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## TABLE OF CONTENTS

ABSTRACT .....	1
PLAIN LANGUAGE SUMMARY .....	2
SUMMARY OF FINDINGS .....	4
BACKGROUND .....	8
OBJECTIVES .....	9
METHODS .....	9
RESULTS .....	12
Figure 1. ....	13
Figure 2. ....	14
Figure 3. ....	15
DISCUSSION .....	16
AUTHORS' CONCLUSIONS .....	18
ACKNOWLEDGEMENTS .....	18
REFERENCES .....	19
ADDITIONAL TABLES .....	21
APPENDICES .....	29
CONTRIBUTIONS OF AUTHORS .....	49
DECLARATIONS OF INTEREST .....	49
SOURCES OF SUPPORT .....	50
DIFFERENCES BETWEEN PROTOCOL AND REVIEW .....	50
INDEX TERMS .....	51

[Prototype Review]

# Immunity after COVID-19 vaccination in people with higher risk of compromised immune status: a scoping review

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## ABSTRACT

### Background

High efficacy in terms of protection from severe COVID-19 has been demonstrated for several SARS-CoV-2 vaccines. However, patients with compromised immune status develop a weaker and less stable immune response to vaccination. Strong immune response may not always translate into clinical benefit, therefore it is important to synthesise evidence on modified schemes and types of vaccination in these population subgroups for guiding health decisions. As the literature on COVID-19 vaccines continues to expand, we aimed to scope the literature on multiple subgroups to subsequently decide on the most relevant research questions to be answered by systematic reviews.

### Objectives

To provide an overview of the availability of existing literature on immune response and long-term clinical outcomes after COVID-19 vaccination, and to map this evidence according to the examined populations, specific vaccines, immunity parameters, and their way of determining relevant long-term outcomes and the availability of mapping between immune reactivity and relevant outcomes.

## Search methods

We searched the Cochrane COVID-19 Study Register, the Web of Science Core Collection, and the World Health Organization COVID-19 Global literature on coronavirus disease on 6 December 2021.

## Selection criteria

We included studies that published results on immunity outcomes after vaccination with BNT162b2, mRNA-1273, AZD1222, Ad26.COV2.S, Sputnik V or Sputnik Light, BBIBP-CorV, or CoronaVac on predefined vulnerable subgroups such as people with malignancies, transplant recipients, people undergoing renal replacement therapy, and people with immune disorders, as well as pregnant and breastfeeding women, and children. We included studies if they had at least 100 participants (not considering healthy control groups); we excluded case studies and case series.

## Data collection and analysis

We extracted data independently and in duplicate onto an online data extraction form. Data were represented as tables and as online maps to show the frequency of studies for each item. We mapped the data according to study design, country of participant origin, patient comorbidity subgroup, intervention, outcome domains (clinical, safety, immunogenicity), and outcomes.

## Main results

Out of 25,452 identified records, 318 studies with a total of more than 5 million participants met our eligibility criteria and were included in the review. Participants were recruited mainly from high-income countries between January 2020 and 31 October 2021 (282/318); the majority of studies included adult participants (297/318).

Haematological malignancies were the most commonly examined comorbidity group (N = 54), followed by solid tumours (N = 47), dialysis (N = 48), kidney transplant (N = 43), and rheumatic diseases (N = 28, 17, and 15 for mixed diseases, multiple sclerosis, and inflammatory bowel disease, respectively). Thirty-one studies included pregnant or breastfeeding women.

The most commonly administered vaccine was BNT162b2 (N = 283), followed by mRNA-1273 (N = 153), AZD1222 (N = 66), Ad26.COV2.S (N = 42), BBIBP-CorV (N = 15), CoronaVac (N = 14), and Sputnik V (N = 5; no studies were identified for Sputnik Light). Most studies reported outcomes after regular vaccination scheme.

The majority of studies focused on immunogenicity outcomes, especially seroconversion based on binding antibody measurements and immunoglobulin G (IgG) titres (N = 179 and 175, respectively). Adverse events and serious adverse events were reported in 126 and 54 studies, whilst SARS-CoV-2 infection irrespective of severity was reported in 80 studies. Mortality due to SARS-CoV-2 infection was reported in 36 studies.

Please refer to our [evidence gap maps](#) for more detailed information.

## Authors' conclusions

Up to 6 December 2021, the majority of studies examined data on mRNA vaccines administered as standard vaccination schemes (two doses approximately four to eight weeks apart) that report on immunogenicity parameters or adverse events. Clinical outcomes were less commonly reported, and if so, were often reported as a secondary outcome observed in seroconversion or immunoglobulin titre studies. As informed by this scoping review, two effectiveness reviews (on haematological malignancies and kidney transplant recipients) are currently being conducted.

## PLAIN LANGUAGE SUMMARY

### Immunity in vulnerable groups after COVID-19 vaccination

#### What did we want to find out?

We wanted to find out which studies on the most commonly used COVID-19 vaccines in vulnerable subgroups have been published, and which outcomes were reported (e.g. effectiveness outcomes, safety, or immune response), to decide on the most relevant questions and answer these in further effectiveness systematic reviews (syntheses of the medical literature).

#### What did we do?

We searched medical databases and trial registries for studies on COVID-19 vaccines that were authorised for use in the European Union (European Medicines Agency (EMA)-approved) and those approved in at least 10 countries worldwide at the time of our search.

We included studies on additional conditions (comorbidities) that can reduce the immune reaction to vaccination, if they had more than 100 participants; they could include any age, sex, ethnicity, or country of recruitment.

We excluded studies looking at the general population and other than preselected COVID-19 vaccines and subgroups.

Once we found the studies, we categorised the vaccines into the following groups: EMA-approved COVID-19 vaccines, other COVID-19 vaccines, and schemes with different COVID-19 vaccines. We summarised the results in an interactive online map. We mapped the study outcomes, the country in which the study was conducted, the study design, and the vulnerable population.

**What did we find?**

We included 318 studies. Most studies came from high-income countries and included adults. We found that haematological malignancies (cancers that affect the blood, bone marrow, and lymph nodes) and solid tumours were examined in many studies, followed by people receiving dialysis and kidney transplants, rheumatic diseases, and others. Thirty-one studies included pregnant or breastfeeding women. The majority of studies explored mRNA vaccines (N = 283 and N = 153 for BNT162b2 and mRNA-1273) at two doses, and EMA-approved vaccines were more commonly administered than other vaccines and schemes with different COVID-19 vaccines.

Outcomes related to immunogenicity (how well a vaccine works, or the ability to stimulate the development of antibodies), especially the presence or absence of antibodies in the blood of patients or an estimate for the amount of these antibodies, were the most frequently reported outcome in more than 170 studies each. In addition, adverse events were assessed often (N = 126 studies), whilst SARS-CoV-2 infection was reported in only 80 studies.

**What are the limitations of the evidence?**

Due to the quick development of the pandemic, the research landscape may have changed. The newer Omicron variant has become the dominant variant, and a new vaccine has been approved by the EMA, which is not covered by our search.

**How up-to-date is this evidence?**

The evidence is up-to-date to December 2021.

**What are the next steps?**

Based on the overview from this review, we have decided to conduct two detailed systematic reviews on haematological malignancies and kidney transplant recipients.

## SUMMARY OF FINDINGS

### Summary of findings 1. Intervention - outcome\*

Intervention	Clinical				Safety				Immunogenicity							
	SARS-CoV-2 infection, any	SARS-CoV-2 infection, asymptomatic	SARS-CoV-2 infection, symptomatic	SARS-CoV-2 infection, hospitalisation	SARS-CoV-2 infection, mortality	Adverse events (any)	Serious adverse events	Specific adverse events	Seroconversion (binding Ab)	Seroconversion (neutralising Ab)	IgG titre	IgM titre	IgA titre	Neutralising Ab titre	B-cell response other	T-cell response
<b>BNT162b2</b>	72	17	17	40	34	102	43	41	162	38	157	7	7	53	4	33
<b>mRNA-1273</b>	37	11	12	23	16	49	13	22	79	17	79	6	3	24	1	18
<b>AZD1222</b>	11	3	3	8	6	25	10	14	29	9	27	1	2	11	0	11
<b>Ad26.COVS.S</b>	10	4	6	7	5	12	5	8	19	1	20	2	1	4	0	1
<b>Sputnik V</b>	3	1	1	2	1	4	1	2	1	0	1	0	0	0	0	0
<b>Sputnik L</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>BBIBPCorV</b>	2	0	0	1	1	13	5	8	4	4	3	0	0	3	0	0
<b>CoronaVac</b>	2	0	1	3	0	13	3	8	5	5	5	0	0	5	0	0
<b>BNT162b2/AZD1222</b>	1	0	0	1	1	2	0	0	2	2	4	0	1	1	0	2
<b>BNT162b2/mRNA-1273</b>	1	0	0	1	1	0	0	0	1	1	1	0	0	1	0	1
<b>Other heterologous schemes</b>	3	1	1	3	1	6	1	4	4	1	4	0	0	1	0	3

Abbreviations: Ab: antibody, Ig: immunoglobulin, SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

An interactive evidence gap map is available at [egmopenaccess.3ieimpact.org/evidence-maps/scoping-review-covid-19-vaccines](https://egmopenaccess.3ieimpact.org/evidence-maps/scoping-review-covid-19-vaccines) (for filtering according to subgroups, please see [Summary of findings 2](#); multicountry studies cannot be filtered).



\*The overall number of studies was 286, excluding studies on pregnant and lactating women due to a different outcome set.

**Summary of findings 2. Subgroup - outcome\***

Subgroup	Clinical (N studies, N population)				Safety			Immunogenicity								
	SARS-CoV-2 infection, any	SARS-CoV-2 infection, asymptomatic	SARS-CoV-2 infection, symptomatic	SARS-CoV-2 infection, hospitalisation	SARS-CoV-2 infection, mortality	Adverse events (any)	Serious adverse events	Specific adverse events	Seroconversion (binding Ab)	Seroconversion (neutralising Ab)	IgG titre	IgM titre	IgA titre	Neutralising Ab titre	B-cell response other	T-cell response
<b>Solid tumours</b>	11 (167,485)	4 (1003)	3 (96,584)	8 (174,587)	6 (166,084)	23 (5645)	10 (2227)	4 (1187)	30 (7851)	8 (1466)	27 (5778)	1 (141)	1 (141)	10 (1409)	1 (136)	4 (807)
<b>Haematological malignancies</b>	16 (37,390)	2 (320)	2 (32,294)	7 (38,206)	5 (35,278)	17 (3154)	10 (2125)	3 (226)	39 (8133)	15 (2553)	35 (6669)	4 (736)	3 (576)	19 (3401)	1 (123)	9 (1459)
<b>Haematological malignancies, stem cell transplant</b>	9 (1379)	1 (113)	1 (113)	3 (437)	4 (457)	15 (1818)	8 (1287)	4 (461)	16 (1863)	3 (392)	18 (2261)	1 (23)	1 (23)	6 (699)	1 (20)	3 (253)
<b>Kidney disease, excluding dialysis</b>	2 (41,759)	1 (162)	1 (162)	2 (41,759)	1 (41,597)	1 (162)	0 (0)	0 (0)	4 (144)	0 (0)	3 (122)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>Dialysis</b>	17 (179,469)	4 (5321)	4 (5622)	10 (166,727)	10 (167,721)	15 (6403)	9 (3473)	0 (0)	41 (181,208)	9 (5106)	38 (21,892)	3 (452)	3 (381)	10 (9869)	0 (0)	8 (4653)
<b>Chronic heart disease</b>	5 (72,841)	1 (615)	3 (71,361)	3 (72,549)	2 (71,934)	5 (1106)	1 (86)	0 (0)	6 (598)	1 (262)	5 (577)	0 (0)	0 (0)	2 (283)	0 (0)	1 (262)
<b>Liver disease</b>	4 (40,275)	0 (0)	0 (0)	2 (40,174)	2 (40,174)	4 (574)	3 (562)	0 (0)	4 (241)	2 (393)	4 (241)	0 (0)	0 (0)	2 (393)	0 (0)	2 (60)
<b>Lung disease</b>	2 (1939)	1 (1893)	1 (1893)	2 (1997)	1 (104)	2 (1939)	1 (16)	0 (0)	3 (380)	1 (46)	2 (62)	0 (0)	0 (0)	1 (46)	0 (0)	1 (46)
<b>Transplant: kidney</b>	14 (7922)	3 (562)	3 (945)	7 (5579)	7 (5703)	14 (1919)	7 (746)	1 (609)	36 (6815)	5 (802)	36 (7492)	1 (148)	0 (0)	12 (2400)	0 (0)	9 (2786)

