SPOR Evidence Alliance
Strategy for Patient-Oriented Research
Alliance pour des données probantes de la SRAP
Stratégie de recherche axée sur le patient

Strategy for Patient-Oriented Research
SPOR
Putting Patients First

COVID-END
COVID-19 Evidence Network to support Decision-making ... in Canada

The effects of vaccination in immunocompromised people

Systematic review of research studies on immunogenicity, safety, and efficacy/effectiveness of COVID-19 vaccines in immunocompromised individuals

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Prepared By:
Dr. Paul Moayyedi

Contact:
Farncombe Family Digestive Health Research Institute, McMaster University
200 Main St. W. HSC 3V3,
Hamilton ON Canada L8N 3Z5

Email: moayyep@mcmaster.ca

Land Acknowledgement(s)

SPOR Evidence Alliance operates from the St. Michael's Hospital, Unity Health Toronto which is located on the traditional land of the Huron-Wendat, the Seneca, and the Mississaugas of the Credit. Today, this meeting place is still the home to many Indigenous people from across Turtle Island.

COVID-END is housed within McMaster University which is located on the traditional territories of the Mississauga and Haudenosaunee nations, and within the lands protected by the "Dish With One Spoon" wampum, an agreement to peaceably share and care for the resources around the Great Lakes.

We are grateful to have the opportunity to work on these lands.

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Project Contributors

Aida Fernandes – Project Manager
Cathy Yuan – Information Specialist
Christie Yuan – Research Associate
Yasamin Farbod – Research Associate
Rapat Pittayanon – Research Associate.
Takeshi Kanno – Research Associate

General Disclaimer

This report was prepared by the Cochrane Gut Review Group on behalf of the SPOR Evidence Alliance and COVID-END. It was developed through the analysis, interpretation, and synthesis of scientific research and/or health technology assessments published in peer-reviewed journals, institutional websites, and other distribution channels. It also incorporates selected information provided by experts and patient/citizen partners with lived experience on the subject matter. This document may not fully reflect all the scientific evidence available at the time this report was prepared. Other relevant scientific findings may have been reported since completion of this synthesis report.

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Abbreviations and Definitions

Abbreviations

- BNT162b2 (Pfizer-BioNTech)
- mRNA-1273 (Moderna)
- AZD1222 (ChAdOx1) (AstraZeneca-Oxford)
- Ad26.COV2.S (Janssen (Johnson & Johnson))
- N/A = not applicable
- N/R = not recorded
- RCT = randomized controlled trials
- Anti-S = antibody to Spike Protein
- Anti-RBD = antibody to Receptor Binding Domain of the Spike Protein
- IMM = immunocompromised
- CVID = Combined Variable Immune Deficiency
- XLA = X-Linked Agammaglobulinemia
- HIV. = human immunodeficiency virus
- IBD = inflammatory bowel disease
- RA = rheumatoid arthritis
- SLE = systemic lupus erythematosus
- MS = multiple sclerosis
- IMM = immunosuppressive therapy
- HM = hematological malignancy
- CLL = chronic lymphocytic leukemia
- CML = chronic myeloid leukemia
- NHL = non-Hodgkins lymphoma
- Allo-HCST = allogeneic hematopoietic stem cell transplant
- RR = relative risk
- 95% CI = 95% confidence interval

Key Definitions:

- Age in tables refers to median or mean age (whichever given in the paper)
- Days, weeks and months given in table refers to median or mean (whichever given in the paper)

EXECUTIVE SUMMARY

Objectives: Vaccination against COVID-19 may be less efficacious in immunocompromised and dialysis patients. We evaluated this in a systematic review of the efficacy, immunogenicity, and safety of vaccines in the immunocompromised and those on dialysis.

Design: This was a rapid systematic review and meta-analysis.

Methods: Two reviewers assessed studies for eligibility and performed data extraction independently. Proportions were calculated for case series and relative risk for comparative studies with 95% confidence intervals and synthesised using a random effects model.

Results: There is approximately a 10% reduction in vaccine efficacy in the immunocompromised compared to the healthy population although overall the vaccine offers approximately 80% protection compared to the immunocompromised that are not vaccinated. Immunogenicity of COVID-19 vaccination is not impacted in persons living with HIV. There is a modest reduction in immunogenicity of COVID-19 vaccination in those with solid malignancy, those taking immunosuppressive therapy and dialysis patients. There is a moderate reduction in immunogenicity of COVID-19 vaccination in patients with hematological malignancy. Immunogenicity is severely impaired in transplant patients and in some patients with a primary immune deficiency. Prior COVID-19 infection increases immunogenicity and mRNA-1273 is slightly more efficacious than BNT162b2 in terms of seroconversion. A third vaccine modestly increases seroconversion in dialysis patients but is more effective in transplant patients. There are no safety concerns with COVID-19 vaccinations in the immunocompromised or in dialysis patients and overall, these groups may experience less adverse events than the healthy population. A more detailed summary of the results is given in the table below.

