectiveness of third doses of mRNA-based COVID-19 vaccines in US veterans	Mid-confidence + Good	
Initial protection against SARS-CoV-2 omicron lineage infection in children and adolescents by BNT162b2 in Israel: an observational study	Mid-confidence + Good	
BNT162b2 and mRNA-1273 Vaccine Effectiveness against SARS-CoV-2 and Variants in the Urban Underserved Population	Mid-confidence + Good	
BNT162b2 vaccine effectiveness against SARS-CoV-2 omicron BA.4 and BA.5	Mid-confidence + Good	
Covid-19 Vaccine Protection among Children and Adolescents in Qatar	Mid-confidence + Good	
Effectiveness of BNT162b2 and CoronaVac in children and adolescents against SARS-CoV-2infection during Omicron BA.2 wave in Hong Kong	Mid-confidence + Good	
Effectiveness of mRNA vaccines against SARS-CoV-2 infections during the periods of Delta and Omicron variant predominance in Japan: The VENUS Study	Mid-confidence + Good	
Effectiveness of a Third Dose of COVID-19 mRNA Vaccine During the Omicron BA.1- and BA.2-Predominant Periods in Japan: The VENUS Study	Mid-confidence + Good	
Effectiveness of Vaccination and Previous Infection Against Omicron Infection and Severe Outcomes in Children Under 12 Years of Age	Mid-confidence + Good	
Coronavirus Disease 19 (COVID-19) Vaccine Effectiveness Against Symptomatic Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection During Delta- Dominant and Omicron-Dominant Periods in Japan: A Multicenter Prospective Case-control Study (Factors Associated with SARS-CoV-2 Infection and the Effectiveness of COVID-19 Vaccines Study)		
Effectiveness of Bivalent mRNA Vaccines in Preventing Symptomatic SARS-CoV-2 Infection — Increasing Community Access to Testing Program, United States, September–November 2022	Mid-confidence + Good	





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Relative effectiveness of a 2nd booster dose of COVID-19 mRNA vaccine up to four months post administration in individuals aged 80 years or more in Italy: A retrospective matched cohort study	Mid-confidence + Good	
Effectiveness of mRNA COVID-19 Vaccine Boosters Against Infection, Hospitalization, and Death: A Target Trial Emulation in the Omicron (B.1.1.529) Variant Era	Mid-confidence + Good	
Estimated BNT162b2 Vaccine Effectiveness Against Infection With Delta and Omicron Variants Among US Children 5 to 11 Years of Age	Mid-confidence + Good	
Effectiveness of mRNA-1273 vaccination against SARS- CoV-2 omicron subvariants BA.1, BA.2, BA.2.12.1, BA.4, and BA.5	Mid-confidence + Good	
Effectiveness of a Second COVID-19 Vaccine Booster Dose Against Infection, Hospitalization, or Death Among Nursing Home Residents — 19 States, March 29–July 25, 2022	Mid-confidence + Good	
Association between primary or booster COVID-19 mRNA vaccination and Omicron lineage BA.1 SARS-CoV-2 infection in people with a prior SARS-CoV-2 infection: A test-negative case–control analysis	Mid-confidence + Good	
Prior SARS-CoV-2 Infection and COVID-19 Vaccine Effectiveness against Outpatient Illness during Widespread Circulation of SARS-CoV-2 Omicron Variant, US Flu VE Network	Mid-confidence + Good	
Relative effectiveness of COVID-19 vaccination and booster dose combinations among 18.9 million vaccinated adults during the early SARS-CoV-2 Omicron period — United States, January 1, 2022–March 31, 2022	Mid-confidence + Good	
Protection afforded by prior infection, vaccination, and hybrid immunity against symptomatic BA.1 and BA.2 Omicron infections	Low confidence + Poor	
<u>BNT162b2 Vaccine Effectiveness Against theSARS-CoV-2</u> Omicron Variant in Children Aged 5 to <u>11 Years</u>	Low confidence + Good	
Real-world vaccine effectiveness of mRNA vaccines for SARS-CoV-2; a test-negative case-control study in a medium-sized clinicLow confidence + Poc Low confidence + Poc		

Quality Assessment		
High Confidence	Study is complete, comprehensive and adequately reports methods, biases, and results	
Medium Confidence	Study is comprehensive but moderately reports methods, biases, and results	
Low Confidence	Study is incomplete and does not adequately report methods, biases, and results	





Effectiveness against hospitalization and/or death

A total of 26 studies reported on hospitalization and/or death (including critical infection, emergency department and urgent care, ICU admissions, and severe outcomes) (<u>6-8</u>, <u>11</u>, <u>15</u>, <u>16</u>, <u>18</u>, <u>19</u>, <u>23</u>, <u>25</u>, <u>26</u>, <u>28-42</u>). Table 3 provides a list of the studies and their quality assessment.