<b>Transplant: heart</b>	2 (150)	1 (23)	0 (0)	1 (23)	1 (23)	4 (253)	3 (237)	1 (46)	8 (474)	1 (16)	9 (540)	1 (46)	0 (0)	4 (207)	0 (0)	2 (62)
<b>Transplant: liver</b>	3 (184)	1 (56)	0 (0)	1 (56)	1 (56)	4 (165)	4 (166)	1 (58)	11 (765)	1 (11)	12 (843)	1 (58)	0 (0)	4 (158)	0 (0)	3 (207)
<b>Transplant: other or mixed</b>	7 (51,842)	0 (0)	2 (2708)	4 (4799)	4 (51,596)	7 (1296)	3 (197)	1 (89)	9 (1652)	2 (171)	10 (2452)	0 (0)	0 (0)	4 (257)	0 (0)	2 (75)
<b>HIV/AIDS</b>	3 (2197)	0 (0)	1 (4)	1 (2103)	1 (2103)	5 (497)	3 (350)	1 (90)	8 (740)	2 (243)	9 (1405)	0 (0)	0 (0)	4 (436)	0 (0)	2 (243)
<b>Multiple sclerosis</b>	2 (1308)	0 (0)	0 (0)	1 (753)	0 (0)	6 (2256)	3 (1332)	6 (2256)	11 (3380)	0 (0)	12 (3510)	0 (0)	0 (0)	0 (0)	0 (0)	3 (603)
<b>Inflammatory bowel disease</b>	5 (36,955)	2 (4483)	2 (4483)	2 (26,910)	2 (26,910)	5 (6720)	2 (424)	4 (6474)	9 (7397)	3 (369)	9 (7397)	0 (0)	1 (58)	4 (805)	0 (0)	1 (4047)
<b>Rheumatoid arthritis</b>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (752)	1 (189)	4 (6245)	3 (458)	1 (129)	3 (458)	0 (0)	0 (0)	1 (129)	0 (0)	0 (0)
<b>Systemic lupus erythematosus</b>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	6 (1742)	2 (149)	6 (1742)	3 (168)	1 (126)	3 (168)	0 (0)	0 (0)	1 (126)	1 (126)	2 (145)
<b>Psoriasis</b>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	4 (1401)	0 (0)	4 (1401)	2 (152)	1 (101)	2 (152)	0 (0)	0 (0)	1 (101)	0 (0)	1 (101)
<b>Mixed rheumatoid diseases</b>	7 (37,940)	2 (1034)	3 (1944)	8 (42,916)	5 (36,757)	15 (10,613)	6 (2587)	9 (7384)	14 (5416)	3 (1678)	12 (5208)	0 (0)	0 (0)	4 (1801)	1 (82)	2 (182)
<b>Other autoimmune diseases</b>	2 (79)	0 (0)	1 (26)	2 (6433)	0 (0)	8 (1628)	0 (0)	3 (1125)	7 (519)	1 (53)	6 (493)	0 (0)	0 (0)	3 (346)	1 (133)	1 (17)
<b>Other</b>	6 (131,575)	2 (10,756)	3 (38,578)	7 (144,720)	6 (142,283)	12 (17,855)	6 (13,905)	10 (3318)	4 (441)	1 (284)	5 (649)	0 (0)	0 (0)	3 (431)	0 (0)	1 (24)

Abbreviations: Ab: antibody; Ig: immunoglobulin, SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

An interactive evidence gap map is available at [egmopenaccess.3ieimpact.org/evidence-maps/scoping-review-covid-19-vaccines-duplicated-subgroups](https://egmopenaccess.3ieimpact.org/evidence-maps/scoping-review-covid-19-vaccines-duplicated-subgroups) (studies are represented as intervention - outcome table, but can be filtered according to subgroup due to duplication of subgroups with multiple patient groups; multicountry studies cannot be filtered; the labelling g + number are artefacts from duplicating a study for representing the subgroups and can be ignored).

\*The overall number of studies was 287, excluding studies on pregnant and lactating women due to a different outcome set.





**Summary of findings 3. Pregnancy studies only; intervention - outcome\***

Intervention	Clinical	Safety	Birth outcomes						Immunogenicity						
	SARS-CoV-2 infection, any	Adverse events (any)	Serious adverse events	Abortion	Still-birth	Preterm birth	Small size for gestational age	Congenital anomaly	Neonatal mortality	IgG titre or seroconversion	IgA titre	IgM titre	Neutralising Ab seroconversion or titre	Cord blood Ab measurements	Other outcomes
<b>BNT162b2</b>	10	10	3	10	9	11	8	4	5	9	2	5	2	7	16
<b>mRNA-1273</b>	7	5	2	7	6	5	4	3	4	5	2	3	1	4	10
<b>AZD1222</b>	2	2	1	3	3	2	1	1	2	0	0	0	0	0	3
<b>Ad26.COV2.S</b>	2	2	0	2	2	1	1	0	1	3	1	1	0	2	6
<b>Sputnik V</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>Sputnik L</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>BBIBPCorV</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>CoronaVac</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>BNT162b2/AZD1222</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>BNT162b2/mRNA-1273</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>Other heterologous schemes</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: Ab: antibody; Ig: immunoglobulin, SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

\*Pregnancy studies only, N = 26.

## BACKGROUND

The coronavirus disease 2019 (COVID-19) outbreak, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was declared a pandemic in March 2020 (WHO 2020). Despite intense international efforts to contain its spread, COVID-19 has resulted in over 500 million confirmed cases and more than 6 million deaths worldwide as of May 2022 (WHO 2022a). Evolving SARS-CoV-2 variants with antigen escape and potentially altered transmission or disease characteristics have raised concerns, as these could impair established disease control measures as well as vaccines and therapeutic approaches (WHO 2022b).

Whilst effective treatments for COVID-19 are limited, active immunisation against SARS-CoV-2 has a substantial impact on case incidences and hospitalisations, therefore vaccination is critical to controlling the pandemic (Pandey 2020). Vaccines have been shown to be highly effective at reducing transmission and preventing severe illness and death from COVID-19 (Public Health Ontario 2021). As of 23 May 2022, 38 vaccines were approved by at least one country, and there are about 200 vaccine candidates under development in clinical trials (Basta 2022; Shrotri 2021). However, the logistical distribution process is time-consuming, and global access to vaccines varies widely (Wouters 2021). The majority of vaccines have been administered in high-income countries. Despite extensive international efforts for equitable access to vaccines such as COVAX (WHO 2022c), unequal access to vaccines continues to leave a substantial proportion of the world's most vulnerable people at high risk of becoming seriously ill from COVID-19.

Diverse technologies are used for COVID-19 vaccine development based on the spike protein as the primary antigen (Krammer 2020), including the most recent and now most widely used nucleic acid vaccines, weakened and inactivated viruses, replicating and non-replicating viral vectors, protein-subunits, and virus-like particles (Barajas-Nava 2021). Most COVID-19 vaccines require a two-dose schedule for primary immunisation, administered weeks apart to allow the induction of long-term immunity. Whilst this holds true for the general population, immunocompromised people frequently fail to achieve serological response, with the lowest probability of seroconversion observed in the solid organ transplant-receiving population, with rates of only about 30% after the second vaccine dose (Lee 2022).

Waning immunity is indicated by evidence showing that vaccine efficacy against symptomatic infection decreases within 6 months by about 20 percentage points in people of all ages and by over 36% in people at least 50 years old (Feikin 2022). Tober-Lau 2021 even indicated an absence of detectable serum neutralising activity against the Delta variant of concern at six-month follow-up in 39% of older participants (median age 82.5 years). At the same time, studies show that the viral load of breakthrough infections decreases after booster vaccination (Levine-Tiefenbrun 2022). Hence, first booster vaccinations have been implemented in numerous countries for the general population. Second doses have recently been authorised for individuals with certain kinds of immunocompromise as well as those aged 50 years and older (CDC 2022).

Reduced immune response can occur due to the underlying cause of immunocompromise itself, such as primary immunodeficiency, malignancy, autoimmune disease, or due to immunosuppressive

treatment itself. For solid malignancies, for example, a generally high immune response has been reported, whereas certain haematologic malignancies like chronic lymphocytic leukaemia show reduced seroconversion rates even if patients are treatment-naïve (Herishanu 2021). Cytotoxic chemotherapies, immune checkpoint inhibitors, and hormonal therapies seem to reduce immune response to only a relatively small extent, but specific immunosuppressive treatment, especially lymphocyte-depleting therapies (CD-20 antibodies, mycophenolate mofetil), chimeric antigen receptor (CAR) T-cell therapy, and stem cell transplantation, are associated with significantly lower seroconversion rates (Thakkar 2021). In solid organ transplant recipients, the use of antimetabolites has been shown to reduce seroresponse, and the temporary hold of antimetabolite treatment substantially increased vaccine response in kidney transplant recipients (Osmanodja 2022; Schrezenmeier 2022).

Several immunoassays that measure humoral and cellular immune responses are commercially available. Qualitative seroresponse and quantification of antibody titres are now usually assessed by determination of SARS-CoV-2-IgG-antibodies against the full spike-trimer, the spike-1-(S1) subunit, and the receptor-binding domain (RBD). Neutralising antibodies primarily bind the RBD, a part of the S1 subunit, and block the interaction of the spike-protein of the virus with the angiotensin-converting enzyme type 2 receptor (ACE2) on the host cell surface, thereby preventing cell entry by SARS-CoV-2, and thus infection. This ability to block viral entry correlates with protection from symptomatic SARS-CoV-2 infection (Khoury 2021), thus neutralising antibody levels seem to be reliable predictors of protection against COVID-19-infection. The gold standard for assessing neutralisation capacity is the plaque reduction neutralisation test (PRNT), which requires biosafety level 3 conditions for isolation of live pathogenic SARS-CoV-2 virus, thereby limiting its large-scale applicability for diagnostic routine (Rubio-Acero 2021). Alternative platforms to evaluate virus neutralisation have been developed: pseudotyped virus neutralisation assays and surrogate enzyme-linked immunosorbent assays measuring inhibition of the RBD binding to the ACE2-receptor (Sholukh 2021). Furthermore, several studies have shown a high correlation between anti-RBD-IgG and anti-S1-IgG titres with virus neutralisation (Mahmoud 2021; Ramos 2022; Rubio-Acero 2021), suggesting the use of binding antibody titres, which are easier to measure, as a correlate of protection (Earle 2021). This has, however, complicated comparison between cohorts, since multiple assays with different thresholds and arbitrary units are being used for immunity assessment worldwide. Though studies investigating different assays report a better correlation of the results within them, absolute titres from different assays are still not interchangeable (Perkmann 2021). The lack of an international consensus for the measurement of immunity after SARS-CoV-2 vaccination also holds true for the assessment of cellular immunity, which likely plays an important role in virologic control and disease severity (Sette 2021). An international standard consisting of pooled convalescent plasma for harmonisation of serological results across laboratories in order to define an antibody cut-off predictable for vaccine efficacy has been established by the World Health Organization (WHO) for the quantification of both neutralising and binding antibodies, which could help reach the goal of defining a common antibody cut-off predictable for vaccine efficacy (WHO 2020).

Another problem to face whilst discussing the feasibility of antibody titres as correlates of protection are the recent variants of concern, particularly the Omicron variant, against which neutralisation capacity after full vaccination is significantly lower than against the wild-type (Cele 2022; Dejnirattisai 2022), resulting in a marked reduction in vaccine effectiveness (Abu-Raddad 2022). The Omicron variant has evolved to escape neutralising activity by incorporating a high number of mutations in the RBD and has been able to spread rapidly in the population (Viana 2022), with several recent studies demonstrating that booster immunisations are required to fight the high immune escape of this variant (Garcia-Beltran 2022; Gruell 2022; Lusvarghi 2021; Schmidt 2022).