Conclusions: COVID-19 vaccination is modestly less efficacious in the immunocompromised and immunogenicity data would suggest transplant patients are particularly vulnerable. A third vaccination increases seroconversion.

Summary of the certainty of the evidence

Outcome	Studies included	Overall certainty of the evidence (GRADE)	Key findings
Risk of infection in the vaccinated immunocompromised compared to the healthy population	3 cohort studies, 7,283,329 participants and 20,087 COVID cases at follow up 2 case control studies involving 498,203 negative and 15,997 positive cases	⊕◯◯◯ Very low[1]	Case control and cohort suggested 90% vaccine efficacy (VE) in the healthy. In the immunocompromised VE was 79% in cohort studies and 88% in case control studies
Immunogenicity of vaccination in persons living with HIV	Second vaccination efficacy evaluated in 6 cohort studies involving 1,241 participants	⊕⊕◯◯ Low[2]	RR =1.00 (95% CI 0.98 to 1.02) no difference between persons living with HIV and healthy controls
Immunogenicity of vaccination in patients taking immunosuppressive therapy	Second vaccination efficacy evaluated in 28 cohort studies with 5,644 participants. Eight case series.	⊕◯◯◯ Very low[1]	76% seroconverted. RR = 0.78 (95% CI 0.72 to 0.85) Approximately a 20% reduction in seroconversion in patients taking immunosuppressive therapy
Immunogenicity of vaccination in solid malignancy patients	Second vaccination efficacy evaluated in 7 cohort studies with 1,365 participants. Six case series.	⊕◯◯◯ Very low[1]	93% seroconverted. RR = 0.92 (95% CI 0.85 to 1.00) Approximately an 8% reduction in seroconversion in solid malignancy patients
Immunogenicity of vaccination in hematological malignancy patients	Second vaccination efficacy evaluated in 15 cohort studies with 3,973 participants. 16 case series.	⊕◯◯◯ Very low[1]	61% seroconverted. RR = 0.62 (95% CI 0.54 to 0.71) Approximately a 40% reduction in seroconversion in hematological malignancy patients
Immunogenicity of vaccination in transplant patients	Second vaccination efficacy evaluated in 23 cohort studies with 3,883 participants. 10 case series.	⊕⊕◯◯ Low[2]	31% seroconverted. RR = 0.33 (95% CI 0.26 to 0.42) Approximately a 70% reduction in seroconversion in transplant patients

Immunogenicity of vaccination in patients with primary immune deficiency	Vaccination efficacy evaluated in 3 cohort studies with 291 participants.	⊕◯◯◯ Very low[3]	RR = 0.33 (95% CI 0.11 to 1.02). Approximately a 70% reduction in seroconversion in patients with primary immune deficiencies.
Immunogenicity of vaccination in dialysis patients	Second vaccination efficacy evaluated in 14 cohort studies with 3,573 participants. 18 case series.	⊕◯◯◯ Very low[1]	89% seroconverted. RR = 0.86 (95% CI 0.82 to 0.91) Approximately a 10% reduction in seroconversion in dialysis patients
Influence of prior COVID infection on seroconversion	27 cohort studies with 7,174 patients	⊕◯◯◯ Very low[1]	RR seroconverting if had prior COVID = 1.36 (95% CI 1.24 to 1.50). Prior COVID increases probability that will seroconvert
Immunogenicity of BNT162b2 versus mRNA-1273	23 cohort studies with 7,046 patients	⊕⊕◯◯ Low[2]	RR seroconverting if had BNT162b2 = 0.94 (95% CI 0.90 to 0.97). mRNA-1273 slightly more effective at seroconverting.
Immunogenicity of a third vaccination	10 before after studies and one RCT with 2,217 patients	⊕⊕⊕◯ Moderate[4]	Overall absolute increase in seroconversion of 14% (95 % CI 7 to 22%). Seroconversion increase was 5% in dialysis patients and 23% in transplant patients
Safety of vaccination in immunocompromised and dialysis patients	11 cohort studies with 3,479 patients	⊕⊕◯◯ Low[2]	Overall adverse events lower in immunocompromised or dialysis patients compared to healthy controls (RR = 0.66; 95% CI 0.54 to 0.80)

[1]The GRADE approach gives the quality of evidence of observational studies as low and further downgraded because of risk of bias of many of the included studies and heterogeneity.
[2]The GRADE approach gives the quality of evidence of observational studies as low. No further reason to downgrade or upgrade the evidence.
[3]The GRADE approach gives the quality of evidence of observational studies as low but this was downgraded further for heterogeneity and imprecision.
[4]The GRADE approach gives the quality of evidence of RCTs as high but this was downgrade for imprecision. The observational studies added additional support for this quality assessment.