Study	Quality Assessment
Comparative effectiveness of third doses of mRNA-based COVID-19 vaccines in US veterans	Mid-confidence + Good
Effectiveness of COVID-19 mRNA Vaccines Against COVID-19– Associated Hospitalizations Among Immunocompromised Adults During SARS-CoV-2 Omicron Predominance — VISION Network, 10	Mid-confidence + Good
States, December 2021–August 2022 Effectiveness of primary series and booster vaccination against SARS-CoV-2 infection and hospitalisation among adolescents aged 12–17 years in Singapore: a national cohort study	Mid-confidence + Good
Prior infection- and/or vaccine-induced protection against Omicron BA.1, BA.2 and BA.4/BA.5-related hospitalisations in older adults: a test-negative case-control study in Quebec, Canada	Mid-confidence + Good
Effectiveness of mRNA-1273, BNT162b2, and BBIBP-CorV vaccines against infection and mortality in children in Argentina, during predominance of delta and omicron covid-19 variants: test negative, case-control study	Mid-confidence + Good
Effectiveness of BNT162b2 COVID-19 vaccination in prevention of hospitalisations and severe disease in adults with SARS-CoV-2 Delta (B.1.617.2) and Omicron (B.1.1.529) variant between June 2021 and July 2022: a prospective test negative case-control study	Mid-confidence + Good
Effectiveness of Messenger RNA-1273 Vaccine Booster Against Coronavirus Disease 2019 in Immunocompetent Adults	Mid-confidence + Good
BNT162b2 vaccine effectiveness against SARS-CoV-2 omicron BA.4 and BA.5	Mid-confidence + Good
Effectiveness of a third BNT162b2 mRNA COVID-19 vaccination during pregnancy a national observational study in Israel	Mid-confidence + Good
Effectiveness of the COVID-19 vaccines against hospitalisation with Omicron sub-lineages BA.4 and BA.5 in England	Mid-confidence + Good
Effectiveness of Vaccination and Previous Infection Against Omicron Infection and Severe Outcomes in Children Under 12 Years of Age	Mid-confidence + Good
Effectiveness of Monovalent mRNA Vaccines Against COVID-19– Associated Hospitalization Among Immunocompetent Adults During BA.1/BA.2 and BA.4/BA.5 Predominant Periods of SARS-CoV-2 Omicron Variant in the United States — IVY Network, 18 States, December 26, 2021–August 31, 2022	Mid-confidence + Good
Estimation of Vaccine Effectiveness of CoronaVac and BNT162b2 Against Severe Outcomes Over Time Among Patients With SARS- CoV-2 Omicron	Mid-confidence + Good
Relative effectiveness of a 2nd booster dose of COVID-19 mRNA vaccine up to four months post administration in individuals aged 80 years or more in Italy: A retrospective matched cohort study	Mid-confidence + Good
Effectiveness of mRNA COVID-19 vaccine booster doses against Omicron severe outcomes	Mid-confidence + Good