In light of the rapid evolution of the virus, a better understanding of the immune response of the vulnerable population after COVID-19 vaccination is critical for the optimisation of vaccination programmes, reducing the fatality rate, and blocking the infection chain.

### Rationale for conducting a scoping review

As COVID-19 is a new, globally spread disease, research on vaccine efficacy against severe COVID-19 in various settings is just developing, with a rapidly increasing number of registered and published clinical trials. However, there is considerable heterogeneity of such studies with regard to study populations, vaccination settings, as well as definition, measurement, and reporting of outcomes. For example, the measurement tools for immunity parameters are in constant development. They may vary widely from study to study and provide differing results (Hillus 2021; Khoury 2021; Muecksch 2020; Patel 2021; Schmidt 2021; Schwarz 2021). Similarly, there is still no clearly defined minimum core outcome set for studies observing immunity. Immune responses to different vaccines, vaccine combinations, and possible booster vaccines after natural infection are hypothesised to vary, and the examined populations and their exposure to different SARS-CoV-2 variants may differ substantially. Although there is evidence of high long-term efficacy of vaccination against hospitalisation and death in the general population (Krause 2021), the question of the duration of immunity in vulnerable individuals like children, immunocompromised individuals, and pregnant women involves numerous scenarios.

A scoping review, a systematic knowledge synthesis approach for identifying important concepts, sources, and knowledge gaps on a broadly defined topic, can provide an overview of the currently published literature (Tricco 2018). We will use the overview and classification of studies identified in this scoping review to flag evidence gaps and clusters of evidence that would allow the formulating of more specific, clearly defined questions for further systematic reviews.

### OBJECTIVES

To provide an overview of the availability of existing literature on immune response and long-term clinical outcomes after COVID-19 vaccination, and to map this evidence according to the examined populations, specific vaccines, immunity parameters, and their way of determining relevant long-term outcomes and the availability of mapping between immune reactivity and relevant outcomes.

## METHODS

The protocol of this scoping review was published in the Open Science Framework (Kreuzberger 2021). We adhered to the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) to ensure complete reporting (Tricco 2018). Please see Appendix 1 for the completed checklist for this scoping review.

Due to the unexpected amount of studies to screen and extract, we modified our inclusion and exclusion criteria during the process to keep the workload feasible. These changes are noted in Differences between protocol and review.

### Criteria for considering studies for this review

#### Target population/intervention

We included studies that quantitatively assessed immunity outcomes after at least one vaccine dose. Hereby, we limited ourselves to those vaccines authorised for use in the European Union by the European Medicines Agency (EMA), and those approved, authorised, licensed, or granted an emergency use authorisation in at least 10 countries worldwide at the time of our search by 6 December 2021. At that time, the following vaccines were authorised by the EMA:

- BNT162b2 (Comirnaty, Pfizer/BioNTech);
- mRNA-1273 (Spikevax, Moderna; and its equivalent TAK-919, Moderna formulation, Takeda);
- AZD1222 (Vaxzevria, Oxford/AstraZeneca; and its equivalent Covishield, Oxford/AstraZeneca formulation, Serum Institute of India);
- Ad26.COV2.S (COVID-19 Vaccine Janssen) (EMA 2021a).

Additional vaccines approved in at least 10 countries worldwide, according to Basta 2022, by 6 December 2021:

- Sputnik V (Gamaleya);
- Sputnik Light (Gamaleya);
- BBIBP-CorV (Vero Cells, Sinopharm (Beijing));
- CoronaVac (Sinovac, COVID-19 Vaccine (Vero Cell) Inactivated).

We excluded vaccines that were under EMA rolling review at the time of our literature search (e.g. NVX-CoV2373 (Novovax CZ AS), CVnCoV, Vidprevtyn) (Shrotri 2021).

Due to the large number of studies identified that were to map, we ad hoc excluded studies focusing on the general population and kept only those on predefined subgroups and medical conditions that may affect vaccine response (e.g. pregnant and breastfeeding women, paediatric studies, haematological malignancies, solid tumours, and more comorbidities; for details, see Table 1).

#### Setting

We did not restrict this scoping review to any specific setting. In contrast to our protocol, we did not capture the predominance of different SARS-CoV-2 variants during study conduct, as this was mostly not reported. The Omicron variant (B.1.1.529) was identified in November 2021 as a new variant of concern (WHO 2022a) and was therefore not covered by our search.

## Study design and publication formats

For our scoping review, we searched for systematic reviews to gain an overview of the literature, redefine eligible outcome measures, and cross-check included primary studies. We included systematic reviews that:

- included only in vivo studies (in humans);
- provided their search strategy; and
- were clear in their inclusion and exclusion criteria.

We did not exclude systematic reviews based on format (i.e. rapid, living, or scoping reviews).

For our primary study search, we included the following study designs with more than 100 participants in our predefined subgroups:

- retrospective cohort study;
- prospective cohort study;
- randomised controlled trial;
- case-control study.

We excluded the following study design: case reports.

We aimed to include:

- peer-reviewed full-text publications;
- articles uploaded to preprint servers (e.g. medRxiv, bioRxiv, ResearchSquare);
- letters to the editor.

We excluded conference abstracts, reports, and other grey literature. In contrast to our protocol, we excluded records from clinical trial registries for ongoing studies; a list of potentially relevant studies can be found in our online database.

## Outcomes

We were interested in exploring the outcomes that were available in the current literature, therefore we did not limit inclusion to specific outcomes, but required at least one of the following:

- clinical outcomes (e.g. SARS-CoV-2 infection, admission to hospital, admission to intensive care unit (ICU), mortality, adverse events, etc.);
- immunity parameters (immunoglobulin titres, neutralising antibody titres, B- or T-cell response).

## Timing

The minimum median follow-up time was 14 days after complete vaccination. One vaccine dose usually represents incomplete vaccination (except for those with previous COVID-19 infection and the Ad26.COV2.S vaccine); two doses are full vaccination independent of precise schedule; and the third dose onwards represents booster doses.

## Unit of analysis

We included aggregated data from studies that investigated immunity after vaccination at the individual level. We therefore excluded studies that looked at the population level, such as at vaccination rates between countries with different vaccination strategies. We did not collect individual participant data.

## Identification of relevant studies

Our Information Specialist (IM) searched the following electronic databases for systematic reviews from November 2019 to 25 August 2021:

- Evidence Aid Coronavirus (COVID-19) ([evidenceaid.org/evidence/coronavirus-covid-19](https://evidenceaid.org/evidence/coronavirus-covid-19));
- Usher Network for COVID-19 Evidence Reviews (<https://www.ed.ac.uk/usher/uncover/register-of-reviews>);
- US Department of Veterans Affairs Evidence Synthesis Program ([www.covid19reviews.org/](https://www.covid19reviews.org/));
- Epistemonikos, L\*OVE List Coronavirus disease (COVID-19) ([app.iloveevidence.com/loves/5e6fdb9669c00e4ac072701d?utm=aiel](https://app.iloveevidence.com/loves/5e6fdb9669c00e4ac072701d?utm=aiel));
- MEDLINE (via Ovid).

We searched the following databases from November 2019 to 6 December 2021 to retrieve potentially relevant primary studies.

- Cochrane COVID-19 Study Register (CCSR) ([www.covid-19.cochrane.org](https://www.covid-19.cochrane.org)), including:
  - PubMed, weekly searches;
  - Embase.com, weekly searches;
  - ClinicalTrials.gov ([www.clinicaltrials.gov](https://www.clinicaltrials.gov)), daily searches;
  - World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) ([www.who.int/trialsearch](https://www.who.int/trialsearch)), weekly searches;
  - medRxiv ([www.medrxiv.org](https://www.medrxiv.org)), weekly searches;
  - Cochrane Central Register of Controlled Trials (CENTRAL), monthly searches.
- Web of Science Core Collection:
  - Science Citation Index Expanded (1945 to present);
  - Emerging Sources Citation Index (2015 to present).
- WHO COVID-19 Global literature on coronavirus disease (<https://search.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/>)

The search strategies for systematic reviews are shown in [Appendix 2](#). The search strategies for primary studies were informed by included systematic reviews and were peer reviewed; they are provided in [Appendix 3](#).

## Study selection

After de-duplication, the resulting records were screened independently by at least two review authors in a two-stage process based on titles and abstracts, then as full-texts, via Covidence ([Covidence](#)). Conflicts at each step were resolved by discussion or by involving a third review author when necessary. We documented the screening process in a PRISMA flow diagram ([Moher 2009](#)), where we described the reasons for exclusion of studies at the full-text stage.

To ensure consistency between review authors, we developed a screening guidance sheet and discussed the screening and conflicts after the first 300 records, and regularly throughout the process. The guidance contained:

- an overview on the screening steps (first-level title and abstract screening versus full-text screening);

- an overview on the inclusion criteria (see table below) and a list of relevant subgroups;
- predefined exclusion reasons at full-text screening; and
- additional notes, e.g. missing full-text publications, how to tag, etc., gathered from questions arising during our weekly meetings.

Population	Vaccines	Study design
<ul style="list-style-type: none"> <li>• Humans only</li> <li>• The age group of children and adolescents (&lt; 18) vs adults of any age<sup>1</sup></li> <li>• Comorbidity, e.g. immunosuppression, cancer, kidney disease, etc.</li> <li>• Pregnant and breastfeeding women</li> </ul>	<ul style="list-style-type: none"> <li>• BNT162b2 (Comirnaty; BioNTech Pfizer)</li> <li>• mRNA-1273 (Spikevax; Moderna)</li> <li>• AZD1222 (Vaxzevria; AstraZeneca)</li> <li>• Ad26.COV2.S (COVID-19 Vaccine Janssen)</li> <li>• Sputnik V (Gamaleya)</li> <li>• Sputnik Light (Gamaleya)</li> <li>• BBIBP-CorV (Sinopharm; Beijing CNBG)</li> <li>• CoronaVac (Sinovac)</li> </ul>	<ul style="list-style-type: none"> <li>• Retrospective cohort study</li> <li>• Prospective cohort study</li> <li>• Randomised controlled trials, vaccination arm</li> </ul>
Setting	Vaccination strategies	Publication format
<ul style="list-style-type: none"> <li>• Any setting (country, time period)</li> <li>• Wild-type or any SARS-CoV-2 virus variant</li> </ul>	<ul style="list-style-type: none"> <li>• Homologue and heterologous</li> <li>• Any number of vaccinations</li> <li>• Natural infection plus vaccine</li> <li>• Any time difference between multiple vaccinations</li> </ul>	<ul style="list-style-type: none"> <li>• Peer-reviewed full-text publications               <ul style="list-style-type: none"> <li>◦ Articles uploaded to preprint servers</li> </ul> </li> </ul>

<sup>1</sup>We originally planned to list studies per age group, i.e. elderly participants separately; however, due to change in eligibility criteria (exclusion of the general population), the account may be incomplete, therefore adult participants are not further divided into age classes.

## Data collection and charting

Two review authors extracted the following data into the data extraction tool in Covidence ([Covidence](#)).

<b>General information</b>	<ul style="list-style-type: none"> <li>• Title</li> <li>• Study author</li> <li>• Year</li> <li>• DOI/link to full text</li> <li>• Study identifier</li> <li>• Publication status/format</li> </ul>
<b>Study characteristics/setting</b>	<ul style="list-style-type: none"> <li>• Study design/source of data</li> <li>• Primary outcome domain (e.g. clinical, immunogenicity, safety)</li> <li>• Centres (single or multiple centres)</li> <li>• Single or multiple countries</li> <li>• Country</li> <li>• City/institution, if single-centre study</li> <li>• Enrolment period</li> </ul>
<b>Participant characteristics</b>	<ul style="list-style-type: none"> <li>• Sample size</li> <li>• Population</li> <li>• Ethnicity reported (yes/no)</li> </ul>
<b>Vaccine characteristics</b>	<ul style="list-style-type: none"> <li>• Vaccine (vaccine, homologous/heterologous)</li> <li>• Dose of vaccine</li> <li>• Vaccination after SARS-CoV-2 infection</li> </ul>

## Outcomes

### Outcomes investigated

- Clinical outcomes measured: number of SARS-CoV-2 infections - any, asymptomatic, symptomatic, leading to hospitalisation or leading to death
- Adverse events, serious adverse events
- Immunity parameters measured immunoglobulin A, M, and G titres, B- or T-cell response

A first version of the data collection form was developed in MS Excel ([MS Excel](#)), and circulated to all review authors for feedback. After feedback was obtained, we transferred the items to Covidence ([Covidence](#)), and three review authors (CH, CSt, NK) piloted the form on a randomly selected sample of studies. Feedback from piloting was discussed at the next group meeting and accepted changes were implemented.

Pairs of review authors charted data independently in duplicate, and one of the two review authors or a third review author could subsequently compare the two extractions and decide on a final version. During data charting, we decided to skip multiple items due to feasibility. After having been exported to MS Excel, data were again checked for duplicate references and final eligibility of studies, and then summarised using the software R ([R Core Team](#)).

### Data synthesis and presentation of results

As we anticipated high heterogeneity in study characteristics, populations, vaccines, and outcomes, we aimed to create an evidence map of studies investigating immunity after vaccination. We classified the data according to various factors, as follows:

- population (i.e. general population, immunosuppressed, risk factors, etc.);
- setting (country);
- vaccine type (e.g. Oxford/AstraZeneca AZD1222, Pfizer/BioNTech BNT162b2, Moderna mRNA-1273, Janssen (Johnson & Johnson) Ad26.COV2.S), combination scheme;
- vaccination scheme (homologous, heterologous);

- availability of outcomes (immune parameters, clinical outcomes).

We used multiple ways of presenting the results of our scoping search, as follows.

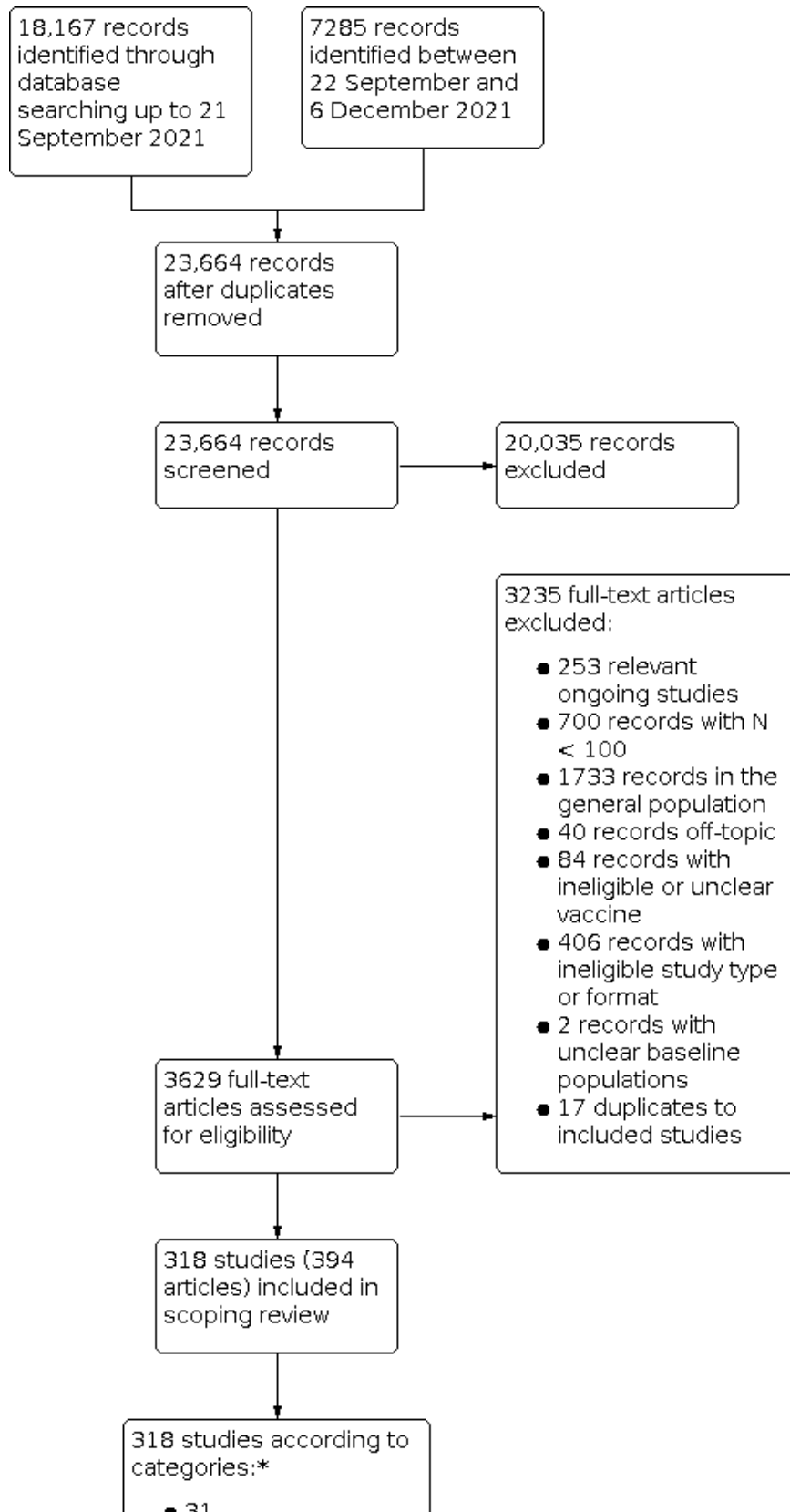
- Table format: we charted data according to general characteristics, population characteristics, vaccine characteristics, and outcomes.
- Evidence gap map: we created an interactive map using the software 3ie EGM ([International Initiative for Impact Evaluation](#)).
- Narratively: we additionally summarised the characteristics narratively in the main body of the review.

## RESULTS

### Results of the search

After de-duplication of our identified 25,452 records, we screened 23,664 records based on title and abstract. We excluded 20,035 records as clearly irrelevant. After title and abstract screening, we decided that including studies of all listed study designs performed in the general population would not be feasible for us regarding data extraction and presentation, therefore we excluded studies on only the general population at the full-text screening stage. After the exclusion of 3235 records including ongoing studies, studies with a sample size smaller than 100 participants, studies on the general population or healthcare workers only, studies that did not specify the vaccine received, and records published as ineligible format (i.e. conference abstracts, commentaries), 318 studies (in 394 articles) were included in our scoping review ([Figure 1](#)).

**Figure 1. PRISMA flow diagram. \*Categories are mutually exclusive and sorted according to the online database. Numbers do not align with Table 1, as one study can include more than one comorbidity subgroup.**



**Figure 1. (Continued)**

- Categories:
- 31 pregnancy/breastfeeding
  - 41 solid tumour
  - 39 haematological malignancies
  - 6 liver disease
  - 69 kidney disease/transplant
  - 65 autoimmune disease
  - 5 HIV
  - 17 solid organ transplant
  - 37 other or mixed comorbidities
  - 8 paediatric

**Description of studies**

**Included studies**

We have presented our studies in an evidence gap map based on a template provided by the International Initiative for Impact Evaluation ([International Initiative for Impact Evaluation](http://International Initiative for Impact Evaluation)). For reasons of clarity of representation, we created two versions of the map:

1. one version for the overall view of studies: [egmopenaccess.3ieimpact.org/evidence-maps/scoping-review-covid-19-vaccines](http://egmopenaccess.3ieimpact.org/evidence-maps/scoping-review-covid-19-vaccines); and
2. one version to filter studies according to subgroups: [egmopenaccess.3ieimpact.org/evidence-maps/scoping-review-covid-19-vaccines-duplicated-subgroups](http://egmopenaccess.3ieimpact.org/evidence-maps/scoping-review-covid-19-vaccines-duplicated-subgroups).

The program does not currently allow us to upload studies including multiple subgroups. The first map thus represents a general overview, but should not be used for filtering, as

only studies with one subgroup will show. However, as the representation of subgroups is the main purpose of this scoping review, we duplicated studies so that it is possible to filter all studies belonging to one population subgroup. In the second map, the overall view is distorted by duplicating studies.

Additional current limitations include the representation of countries and study design: a) studies with multiple countries cannot be filtered according to country, and the People's Republic of China is missing in the drop-down option; and b) randomised controlled trials can be filtered in the overall map (map 1), but not in the subgroup map.

Static versions of the map are included as summary of findings tables ([Summary of findings 1](#); [Summary of findings 2](#); [Summary of findings 3](#)) and in [Figure 2](#) and [Figure 3](#). The data and references to included and excluded studies can be accessed via the [Open Science Framework project](#) website. A list of references of included studies, sorted by subgroups, is provided in [Appendix 4](#).

**Figure 2. Heat map: intervention - outcome.**

Intervention	Clinical					Safety			Immunogenicity							
	SARS-CoV-2 infection, any	SARS-CoV-2 infection, asymptomatic	SARS-CoV-2 infection, symptomatic	SARS-CoV-2 infection, hospitalisation	SARS-CoV-2 infection, mortality	Adverse events (any)	Serious adverse events	Specific adverse events	Seroconversion (binding Ab)	Seroconversion (nAb)	IgG titre	IgM titre	IgA titre	nAb titre	B cell response, other	T cell response
BNT162b2	72	17	17	40	34	102	43	41	162	38	157	7	7	53	4	33
mRNA1273	37	11	12	23	16	49	13	22	79	17	79	6	3	24	1	18
AZD1222	11	3	3	8	6	25	10	14	29	9	27	1	2	11		11
Ad26.COV2.S	10	4	6	7	5	12	5	8	19	1	20	2	1	4		1
Sputnik V	3	1	1	2	1	4	1	2	1		1					
Sputnik L																
BBIBPCorV	2			1	1	13	5	8	4	4	3			3		
CoronaVac	2		1	3		13	3	8	5	5	5			5		
BNT162b2/AZD1222	1			1	1	2			2	2	4		1	1		2
BNT162b2/mRNA1273	1			1	1				1	1	1			1		1
Other heterologous schemes	3	1	1	3	1	6	1	4	4	1	4			1		3

Colours indicate the number of studies; red = lowest to green = highest; Total N = 287  
Abbreviations: Ab = antibody, Ig = immunoglobulin, nAb = neutralising antibody; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2



**Figure 3. Heat map: subgroup - outcome.**

Subgroup	Clinical					Safety			Immunogenicity							
	SARS-CoV-2 infection, any	SARS-CoV-2 infection, asymptomatic	SARS-CoV-2 infection, symptomatic	SARS-CoV-2 infection, hospitalisation	SARS-CoV-2 infection, mortality	Adverse events (any)	Serious adverse events	Specific adverse events	Seroconversion (binding Ab)	Seroconversion (nAb)	IgG titre	IgM titre	IgA titre	Neutralising Ab titre	B cell response, other	T cell response
Solid tumours	11	4	3	8	6	23	10	4	30	8	27	1	1	10	1	4
Haematological malignancies	16	2	2	7	5	17	10	3	39	15	35	4	3	19	1	9
Haematological malignancies, stem cell transplant	9	1	1	3	4	15	8	4	16	3	18	1	1	6	1	3
Kidney disease, excl. dialysis	2	1	1	2	1	1			4		3					
Dialysis	17	4	4	10	10	15	9		41	9	38	3	3	10		8
Chronic heart disease	5	1	3	3	2	5	1		6	1	5			2		1
Liver disease	4			2	2	4	3		4	2	4			2		2
Lung disease	2	1	1	2	1	2	1		3	1	2			1		1
Transplant: kidney	14	3	3	7	7	14	7	1	36	5	36	1		12		9
Transplant: heart	2	1		1	1	4	3	1	8	1	9	1		4		2
Transplant: liver	3	1		1	1	4	4	1	11	1	12	1		4		3
Transplant: other or mixed	7		2	4	4	7	3	1	9	2	10			4	2	2
HIV/AIDS	3		1	1	1	5	3	1	8	2	9			4		2
Multiple sclerosis	2			1		6	3	6	11		12					3
Inflammatory bowel disease	5	2	2	2	2	5	2	4	9	3	9		1	4		1
Rheumatoid arthritis						3	1	4	3	1	3			1		
Systemic lupus erythematosus						6	2	6	3	1	3			1	1	2
Psoriasis						4		4	2	1	2			1		1
Mixed rheumatoid diseases	7	2	3	8	5	15	6	9	14	3	12			4	1	2
Other autoimmune diseases	2		1	2		8		3	7	1	6			3	1	1
Other	6	2	3	7	6	12	6	10	4	1	5			3		1

Colours indicate the number of studies; red = lowest to green = highest; Total N = 287  
Abbreviations: Ab = antibody; Ig = immunoglobulin; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2

**Study characteristics**

Of the 318 included studies, 181 were published as full text, 110 as letters to the editor, research letters, or short communication, and 27 as preprints. The majority of the included studies were prospective cohort studies (N = 203). We also included 47 retrospective cohort studies, 32 cross-sectional studies, 15 studies based on registry or surveillance system data, 8 case-control studies, 7 randomised controlled trials, 5 mixed cohorts, and 1 diagnostic test accuracy study. The majority of studies were conducted in a single centre (N = 165); 146 were multicentre studies, and 7 studies did not report the number of centres (Table 2).