Table 3. Studies on Effectiveness aga	ainst Hospitalization and/or Death
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Effectiveness of mRNA COVID-19 Vaccine Boosters Against Infection, Hospitalization, and Death: A Target Trial Emulation in the	Mid-confidence + Good
Omicron (B.1.1.529) Variant Era	
Effectiveness and durability of BNT162b2 vaccine against hospital	
and emergency department admissions due to SARS-CoV-2 omicron	Mid-confidence + Good
sub-lineages BA.1 and BA.2 in a large health system in the USA: a	
test-negative, case-control study	
Effectiveness of mRNA-1273 vaccination against SARS-CoV-2	Mid-confidence + Good
omicron subvariants BA.1, BA.2, BA.2.12.1, BA.4, and BA.5	
Effectiveness of a Second COVID-19 Vaccine Booster Dose Against	
Infection, Hospitalization, or Death Among Nursing Home Residents	Mid-confidence + Good
<u>— 19 States, March 29–July 25, 2022</u>	
Early Estimates of Bivalent mRNA Vaccine Effectiveness in	
Preventing COVID-19–Associated Hospitalization Among	Mid-confidence + Good
Immunocompetent Adults Aged ≥65 Years — IVY Network, 18	
States, September 8–November 30, 2022	
Early Estimates of Bivalent mRNA Vaccine Effectiveness in	
Preventing COVID-19–Associated Emergency Department or Urgent	Mid-confidence + Good
Care Encounters and Hospitalizations Among Immunocompetent	Mid-confidence + Good
Adults — VISION Network, Nine States, September-November 2022	
Relative effectiveness of COVID-19 vaccination and booster dose	
combinations among 18.9 million vaccinated adults during the early	Mid confidence + Cood
SARS-CoV-2 Omicron period — United States, January 1, 2022-	Mid-confidence + Good
March 31, 2022	
Relative effectiveness of COVID-19 vaccination with 3 compared to 2	
doses against SARS-CoV-2 B.1.1.529 (Omicron) among an	Mid-confidence + Poor
Australian population with low prior rates of SARS-CoV-2 infection	
Effectiveness of Messenger RNA-based Vaccines During the	
Emergence of the Severe Acute Respiratory Syndrome Coronavirus	Mid-confidence + Poor
2 Omicron Variant	
Protection afforded by prior infection, vaccination, and hybrid	
immunity against symptomatic BA.1 and BA.2 Omicron infections	Low confidence + Poor
BNT162b2 Vaccine Effectiveness Against the SARS-CoV-2 Omicron	
Variant in Children Aged 5 to 11 Years	Low confidence + Good
variant in Children Aged 5 to 11 teals	

Quality Assessment		
High Confidence	Study is complete, comprehensive and adequately reports methods, biases, and results	
Medium Confidence	Study is comprehensive but moderately reports methods, biases, and results	
Low Confidence	Study is incomplete and does not adequately report methods, biases, and results	





Effectiveness of bivalent booster

Six studies reported on the effectiveness of bivalent booster against Omicron infection and hospitalization ($\underline{8}$, $\underline{13}$, $\underline{19}$, $\underline{28}$, $\underline{29}$, $\underline{43}$). Table 4 provides a list of the studies and their quality assessment.

Table 4. Studies on Effectiveness of Bivalent Booster

Study	Quality Assessment
Comparative effectiveness of third doses of mRNA-based COVID-19 vaccines in US veterans	Mid-confidence + Good
Effectiveness of Vaccination and Previous Infection Against Omicron Infection and Severe Outcomes in Children Under 12 Years of Age	Mid-confidence + Good
Effectiveness of Bivalent mRNA Vaccines in Preventing Symptomatic SARS-CoV-2 Infection — Increasing Community Access to Testing Program, United States, September–November 2022	Mid-confidence + Good
Effectiveness of Bivalent Boosters against Severe Omicron Infection	Mid-confidence + Good
Early Estimates of Bivalent mRNA Vaccine Effectiveness in Preventing COVID-19–Associated Hospitalization Among Immunocompetent Adults Aged ≥65 Years — IVY Network, 18 States, September 8–November 30, 2022	Mid-confidence + Good
Early Estimates of Bivalent mRNA Vaccine Effectiveness in Preventing COVID-19–Associated Emergency Department or Urgent Care Encounters and Hospitalizations Among Immunocompetent Adults — VISION Network, Nine States, September–November 2022	Mid-confidence + Good

Quality Assessment		
High Confidence	Study is complete, comprehensive and adequately reports methods, biases, and results	
Medium Confidence	Study is comprehensive but moderately reports methods, biases, and results	
Low Confidence	Study is incomplete and does not adequately report methods, biases, and results	





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Effectiveness against BA.4 and/or BA.5

Seven studies evaluated the vaccine effectiveness of COVID-19 vaccines for the Omicron BA.4 and/or BA.5 subvariants ($\underline{6}$, $\underline{15}$, $\underline{20}$, $\underline{33}$, $\underline{36}$, $\underline{38}$, $\underline{41}$). Table 5 provides a list of the studies and their quality assessment.