**Population**

Across studies, participants were enrolled between 30 January 2020 and 31 October 2021. The early enrolment start date can be explained by the fact that although vaccination was not yet available at the beginning of the pandemic, the identified studies published data on ongoing cohorts that started in early 2020. Participants were recruited mainly from high-income countries (282/318), most commonly the United States (N = 81), Israel (N = 51), the United Kingdom (N = 31), France (N = 28), and Italy (N = 24); 12 studies were conducted in multiple countries. Eighty-four studies reported that they included participants with previous SARS-CoV-2 infection, although this was usually a large minority of participants. Information on race or ethnicity as at least baseline characteristics was provided in 98 studies. The complete list of countries and population characteristics can be found in Table 1.

Most studies included adults only (N = 297), whilst 10 reports focused on adolescents and children. Overall, 26 studies included pregnant women, and 7 studies included breastfeeding women. Of the pregnancy and breastfeeding studies combined (N = 31), 13 studies included data on neonates in addition to parturient data (i.e. cord blood immunoglobulin values).

We identified 47 studies on participants with solid tumours and 54 studies on participants with haematological malignancies. Included in these or in addition to them, 22 studies explored vaccination in stem cell transplant recipients.

Six studies included participants with kidney disease; 48 studies included dialysis patients; and 43 studies included participants having received a kidney or combined kidney-pancreas transplant. Nine, seven, and five studies investigated outcomes in participants with chronic heart disease, liver disease, and lung disease, respectively. Heart and liver transplant patients were investigated in 9 and 12 studies each, and 19 studies included other transplant patients or a group of mixed transplant patients without reporting subgroup data. Ten studies included participants with HIV/AIDS.

Several studies combined participants with multiple autoimmune and rheumatic diseases (N = 13 and N = 28, respectively); however, separate data were reported for multiple sclerosis in 17 studies, inflammatory bowel disease in 15 studies, rheumatoid arthritis in 5 studies, systemic lupus erythematosus in 7 studies, and psoriasis in 5 studies. Other patient populations were reported in 24 studies and included, amongst others, chronic neurological diseases in general, dementia, epilepsy, schizophrenia, mixed groups of immunosuppressed patients if not assigned to any of the above-mentioned subgroups, myelodysplastic disorders, chronic hepatitis B infection, substance use disorders, mastocytosis, bleeding disorders, immune thrombocytopenia, spinal cord injuries, asthma reported separately, and allergies.

Studies do not add up to 318 included records, as studies commonly reported multiple participant subgroups. For a detailed description to filter the subgroups, please refer to the evidence gap map or the data extraction file at OSF.

## Intervention

We identified 283 studies that included participants vaccinated with BNT162b2, of which 171 reported outcomes after one dose; 258 reported outcomes after the second dose; and 14 studies reported results after a third booster dose (Table 3). mRNA-1273 was examined in 153 studies, of which 92 reported outcomes after the first dose; 140 studies reported outcomes after the second dose; 6 studies reported outcomes after a booster dose.

AZD1222 was vaccinated in 66 studies, of which 48, 52, and 1 study reported outcomes after one, two, and three doses, respectively. In 42 studies, AD26.COVS was given, and of these 41 studies reported outcomes after one dose (the full vaccination scheme), and one study reported outcomes after a second dose.

The remaining vaccines were examined much less frequently: BBIBP-CorV was vaccinated in 15 studies, and CoronaVac in 14 studies. Sputnik V was applied in five studies, and no study adhering to our search frame was found for Sputnik Light. Heterologous vaccination schemes were reported in 16 studies.

Frequently, if multiple vaccines were administered in the same study, outcomes were reported only for groups who received different vaccines together (N = 94).

In total, 211 studies reported results after one dose, 288 studies after two doses, and 16 studies after three doses. No study identified up to our search date explored reported outcomes after a fourth vaccine dose in our defined subgroups.

## Outcomes

### Comorbidity subgroups

Out of 287 studies that included comorbidity or paediatric subgroups, 80 studies reported the occurrence of any SARS-CoV-2 infection (Table 4). Only 19 studies each divided these into asymptomatic and symptomatic infections. Forty-four studies reported hospitalisation due to SARS-CoV-2 infection, and 36 studies reported mortality (including studies reporting that no deaths occurred).

Adverse events in any form were reported in 126 studies, and serious adverse events were reported in 54 studies. Another 50 studies reported specific adverse events (e.g. disease flares for autoimmune diseases).

Immunogenicity was the most commonly reported outcome domain, with 179 studies reporting seroconversion based on binding antibody measurements and 49 studies based on neutralising antibodies.

Immunoglobulin G (IgG) titres were reported in 175 studies, whilst immunoglobulin A (IgA), immunoglobulin M (IgM), and neutralising antibodies (NAbs) were less frequent (7, 9, and 64 studies, respectively).

Other B-cell response outcomes were reported in 4 studies, while T-cell responses, such as interferon-gamma measurements, were examined in 37 studies.

### Studies on pregnant and breastfeeding women

Overall, 31 studies included pregnant and/or breastfeeding women (N = 26 and N = 7, respectively; see Table 5). Of the 26 studies

on pregnant women, 10 reported the occurrence of SARS-CoV-2 infections; 10 reported adverse events; and 3 reported serious adverse events. Overall, 19 studies reported birth outcomes (abortion: 11 studies, stillbirth: 10 studies, preterm birth: 12 studies, small for gestational age: 8 studies, congenital anomalies: 4 studies, and neonate mortality: 6 studies). Immunogenicity was reported in nine studies, led by the outcome IgG titres or seroconversion in all nine studies, antibody titres in cord blood (7 studies), whilst IgM and IgA titres and NAb titres or seroconversion were reported less frequently (5, 2, and 2 studies, respectively).

## Excluded studies

We excluded 3235 records at full-text stage for the following reasons:

- 253 records were ongoing studies that potentially include subgroups;
- 700 records were on studies with fewer than 100 participants;
- 1733 records included participants from the general population;
- 40 records were off-topic, i.e. studies on immunity after infection, seroprevalence studies;
- 84 records assessed ineligible/unclear vaccines;
- 406 records were published in an ineligible format (i.e. conference abstract) or study design (e.g. cases only without baseline population);
- 2 records had an unclear baseline population;
- 17 were duplicates of included studies.

A complete list of excluded studies can be found at [OSF](#).

## DISCUSSION

### Summary of the main results

This review provides an overview of vaccination research activities on different vaccines approved in the European Union or in at least 10 countries worldwide at the time of our search 6 December 2021, and in relation to our prioritised endpoints of clinical efficacy, immunogenicity, and safety. We identified 318 eligible studies that explored at least 1 out of 8 predefined COVID-19 vaccines in comorbidity subgroups, paediatric populations, or pregnant and breastfeeding women. The most commonly included patient populations were those with haematological malignancies, followed by patients with solid tumours, kidney disease including dialysis, and kidney transplant patients. Vaccine reaction to autoimmune diseases was commonly explored, although more often in populations with mixed diagnoses than separately. Of the autoimmune diseases, multiple sclerosis and inflammatory bowel disease were often reported separately. The majority of studies were conducted in high-income countries (United States, Israel, Europe).

In our defined comorbidity subgroups, BNT162b2 was the most commonly used vaccine (N = 283 studies), followed by mRNA-1273, AZD1222, and AD26.COVS. Results on vaccines that were not authorised by the EMA, but that were approved by at least 10 countries at the time of our search (Sputnik V and L, BBIBP-CorV, CoronaVac), were rarely published. The majority of studies reported results after a standard vaccination scheme, which is usually after two vaccine doses (except for AD26.COVS).

The most commonly reported outcomes were seroconversion (62.2% of studies) and IgG titres (61.0% of studies) based on binding antibody titres in serum, followed by reporting of adverse events in 43.9% of studies. Any SARS-CoV-2 infection was reported in 27.9% of studies. Neutralising antibody seroconversion and titres were reported in 17.1% and 22.3% of studies, respectively.

To summarise, most of the identified evidence was for mRNA vaccines, whilst data for vector- and protein-based vaccines, as well as vaccines based on inactivated virus, remain incomplete in relation to our endpoints and for the subgroups selected for this review. Evidence regarding heterologous vaccination schemes also remains very deficient.

We found that significantly more studies focused on the immunological effects and safety aspects of the vaccines than on their clinical efficacy, that is reduction in infections in general and severe infections with hospitalisation. With regard to immunogenicity, the humoral IgG response was examined most intensively, less frequently the capacity of the antibodies to neutralise the SARS-CoV-2 virus. Data on T-cell immune responses were much more limited, whilst evidence on other B-cell parameters is largely deficient.

### Overall completeness and applicability of evidence

Due to the extreme output of COVID-19-related research, in particular vaccine research that is not comparable with any other topic in medical research before, it is extremely difficult to stay up-to-date with peer-reviewed as well as pre-printed manuscripts included in this scoping review, as evidence is growing exponentially.

A concern regarding this quick expansion of the literature, and the SARS-CoV-2 situation itself, is the change of research focus with any new variant of concern that shows different virological and clinical characteristics. Vaccines developed for one variant might have only limited efficacy for another variant, especially due to mutations in the targeted spike protein, which differs significantly between variants. Due to the time limit of the search in December 2021, this scoping review lacks studies that have been carried out on the currently predominant Omicron variant of concern. In addition, since our search, a new vaccine, Novavax, was approved by the EMA in December 2021, which is not included in this review (EMA 2021a; EMA 2021b). This limits overall completeness as well as applicability to a certain extent.

Due to the vast amount of studies presenting SARS-CoV-2 vaccination data, we had to limit ourselves in several ways. Foremost, we chose eight vaccines as feasible choices for efficient data collection. However, data on several vaccines administered to significant population sizes (e.g. Covaxin (BBV152) in India or Convidecia (Ad5-nCoV) primarily in China) and possibly heterologous application schemes are thus missing. Likewise, whilst we listed children and adolescents amongst our vulnerability subgroups separately - a status based foremost on general medical terms rather than COVID-19 disease load itself - we refrained from doing so for other subgroups of age because subgroups of elderly are often reported in publications on the general population, which we could have missed out on if not presented in the abstract, resulting in an incomplete account of this group. In particular the representation of studies including elderly, which have been threatened by high mortality rates from COVID-19 and - at least

theoretically - may be at risk for a weaker immune response to vaccination due to age (Brockmann 2022; Collier 2021) would have been highly important. Furthermore, we neglected the types of treatment (including immunosuppressive regimens); different treatments are associated with different seroconversion rates and antibody titres (Ligumsky 2022), and thus may have a significant impact on the immune response. A reduced immune response may therefore not only be a consequence of the underlying disease, but may also be related to the complex confounder of drug treatments. Finally, including studies of at least 100 participants of a particular subgroup was chosen as an arbitrary lower study-size limit to ensure the practicability of data extraction as well as the robustness of findings. Likewise, we are aware that as a result studies on particularly rare diseases and thus smaller achievable subgroups (e.g. subgroups of rare inborn errors of immunity, subgroups on patients on specific biological therapeutics) may be underrepresented in this review. Similarly, this inclusion criterion also led to the exclusion of the first studies reporting on results of four vaccinations in subgroups as well as studies reporting on extensive or elaborate immunological diagnostics with small sample sizes.

Nevertheless, this scoping review might serve as an overview of the available evidence for the clinician who is as overwhelmed by the literature as the researcher trying to scope the evidence. By concentrating on patients with an expected reduced vaccination response due to the underlying disease or drug-based immunosuppression, we aimed to help clinicians achieve an overview of which studies exist for guidance and for researchers identifying knowledge gaps. This scoping review might help to stimulate research closing these knowledge gaps, which is clinically extremely important to avoid severe disease courses.

### Potential biases in the review process

One of the potential sources of bias in the review process is that although we published a protocol before commencing this scoping review, due to the large number of studies identified by our search, we had to change our eligibility criteria from a very broad scope to a somewhat more limited scope (see [Differences between protocol and review](#)). Abstracts that included the general population, but that reported on subgroups only within the main body of their publication, may have been excluded on the level of title and abstract screening as a result of our deviations.

Due to heterogeneity in data extraction, we also reduced the number of items to extract per study to reduce workload. All changes were discussed in weekly sessions with all present review authors and communicated via e-mail to those who were absent.

This review was conducted by a large group of authors, which may have introduced heterogeneity in screening and data extraction. The completed data extraction sheet was therefore randomly checked for consistency between extractions by one review author.

We identified no other potential sources of bias.

### Implications for a subsequent effectiveness review

This scoping review identified areas with insufficient evidence, and thereby crucially informs future systematic reviews. With the help of this scoping review, reasonable comparisons and outcome measures have been identified and have been transferred to two resulting systematic reviews, which accelerated the time-critical

process of conducting a systematic review in the rapidly evolving research landscape of SARS-CoV-2 vaccination. These systematic reviews focus on the overall response to vaccines in haematological malignancies, [Piechotta 2022](#), and kidney transplant recipients ([Hausinger 2022](#)), the latter also including the most recent EMA-approved vaccine, Novavax. An interesting question is whether those individuals who did not seroconvert after the standard scheme (usually two doses) will seroconvert after one or more booster doses; another important point to consider is that although a lot of focus lies on immune parameters, these do not always translate into clinical improvements. Other systematic reviews on immunocompromised groups are constantly emerging (e.g. [Lee 2022](#)), thus before commencing additional systematic reviews, the search used to identify systematic reviews could be updated.

## AUTHORS' CONCLUSIONS

The majority of evidence on our predefined subgroups up to 6 December 2021 reported immunogenicity surrogate parameters or adverse events after mRNA vaccines administered as standard scheme. Clinical efficacy outcomes were less commonly reported, and if so, often as a secondary outcome observed in seroconversion or immunoglobulin titre studies, with a similar follow-up time. There was considerably more data for European Medicines Agency-approved vaccines than the additionally defined vaccines approved in more than 10 countries, or heterologous vaccination schemes.

Overall, based on insights from this scoping review, we defined two follow-up review questions in response to data availability, one on the effectiveness and safety of COVID-19 vaccines in haematological malignancies, and the other in kidney transplant recipients.

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- Sign-off Editor (final editorial decision): Harald Herkner, Medical University of Vienna, Austria; Coordinating Editor of the Cochrane Emergency and Critical Care Group
- Managing Editor (selected peer reviewers, collated peer-reviewer comments, provided editorial guidance to authors, edited the article): Joey Kwong, Cochrane Central Editorial Service
- Editorial Assistant (conducted editorial policy checks and supported editorial team): Leticia Rodrigues, Cochrane Central Editorial Service
- Copy Editor (copy-editing and production): Lisa Winer, Cochrane Copy Edit Support
- Peer reviewers (provided comments and recommended an editorial decision): Alexandre R Marra, Hospital Israelita Albert Einstein, Sao Paulo, SP, Brazil; the University of Iowa Hospitals and Clinics, Iowa City, IA, USA (clinical review); Abhijit Dutta, Maynaguri RH, Department of Health & Family Welfare (Govt. of West Bengal), India (consumer review); Robert Walton, Cochrane UK (summary versions review); Nuala Livingstone, Cochrane Evidence Production and Methods Directorate (methods review); Robin Featherstone, Cochrane Central Editorial Service (search review). Two additional peer reviewers provided clinical peer review but chose not to be publicly acknowledged.

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Shrotri M, Swinnen T, Kampmann B, Parker E. An interactive website tracking COVID-19 vaccine development. *Lancet Global Health* 2021;**9**(5):e590-2. [DOI: [10.1016/S2214-109X\(21\)00043-7](https://doi.org/10.1016/S2214-109X(21)00043-7)]

### Thakkar 2021

Thakkar A, Gonzalez-Lugo JD, Goradia N, Gali R, Shapiro LC, Pradhan K, et al. Seroconversion rates following COVID-19 vaccination among patients with cancer. *Cell Press* 2021;**39**(8):1081-90. [DOI: [10.1016/j.ccell.2021.06.002](https://doi.org/10.1016/j.ccell.2021.06.002)]

### Tober-Lau 2021

Tober-Lau P, Schwarz T, Vanshylla K, Hillus D, Gruell H, Suttorp N, et al. Long-term immunogenicity of BNT162b2 vaccination in older people and younger health-care workers. *Lancet Respiratory Medicine* 2021;**9**(11):e104-5. [DOI: [10.1016/S2213-2600\(21\)00456-2](https://doi.org/10.1016/S2213-2600(21)00456-2)]

### Tricco 2018

Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. *Annals of Internal Medicine* 2018;**169**(7):467-73. [DOI: [10.7326/M18-0850](https://doi.org/10.7326/M18-0850)]

### Viana 2022

Viana R, Moyo S, Amoako DG, Tegally H, Scheepers C, Althaus CL, et al. Rapid epidemic expansion of the SARS-CoV-2 Omicron variant in southern Africa. *Nature* 2022;**603**:679-86. [DOI: [10.1038/s41586-022-04411-y](https://doi.org/10.1038/s41586-022-04411-y)]

### WHO 2020

World Health Organization. Establishment of the WHO international standard and reference panel for anti-SARS-CoV-2 antibody. [www.who.int/publications/m/item/WHO-BIS-2020.2403](http://www.who.int/publications/m/item/WHO-BIS-2020.2403) (accessed 31 May 2022).

### WHO 2022a

World Health Organization. WHO Coronavirus Disease (COVID-19) Dashboard. [www.covid19.who.int](http://www.covid19.who.int) (accessed 15 May 2022).

### WHO 2022b

World Health Organization. Tracking SARS-CoV-2 variants. [www.who.int/activities/tracking-SARS-CoV-2-variants](http://www.who.int/activities/tracking-SARS-CoV-2-variants) (accessed 31 May 2022).

### WHO 2022c

World Health Organization. COVAX - Working for global equitable access to COVID-19 vaccines. [www.who.int/initiatives/act-accelerator/covax](http://www.who.int/initiatives/act-accelerator/covax) (accessed 15 May 2022).

### Wouters 2021

Wouters OJ, Shadlen KC, Salcher-Konrad M, Pollard AJ, Larson HJ, Teerawattananon Y, et al. Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment. *Lancet* 2021;**397**(10278):1023-34. [DOI: [10.1016/S0140-6736\(21\)00306-8](https://doi.org/10.1016/S0140-6736(21)00306-8)]

## ADDITIONAL TABLES

**Table 1. Characteristics of identified studies: population**

Characteristic	Number of studies	Number of participants (sum)	Number of participants (median, range)
Enrolment period (minimum start, maximum end)	30 January 2020 to 31 October 2021		
Missing dates	79		
Overall	318	5,061,795	317 (100 to 1,277,747)
Age class			
Adult	297		
Paediatric	10		
Adult - neonate	13		
Include previously SARS-CoV-2-positive participants	84		
Report ethnicity in at least the baseline characteristics	98		
Population: comorbidities			
Solid tumours	47	183,974	200 (34 to 95,935)
Haematological malignancies	54	46,928	149 (14 to 32,156)
Haematological malignancies, stem cell transplant	22	2456	108.5 (12 to 397)
Kidney disease	6	41,903	50.5 (21 to 41,597)
Dialysis	48	189,142	172.5 (26 to 142,826)
Chronic heart disease	9	73,147	178 (21 to 70,716)
Liver disease	7	40,796	92 (12 to 40,074)
Lung disease	5	2377	104 (16 to 1893)
Transplant: kidney	43	12,991	148 (19 to 2350)
Transplant: heart	9	540	46 (16 to 134)
Transplant: liver	12	843	60 (11 to 161)
Transplant: other or mixed	19	56,514	187 (5 to 48,213)
HIV/AIDS	10	3508	105 (4 to 2103)
Multiple sclerosis	17	6331	239 (58 to 912)
Inflammatory bowel disease	15	40,842	436 (58 to 14,697)
Rheumatoid arthritis	5	6385	189 (129 to 5493)



**Table 1. Characteristics of identified studies: population** (Continued)

	Systemic lupus erythematosus	7	1761	126 (19 to 696)
	Psoriasis	5	1452	101 (51 to 788)
	Rheumatic diseases, mixed	28	55,175	393.5 (45 to 35,475)
	Other autoimmune diseases	13	8344	108 (17 to 6380)
	Other	24	161,134	287 (24 to 279,145)
Population: healthy				
	Pregnancy	26	360,738	1071 (84 to 130,875)
	Breastfeeding	7	12,433	180 (31 to 6815)
Comparator group	Healthy control	116	3,523,037	91.5 (7 to 963,962)
Country				
	Multiple countries	12		
	Austria	3		
	Belgium	3		
	Brazil	3		
	Canada	7		
	China	9		
	Denmark	2		
	France	28		
	Germany	10		
	Greece	7		
	India	2		
	Iran, Islamic Rep.	5		
	Israel	51		
	Italy	24		
	Kuwait	2		
	Lithuania	2		
	Norway	3		
	Poland	4		

**Table 1. Characteristics of identified studies: population** *(Continued)*

Portugal	4
Qatar	2
Spain	10
Switzerland	2
United Kingdom	31
United States	81
Other*	11

Abbreviations: SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

\*1 study each: Argentina, Australia, Japan, Mexico, the Netherlands, Peru, Russian Federation, Saudi Arabia, South Africa, Sweden, United Arab Emirates.

**Table 2. Characteristics of identified studies: general information**

Characteristic	Number of studies
Overall	318
Publication format	
Full text	181
Letter to the editor/research letter	110
Preprint	27
Study design	
Randomised controlled trial	7
Prospective cohort study	203
Retrospective cohort study	47
Registry or surveillance system	15
Cross-sectional study	32
Case-control study	8
Diagnostic test accuracy study	1
Mixed	5
Centres	
Single centre	165

**Table 2. Characteristics of identified studies: general information** (Continued)

Multiple centres	146
Not reported	7

**Table 3. Characteristics of identified studies: interventions\***

Characteristic	Intervention	Dose	Number of studies
Vaccine			
	Study included non-vaccinated		63
	BNT162b2		283
		1 dose	171
		2 doses	258
		3 doses (booster)	14
	mRNA-1273		153
		1 dose	92
		2 doses	140
		3 doses (booster)	6
	AZD1222		66
		1 dose	48
		2 doses	52
		3 doses (booster)	1
	Ad26.COV2.S		42
		1 dose	41
		2 doses (booster)	1
		3 doses (booster)	0
	Sputnik V		5
		1 dose	3
		2 doses	4
		3 doses (booster)	0
	Sputnik Light		0

**Table 3. Characteristics of identified studies: interventions\*** (Continued)

BBIBP-CorV	15
1 dose	12
2 doses	13
3 doses (booster)	0
CoronaVac	14
1 dose	13
2 doses	13
3 doses (booster)	0
Heterologous schemes	16
Reporting of intervention: multiple vaccines analysed together only	94
1 dose	74
2 doses	81
3 doses	5
Dose	
1 dose	211
2 doses	288
3 doses	16
4 doses	0

\*For all vaccines except Ad26.COV2.S, one vaccine dose represents incomplete vaccination; two doses constitute full vaccination; and three or more doses are additional boosters. We extracted these data independent of the exact dosing schedule.