Table 5.	Studies on	Effectiveness	against BA.4	and/or BA	.5 Subvariant
	olucio on	LICOUVENESS	against DA.4		

Study	Quality Assessment
Effectiveness of COVID-19 mRNA Vaccines Against COVID-19– Associated Hospitalizations Among Immunocompromised Adults During SARS-CoV-2 Omicron Predominance — VISION Network, 10 States, December 2021–August 2022	Mid-confidence + Good
Prior infection- and/or vaccine-induced protection against Omicron BA.1, BA.2 and BA.4/BA.5-related hospitalisations in older adults: a test-negative case-control study in Quebec, Canada	Mid-confidence + Good
BNT162b2 vaccine effectiveness against SARS-CoV-2 omicron BA.4 and BA.5	Mid-confidence + Good
Effectiveness of Monovalent mRNA Vaccines Against COVID-19– Associated Hospitalization Among Immunocompetent Adults During BA.1/BA.2 and BA.4/BA.5 Predominant Periods of SARS-CoV-2 Omicron Variant in the United States — IVY Network, 18 States, December 26, 2021–August 31, 2022	Mid-confidence + Good
Effectiveness of mRNA COVID-19 vaccine booster doses against Omicron severe outcomes	Mid-confidence + Good
Estimated BNT162b2 Vaccine Effectiveness Against Infection With Delta and Omicron Variants Among US Children 5 to 11 Years of Age	Mid-confidence + Good
Effectiveness of mRNA-1273 vaccination against SARS-CoV-2 omicron subvariants BA.1, BA.2, BA.2.12.1, BA.4, and BA.5	Mid-confidence + Good

Quality Assessment		
High Confidence	Study is complete, comprehensive and adequately	
	reports methods, biases, and results	
Medium Confidence	Study is comprehensive but moderately reports	
	methods, biases, and results	
Low Confidence	Study is incomplete and does not adequately report	
	methods, biases, and results	





Effectiveness in Immunocompromised Individuals

Eleven studies included immunocompromised participants, but only 1 study stratified results for immunocompromised individuals (<u>33</u>). Table 6 provides a list of the studies and their quality assessment.

Table 6. Studies on Effectiveness in Immunocompromised Individuals

Study	Quality Assessment
Effectiveness of COVID-19 mRNA Vaccines Against COVID-19– Associated Hospitalizations Among Immunocompromised Adults	
During SARS-CoV-2 Omicron Predominance — VISION Network, 10 States, December 2021–August 2022	Mid-confidence + Good

Quality Assessment		
High Confidence	Study is complete, comprehensive and adequately reports methods, biases, and results	
Medium Confidence	Study is comprehensive but moderately reports methods, biases, and results	
Low Confidence	Study is incomplete and does not adequately report methods, biases, and results	





Effectiveness in Elderly Adults

Nine studies evaluated the effectiveness of COVID-19 vaccines in older adults and stratified it by older age groups (≥ 60 years old) (5, 8, 12, 13, 16, 26, 32, 34, 38). Table 7 provides a list of the studies and their quality assessment.

Study	Quality Assessment
Comparative effectiveness of third doses of mRNA-based COVID-19 vaccines in US veterans	Mid-confidence + Good
BNT162b2 and mRNA-1273 Vaccine Effectiveness against SARS- CoV-2 and Variants in the Urban Underserved Population	Mid-confidence + Good
Effectiveness of BNT162b2 COVID-19 vaccination in prevention of hospitalisations and severe disease in adults with SARS-CoV-2 Delta (B.1.617.2) and Omicron (B.1.1.529) variant between June 2021 and July 2022: a prospective test negative case-control study	Mid-confidence + Good
Effectiveness of Messenger RNA-1273 Vaccine Booster Against Coronavirus Disease 2019 in Immunocompetent Adults	Mid-confidence + Good
Effectiveness of a Third Dose of COVID-19 mRNA Vaccine During the Omicron BA.1- and BA.2-Predominant Periods in Japan: The VENUS Study	Mid-confidence + Good
Effectiveness of Bivalent mRNA Vaccines in Preventing Symptomatic SARS-CoV-2 Infection — Increasing Community Access to Testing Program, United States, September–November 2022	Mid-confidence + Good
Effectiveness of mRNA COVID-19 vaccine booster doses against Omicron severe outcomes	Mid-confidence + Good
Effectiveness of mRNA COVID-19 Vaccine Boosters Against Infection, Hospitalization, and Death: A Target Trial Emulation in the Omicron (B.1.1.529) Variant Era	Mid-confidence + Good
Relative effectiveness of COVID-19 vaccination and booster dose combinations among 18.9 million vaccinated adults during the early SARS-CoV-2 Omicron period — United States, January 1, 2022– March 31, 2022	Mid-confidence + Good

Quality Assessment		
High Confidence	Study is complete, comprehensive and adequately	
Thigh confidence	reports methods, biases, and results	
Medium Confidence	Study is comprehensive but moderately reports	
	methods, biases, and results	
Low Confidence	Study is incomplete and does not adequately report	
	methods, biases, and results	





Effectiveness in Pregnant Women

Only 1 study evaluated the effectiveness of COVID-19 vaccination in pregnant women (31). Table 8 provides the quality assessment of this study.