**Table 4. Characteristics of identified studies: outcomes\***

Outcome domain	Outcome	Number of studies*	Percentage of studies*
Overall		287	
Clinical			
	SARS-CoV-2 infection, any	80	27.9
	SARS-CoV-2 infection, asymptomatic	19	6.6
	SARS-CoV-2 infection, symptomatic	19	6.6
	SARS-CoV-2 infection, hospitalisation	44	15.3

**Table 4. Characteristics of identified studies: outcomes\*** (Continued)

	SARS-CoV-2 infection, mortality	36	12.5
Safety			
	Any adverse events	126	43.9
	Serious adverse events	54	18.8
	Disease-specific adverse events	50	17.4
Immunogenicity			
	Seroconversion, binding Ab	179	62.2
	Seroconversion, neutralising Ab	49	17.1
	IgG titres	175	61.0
	IgA titres	7	2.4
	IgM titres	9	3.1
	Neutralising Ab titres	64	22.3
	B-cell response	4	1.4
	T-cell response	37	12.9

Abbreviations: Ab: antibody; Ig: immunoglobulin, SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

\*Excluding studies on pregnant and lactating women.

**Table 5. Characteristics of identified studies on pregnancy and breastfeeding: outcomes**

Outcome domain	Outcome	Number of studies	Percentage of studies
<b>Pregnancy</b>		<b>26</b>	
Clinical			
	SARS-CoV-2 infection, any	10	38.5
Safety			
	Any adverse events	10	38.5
	Serious adverse events	3	11.5
Birth outcomes			
	Abortion	11	42.3
	Stillbirth	10	38.5

**Table 5. Characteristics of identified studies on pregnancy and breastfeeding: outcomes** (Continued)

Preterm birth	12	46.2
Small for gestational age	8	30.8
Congenital anomalies	4	15.4
Neonate mortality	6	23.1
Immunogenicity		
IgG titres or seroconversion, mother	9	34.6
NAb titres or seroconversion, mother	2	7.7
IgM titres	5	19.2
IgA titres	2	7.7
Ab titres in cord blood	7	26.9
Additional outcomes	17	65.4
<b>Breastfeeding</b>	<b>7</b>	
Clinical		
SARS-CoV-2 infection, any	1	14.3
Safety		
Any adverse events, mother	6	85.7
Any adverse events, neonate	5	71.4
Immunogenicity		
IgG titres or seroconversion, serum, mother	3	42.9
NAb titres or seroconversion, serum, mother	1	14.3
IgM titres, mother	2	28.6
IgA titres, serum, mother	3	42.9
B- or T-cell response, mother	0	0
IgG titres or seroconversion, milk	3	42.9
IgA titres, milk	3	42.9
Ab titres or seroconversion in serum, neonate	0	0

Abbreviations: Ab: antibody; Ig: immunoglobulin, NAb: neutralising antibodies; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

## APPENDICES

### Appendix 1. PRISMA-ScR checklist

Recommended section	Item	PRISMA-ScR checklist item	Reported	Section
<b>TITLE</b>				
Title	1	Identify the report as a scoping review.	yes	Title
<b>ABSTRACT</b>				
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	yes	Abstract
<b>INTRODUCTION</b>				
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	yes	Background - Rationale for conducting a scoping review
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g. population or participants, concepts, and context) or other relevant key elements used to conceptualise the review questions and/or objectives.	yes	Objectives
<b>METHODS</b>				
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	yes	Methods
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g. years considered, language, and publication status), and provide a rationale.	yes	Methods
Information sources	7	Describe all information sources in the search (e.g. databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	yes	Methods and appendices
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	yes	Appendices

(Continued)

Selection of sources of evidence	9	State the process for selecting sources of evidence (i.e. screening and eligibility) included in the scoping review.	yes	Methods
Data charting process	10	Describe the methods of charting data from the included sources of evidence (e.g. calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	yes	Methods
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	Yes	Methods
Critical appraisal of individual sources of evidence	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	NA	-
Synthesis of results	13	Describe the methods of handling and summarising the data that were charted.	yes	Methods
<b>RESULTS</b>				
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	yes	Methods, Figure 1
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	yes	Online data maps ( <a href="https://egmopenaccess.3ieim-pact.org/evidence-maps/scoping-review-covid-19-vaccines">egmopenaccess.3ieim-pact.org/evidence-maps/scoping-review-covid-19-vaccines</a> ; <a href="https://egmopenaccess.3ieim-pact.org/evidence-maps/scoping-review-covid-19-vaccines-duplicated-subgroups">egmopenaccess.3ieim-pact.org/evidence-maps/scoping-review-covid-19-vaccines-duplicated-subgroups</a> ) and at OSF ( <a href="https://osf.io/qm-cgv/">osf.io/qm-cgv/</a> )
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	Not done	-
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	partly	Online at OSF ( <a href="https://osf.io/qm-cgv/">osf.io/qm-cgv/</a> )



(Continued)

Synthesis of results	18	Summarise and/or present the charting results as they relate to the review questions and objectives.	yes	Results, table 1, table 2, table 3, table 4
<b>DISCUSSION</b>				
Summary of evidence	19	Summarise the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	yes	Discussion - Summary of the main results
Limitations	20	Discuss the limitations of the scoping review process.	yes	Discussion
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	yes	Discussion, Authors' conclusions
<b>FUNDING</b>				
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	no/yes	Sources of funding of included studies not described; source of funding for scoping review reported

 See [Tricco 2018](#)

## Appendix 2. Search strategies for systematic reviews, up to 25 August 2021

### 1. Evidence Aid Coronavirus (Covid-19)

*searched and screened:* vaccin, mRNA, BNT162b2, Astrazeneca, AZD, JNJ, Chad, Ad26, moderna, Pfizer, BioNTech, Covishield, Janssen, Johnsons, rAd5, rAd26, Sputnik, BBiBP, sinopharm, CoronaVac, vero cell or TAK-919 or boost and screened (24.08.2021)

### 2. Usher Network for COVID-19 Evidence Reviews

*searched and screened:* vaccin, mRNA, BNT162b2, Astrazeneca, AZD, JNJ, Chad, Ad26, moderna, Pfizer, BioNTech, Covishield, Janssen, Johnsons, rAd5, rAd26, Sputnik, BBiBP, sinopharm, CoronaVac, vero cell or TAK-919 or boost and screened (24.08.2021)

### 3. U.S. Veterans' Affairs (VA) Evidence Synthesis Program

*searched and screened:* vaccin, mRNA, BNT162b2, Astrazeneca, AZD, JNJ, Chad, Ad26, moderna, Pfizer, BioNTech, Covishield, Janssen, Johnsons, rAd5, rAd26, Sputnik, BBiBP, sinopharm, CoronaVac, vero cell or TAK-919 or boost and screened (24.08.2021)

### 4. L\*OVE

Searched by PICO (24.08.2021)

Public health	SARS-CoV-2 vaccines	RNA vaccines: BNT162b1; Pfizer-BioNTech COVID-19 vaccine or moderna COVID-19 vaccine
Public health vaccine	SARS-CoV-2 vaccines	vector vaccines: Janssen AD26.COVS, Oxford-AstraZeneca COVID-19 vaccine, Sputnik V COVID-19 vaccine
Public health	SARS-CoV-2 vaccines	inactivated vaccines: CoronaVac, BBiBP-CorV, SARS-CoV-2 vaccine (vero cells)

### 5. MEDLINE (via Ovid) (searched 25.08.2021)

- # Searches
- 1 COVID-19 Vaccines/
  - 2 (vaccin\* adj3 (COVID\* or COVID-19\* or COVID19\* or "SARS-CoV-2" or "SARS-CoV2" or SARSCoV2 or "SARSCoV-2" or "coronavirus disease 2019" or nCoV-19)).tw,kf.
  - 3 COVID-19/ or SARS-CoV-2/
  - 4 (COVID\* or COVID-19\* or COVID19\* or "SARS-CoV-2" or "SARS-CoV2" or SARSCoV2 or "SARSCoV-2" or "coronavirus disease 2019" or nCoV-19).tw,kf.
  - 5 or/3-4
  - 6 (vaccin\* adj1 (respons\* or candidate\*)).tw. or boost\*.tw. or (vaccin\* adj1 therap\*).ti.
  - 7 (vaxzevria\* or AZD1222\* or AZD-1222 or covishield\* or ChAdOx1\*).af. or AstraZeneca.tw,kf. or (oxford adj2 vaccin\*).tw,kf.
  - 8 (biontech\* or pfizer\*).tw,kf. or (comirnaty\* or BNT162b2\* or BNT-162b2\* or tozinameran\*).af.
  - 9 (moderna\* or spikevax\* or mRNA-1273\* or mRNA1273\* or TAK-919\* or TAK919\* or modernatx\*).af.
  - 10 (JNJ-78436735\* or JNJ78346735\* or "Ad26.COVID.S\*" or Ad26COV51).af. or ("Johnson&Johnson" or Janssen).tw,kf.
  - 11 ("BBIBP-CorV\*" or BBIBPCorV\* or sinopharm\* or "sino-pharm\*").af.
  - 12 (coronaVac\* or "corona-Vac\*" or sinovac\* or "sino-vac\*" or PiCoVacc\* or "PiCo-Vacc\*" or "vero adj1 cell?").af.
  - 13 (gamaleya\* or "Gam-COVID-Vac\*" or rAd26\* or "recombinant adenovirus type 26 vector" or rAd5\* or "recombinant adenovirus type 5 vector" or "adenoviral vector5").af. or sputnik\*.tw,kf.
  - 14 or/6-13
  - 15 1 or 2 or (5 and 14)
  - 16 cochrane database of systematic reviews.jn. or search\*.tw. or meta analysis.pt. or medline.tw. or systematic review.tw. or systematic review.pt. [17. Wong 2006 – systematic reviews filter –modified by adding systematic review.pt]
  - 17 15 and 16

### Appendix 3. Search strategies for primary literature, up to 6 December 2021

#### 1. CCSR – Cochrane COVID-19 Study Register

vaccin\* or biontech\* or pfizer\* or corminaty\* or comirnaty\* or BNT162\* or "BNT 162" or "bnt 162b2" or tozinameran\* or moderna\* or spikevax\* or 1273\* or mRNA1273\* or "TAK-919" or "CX-024414" or CX024414\* or astrazeneca\* or vaxzevria\* or AZD1222\* or covishield\* or ChAdOx\* or Janssen\* or "JNJ-78436735" or JNJ78436735\* or VAC31518\* or "VAC-31518" or "Johnson COVID-19" or "Johnson COVID19" or Ad26\* or Ad5\* or Sputnik\* or rAd26\* or rAd5\* or gamaleya\* or "Gam-COVID-Vac" or "recombinant adenovirus type" or "adenovirus vector" or "combined vector" or BBIBP\* or sinopharm\* or sinovac\* or PiCoVac\* or Coronavac\* or "heterologous boost" or "heterologous booster" or "homologous boost" or "homologous booster" or "post-boost" or "post-booster" or "boost schedule" or "boost schedules" or "bost dose" or "booster dose" or "after boost" or "after booster" or "variant boost" or "variant booster" or "nonvariant boost" or "nonvariant booster" or "non-variant boost" or "non-variant booster" or "delayed boost" or "delayed booster" or boosted or "prime boost" or "prime booster" or "boost regimen" or "three dosis" or "three doses" or "third dosis" or "third doses" or "third dose"

#### filter according to:

- Study Characteristics:  
 Study Design  
 - Case Series/Case Control/Cohort  
 - Cross-sectional  
 - Parallel/Crossover  
 - Other  
 - Time series

- Unclear

Study Characteristics: Intervention Assignment

- Randomised
- Quasi-Randomised
- Unclear

## 2. Web of Science

### #1 search string Covid

(TI=(COVID OR COVID19 OR "SARS-CoV-2" OR "SARS-CoV2" OR SARSCoV2 OR "SARSCoV-2" OR "SARS coronavirus 2" OR "2019 nCoV" OR "2019nCoV" OR "2019-novel CoV" OR "nCov 2019" OR "nCov 19" OR "severe acute respiratory syndrome coronavirus 2" OR "novel coronavirus disease" OR "novel corona virus disease" OR "corona virus disease 2019" OR "coronavirus disease 2019" OR "novel coronavirus pneumonia" OR "novel corona virus pneumonia" OR "severe acute respiratory syndrome coronavirus 2")) OR AB=(COVID OR COVID19 OR "SARS-CoV-2" OR "SARS-CoV2" OR SARSCoV2 OR "SARSCoV-2" OR "SARS coronavirus 2" OR "2019 nCoV" OR "2019nCoV" OR "2019-novel CoV" OR "nCov 2019" OR "nCov 19" OR "severe acute respiratory syndrome coronavirus 2" OR "novel coronavirus disease" OR "novel corona virus disease" OR "corona virus disease 2019" OR "coronavirus disease 2019" OR "novel coronavirus pneumonia" OR "novel corona virus pneumonia" OR "severe acute respiratory syndrome coronavirus 2"))

### #2 search string vaccine - vaccine names

(TI=(biontech\* or pfizer\* or corminaty\* or comirnaty\* or BNT162\* or "BNT 162" or "bnt 162b2" or tozinameran\* or moderna\* or spikevax\* or 1273\* or mRNA1273\* or "TAK-919" or "CX-024414" or CX024414\* or astrazeneca\* or vaxzevria\* or AZD1222\* or covishield\* or ChAdOx\* or Janssen or "JNJ-78436735" or JNJ78436735\* or "Johnson COVID-19" or "Johnson COVID19" or Ad26\* or Ad5\* or VAC31518\* or Sputnik\* or rAd26\* or rAd5\* or gamaleya\* or "Gam-COVID-Vac" or "recombinant adenovirus type" or "adenovirus vector" or "combined vector" or BBIBP\* or sinopharm\* or sinovac\* or PiCoVac\* or Coronavac\*)) OR AB=(biontech\* or pfizer\* or corminaty\* or comirnaty\* or BNT162\* or "BNT 162" or "bnt 162b2" or tozinameran\* or moderna\* or spikevax\* or 1273\* or mRNA1273\* or "TAK-919" or "CX-024414" or CX024414\* or astrazeneca\* or vaxzevria\* or AZD1222\* or covishield\* or ChAdOx\* or Janssen or "JNJ-78436735" or JNJ78436735\* or "Johnson COVID-19" or "Johnson COVID19" or Ad26\* or Ad5\* or VAC31518\* or Sputnik\* or rAd26\* or rAd5\* or gamaleya\* or "Gam-COVID-Vac" or "recombinant adenovirus type" or "adenovirus vector" or "combined vector" or BBIBP\* or sinopharm\* or sinovac\* or PiCoVac\* or Coronavac\*))

### #3 search string booster

(TI=(boost\*)) OR AB=(boost\*)

### #4 search string "third dose"

(TI=("three dosis" or "three doses" or "third dosis" or "third doses" or "third dose")) OR AB=("three dosis" or "three doses" or "third dosis" or "third doses" or "third dose")

### #5 search string SARS-CoV-2 vaccine

(TI=((vaccin\* NEAR/5 (COVID OR COVID19 OR "SARS-CoV-2" OR "SARS-CoV2" OR SARSCoV2 OR "SARSCoV-2" OR "SARS coronavirus 2" OR "2019 nCoV" OR "2019nCoV" OR "2019-novel CoV" OR "nCov 2019" OR "nCov 19" OR "severe acute respiratory syndrome coronavirus 2" OR "novel coronavirus disease" OR "novel corona virus disease" OR "corona virus disease 2019" OR "coronavirus disease 2019" OR "novel coronavirus pneumonia" OR "novel corona virus pneumonia" OR "severe acute respiratory syndrome coronavirus 2")))) OR AB=((vaccin\* NEAR/5 (COVID OR COVID19 OR "SARS-CoV-2" OR "SARS-CoV2" OR SARSCoV2 OR "SARSCoV-2" OR "SARS coronavirus 2" OR "2019 nCoV" OR "2019nCoV" OR "2019-novel CoV" OR "nCov 2019" OR "nCov 19" OR "severe acute respiratory syndrome coronavirus 2" OR "novel coronavirus disease" OR "novel corona virus disease" OR "corona virus disease 2019" OR "coronavirus disease 2019" OR "novel coronavirus pneumonia" OR "novel corona virus pneumonia" OR "severe acute respiratory syndrome coronavirus 2"))))

### #6 search string combining COVID with vaccine names, booster and third dose

#1 AND (#2 OR #3 OR #5)

### #7 search string SARS-Cov-2 vaccine (general) and COVID with vaccine names booster and third dose

#5 OR #6

## 3. WHO COVID-19 Global literature

## search 1

biontech\* or pfizer\* or corminaty\* or comirnaty\* or BNT162\* or "BNT 162" or "bnt 162b2" or tozinameran\* or moderna\* or spikevax\* or 1273\* or mRNA1273\* or "TAK-919" or "CX-024414" or CX024414\* or astrazeneca\* or vaxzevria\* or AZD1222\* or covishield\* or ChAdOx\* or Janssen\* or "JNJ-78436735" or JNJ78436735\* or VAC31518\* or "VAC-31518" or "Johnson COVID-19" or "Johnson COVID19" or Ad26\* or Ad5\* or Sputnik\* or rAd26\* or rAd5\* or gamaleya\* or "Gam-COVID-Vac" or "recombinant adenovirus type" or "adenovirus vector" or "combined vector" or BBIBP\* or sinopharm\* or sinovac\* or PiCoVac\* or Coronavac\* or "heterologous boost" or "heterologous booster" or "homologous boost" or "homologous booster" or "post-boost" or "post-booster" or "boost schedule" or "boost schedules" or "bost dose" or "booster dose" or "after boost" or "after booster" or "variant boost" or "variant booster" or "nonvariant boost" or "nonvariant booster" or "non-variant boost" or "non-variant booster" or "delayed boost" or "delayed booster" or boosted\* or "prime boost" or "prime booster" or "boost regimen" or "three dosis" or "three doses" or "third dosis" or "third doses" or "third dose"

## search 2

Vaccin\*  
AND

COVID or COVID19 or "SARS-CoV-2" or "SARS-CoV2" or SARSCoV2 or "SARSCoV-2" or "SARS coronavirus 2" or "2019 nCoV" or "2019nCoV" or "2019-novel CoV" or "nCov 2019" or "nCov 19" or "severe acute respiratory syndrome coronavirus 2" or "novel coronavirus disease" or "novel corona virus disease" or "corona virus disease 2019" or "coronavirus disease 2019" or "novel coronavirus pneumonia" or "novel corona virus pneumonia" or "severe acute respiratory syndrome coronavirus 2"

## Appendix 4. References of included studies

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## 10. Studies on paediatric participants

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## DECLARATIONS OF INTEREST

Nina Kreuzberger: no relevant interests; staff role at Cochrane Haematology, University Hospital Cologne, Germany; member of the prognosis methods group.

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Kanika Vanshylla: patent regarding SARS-2 neutralising antibodies filed by the University of Cologne (pending); Tober-Lau P, Gruell H, Vanshylla K, et al. doi:10.3201/eid2805.220271 COVIM: "NaFoUniMedCovid19" Bundesministerium für Bildung und Forschung Federal Institute for Drugs and Medical Devices German Center for Infection Research (DZIF); Vanshylla K, Tober-Lau P, Gruell H, et al. doi:10.1016/S1473-3099(22)00135-9 COVIM: "NaFoUniMedCovid19" Bundesministerium für Bildung und Forschung Federal Institute for Drugs and Medical Devices German Center for Infection Research (DZIF) Deutsche Forschungsgemeinschaft (DFG); Gruell H, Vanshylla K, Tober-Lau P, et al. doi:10.1038/s41591-021-01676-0 COVIM: "NaFoUniMedCovid19" Bundesministerium für Bildung und Forschung Federal Institute for Drugs and Medical Devices German Center for Infection Research (DZIF) Deutsche Forschungsgemeinschaft (DFG); Mellinghoff SC, Robrecht S, Mayer L, et al. doi:10.1038/s41375-021-01500-1 German Center for Infection Research (DZIF) Mildred Scheel School of Oncology German Cancer Aid; Müller L, Andrée M, Ostermann PN, et al. doi:10.3389/fmed.2021.746644 VIRUS Alliance NRW (VIRAL) from the Ministry of Culture and Science NRW Jürgen Manchot Foundation; Tober-Lau P, Schwarz T, Vanshylla K, et al. doi:10.1016/S2213-2600(21)00456-2 COVIM: "NaFoUniMedCovid19" Bundesministerium für Bildung und Forschung Berlin Institute of Health (BIH) and Berlin University Alliance Deutsche Forschungsgemeinschaft (DFG); Hillus D, Schwarz T, Tober-Lau P, et al. doi:10.1016/S2213-2600(21)00357-X COVIM: "NaFoUniMedCovid19" Bundesministerium für Bildung und Forschung, Laboratory of Experimental Immunology, Institute of Virology, Faculty of Medicine and University Hospital Cologne, University of Cologne, Cologne, Germany.

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## SOURCES OF SUPPORT

### Internal sources

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- Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany, Germany  
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### External sources

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## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

During the review process, we modified several decisions made at protocol stage during weekly group discussions, as follows.

	Protocol stage	Full review	Reasons
<b>Inclusion criteria</b>	Complete vaccination	From one vaccine onwards	To obtain a more comprehensive account of outcome reporting (we also listed outcomes that were reported after one dose in publications on two or more doses).

	No restriction on population; we planned to include any study on healthy general population as well as subgroups $\geq 100$ participants	Limitation to certain subgroups $\geq 100$ participants	Feasibility; inclusion and data extraction of $\geq 2000$ publications not feasible
	$\geq 10$ participants for studies with booster vaccination	$\geq 100$ participants for studies with booster vaccination	Increase in available booster studies as compared to time point of protocol registration
	We originally planned to list studies per age group, i.e. children, young adults, adults, elderly.	The age group of children and adolescents ( $< 18$ ) vs adults of any age	Due to change in inclusion criteria (limit to certain subgroups), the account may be incomplete, therefore adult participants are not further divided into age classes.
	Ongoing studies (e.g. trial registry entries, study protocols) without accompanying full-text publication included	Ongoing studies listed along with excluded studies in an online appendix	The relevant ongoing studies are available via an online repository, but are not further sorted in the scoping review. As many of the included studies are based on retrospective data, a detailed charting on registered trials would provide an incomplete account on what to expect in the near future.
<b>Data extraction</b>	Data extraction to be performed in a standardised MS Excel file	The Covidence data extraction form option	Easier implementation of duplicate extraction with numerous extractors.
	Capturing the predominance of different SARS-CoV-2 variants during study conduct	SARS-CoV-2 variants during study conduct were not captured.	The majority of publications would not have reported this, which would have resulted in guesses based on date and place of enrolment.
<b>Outcomes</b>	Correlation between immunity parameters and clinical outcomes, transmissibility, time to infection	Correlation between immunity parameters and clinical outcomes, transmissibility, and time to infection were not assessed.	This led to very heterogeneous data extraction and was not feasible.

## INDEX TERMS

### Medical Subject Headings (MeSH)

Ad26COVS1; BNT162 Vaccine; ChAdOx1 nCoV-19; \*COVID-19 [epidemiology] [prevention & control]; COVID-19 Vaccines; \*Hematologic Neoplasms; SARS-CoV-2; Vaccination; \*Vaccines

### MeSH check words

Adult; Child; Female; Humans; Pregnancy