Table 8. Studies on Effectiveness in Pregnant Women

Study	Quality Assessment
Effectiveness of a third BNT162b2 mRNA COVID-19 vaccination during pregnancy a national observational study in Israel	Mid-confidence + Good
during pregnancy a national observational study in Israel	

Quality Assessment		
High Confidence	Study is complete, comprehensive and adequately reports methods, biases, and results	
Medium Confidence	Study is comprehensive but moderately reports methods, biases, and results	
Low Confidence	Study is incomplete and does not adequately report methods, biases, and results	





Safety and Adverse Events

Myocarditis & Pericarditis

Overall 14 studies reported on the risk of myocarditis and pericarditis after receiving COVID-19 vaccines (44-57). Table 9 provides a list of the studies and their quality assessment.

Table 9. Studies on Myocarditis and Pericarditis

Study	Quality Assessment
<u>Myocarditis and pericarditis associated with SARS-CoV-2 vaccines:</u> <u>A population-based descriptive cohort and a nested self-controlled</u> <u>risk interval study using electronic health care data from four</u> <u>European countries</u>	High confidence + Good
Analysis of Myocarditis Among 252 Million mRNA-1273 Recipients Worldwide	High confidence + Good
Increased risk of myocarditis and pericarditis and reduced likelihood of severe clinical outcomes associated with COVID-19 vaccination: a cohort study in Lombardy, Italy	Mid-confidence + Good
Comparative assessment of myocarditis and pericarditis reporting rates related to mRNA COVID-19 vaccines in Europe and the United States	Mid-confidence + Good
Booster Vaccination with SARS-CoV-2 mRNA Vaccines and Myocarditis Risk in Adolescents and Young Adults: A Nordic Cohort Study of 8.9 Million Residents	Mid-confidence + Good
Risks of Myocarditis and Pericarditis Following Vaccination with SARS-CoV-2 mRNA Vaccines in Japan: An Analysis of Spontaneous Reports of Suspected Adverse Events	Mid-confidence + Good
Observed versus expected rates of myocarditis after SARS-CoV-2 vaccination: a population-based cohort study	Mid-confidence + Good
Comparative Risk of Myocarditis/Pericarditis Following Second Doses of BNT162b2 and mRNA-1273 Coronavirus Vaccines	Mid-confidence + Good
Evaluation of Potential Adverse Events Following COVID-19 mRNA Vaccination Among Adults Aged 65 Years and Older: A Self- Controlled Study in the U.S	Mid-confidence + Good
Acute myocarditis following a third dose of COVID-19 mRNA vaccination in adults	Mid-confidence + Good
Adverse events following the BNT162b2 mRNA COVID-19 Vaccine (Pfizer-BioNTech) in Aotearoa New Zealand	Mid-confidence + Good
Adverse events of special interest following the use of BNT162b2 in adolescents: a population-based retrospective cohort study	Mid-confidence + Good
Risk of Myocarditis and Pericarditis Following Coronavirus Disease 2019 Messenger RNA Vaccination—A Nationwide Study	Mid-confidence + Good
Safety of the fourth COVID-19 BNT162b2 mRNA (second booster) vaccine: a prospective and retrospective cohort study	Mid-confidence + Good

Quality Assessment		
High Confidence	Study is complete, comprehensive and adequately	
	reports methods, biases, and results	
Medium Confidence	Study is comprehensive but moderately reports	
	methods, biases, and results	
Low Confidence	Study is incomplete and does not adequately report	
	methods, biases, and results	



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Transmission

Table 10. Studies on Transmission

Only one study evaluated the mRNA vaccine effectiveness against SARS-CoV-2 transmission from home care cases to household contacts (58). The study found that for the Omicron variant, a 64% vaccine effectiveness against transmission was found among infected individuals who received mRNA vaccination less than 90 days from their most recent dose (58). Table 10 provides the quality assessment of this study.

Study	Quality Assessment
mRNA vaccine effectiveness against SARS-CoV-2 B.1.617.2 (Delta) and B.1.1.529 (Omicron) variant transmission from home care cases to household contacts in South Korea	Mid confidence + Good

Quality Assessment	
High Confidence	Study is complete, comprehensive and adequately reports methods, biases, and results
Medium Confidence	Study is comprehensive but moderately reports methods, biases, and results
Low Confidence	Study is incomplete and does not adequately report methods, biases, and results

Long COVID

No studies on the effects of COVID-19 vaccines on long-COVID were included in this monthly report.





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