Introduction

Research Question

What is the effectiveness, immunogenicity, and safety of COVID-19 vaccines in immunocompromised persons and patients on dialysis?

Rationale

COVID-END finds and uses the best available evidence available to support decision-making about COVID-19 pandemic response. To this end, this report summarizes the current evidence regarding the effects of vaccinations in immunocompromised individuals. Specifically, this rapid review synthesizes the body of evidence on the immunogenicity, safety, and efficacy/effectiveness of COVID-19 vaccines in immunocompromised persons to inform decisions regarding booster vaccinations.

PICOST Framework

	Inclusion Criteria	Exclusion Criteria
Population	Immunocompromised individuals, as defined by persons with HIV infection, primary immune or complement deficiency, malignancy, transplant, or on immunosuppressive therapy. Also, individuals on dialysis (including hemodialysis and peritoneal dialysis) are included.	
Intervention	COVID-19 vaccines which Canada has currently authorized for use: BNT162b2 (Pfizer-BioNTech); mRNA-1273 (Moderna); AZD1222 (ChAdOx1) (AstraZeneca-Oxford) and Ad26.COV2.S (Johnson & Johnson).	Vaccines not approved in Canada
Comparisons	Healthy controls or disease controls (for immunosuppression e.g. inflammatory bowel disease – outcome of vaccines in those with and without immunosuppressive therapy)	

Outcomes	1. Immunogenicity: • Humoral immune responses (e.g. binding antibodies, neutralizing antibodies); 2. Safety: • Overall adverse events • Individual events of interest 3. Effectiveness: • confirmed SARS-CoV-2 infection (PCR or serologic); • asymptomatic infection, symptomatic COVID-19 disease; • hospitalizations due to COVID-19; ICU admissions due to COVID-19; • deaths due to COVID-19	
Setting	Population through to tertiary care	
Study designs	Interventional trials, cohort, case-control, or before after studies. Case series with at least 100 participants for efficacy and safety and 10 participants for immunogenicity	Case reports Case series with <100 participants for efficacy and safety and <10 participants for immunogenicity

Methods

Search

A daily scan of the literature (published and preprint) is conducted by the Emerging Science Group at the Public Health Agency of Canada (PHAC). The scan has compiled COVID-19 literature since the beginning of the outbreak and is updated daily. Searches to retrieve relevant COVID-19 literature are conducted in Pubmed, Scopus, BioRxiv, MedRxiv, ArXiv, SSRN, Research Square and cross-referenced with the COVID-19 information centers run by Lancet, BMJ, Elsevier, Nature and Wiley using key terms: COVID-19, SARS-CoV-2, SARS-Coronavirus-2, nCov, "novel CoV", (novel AND coronavirus). Daily alerts from Epistemonikos' L·OVE and McMaster PLUS are also scanned. For this report, the search is up to date as of August 11, 2021. The Evidence Xtraction Team for Research Analysis (EXTRA) team at PHAC performed a first level screening of titles and abstracts in DistillerSR by a single reviewer using a combination of manual review and DistillerAI's natural language processing technology. A second reviewer screened full text results of potentially relevant articles to identify articles on COVID-19 vaccines in immunocompromised persons or persons on dialysis. Following this initial screening, 316 potentially relevant titles were identified for further screening.

We reviewed any items tagged as being on autoimmune populations or other chronic conditions, as well as searching all fields for the following terms:

immunocompromised OR immunosuppressed OR immunosuppression OR immunosuppressive OR immunosuppressives OR autoimmune OR cancer OR cancers OR solid tumor OR solid tumors OR solid tumour OR solid tumours OR chemotherapy OR malignancies OR leukemia OR HIV OR rheumatic OR rheumatoid arthritis OR multiple sclerosis OR dialysis OR hemodialysis OR hemodialysis OR transplant OR transplants OR biologic OR biologics OR anti-interleukins OR anti-interleukin OR corticosteroids OR kinase inhibitors OR kinase inhibitor OR calcineurin inhibitors OR calcineurin inhibitor OR mTOR inhibitor OR mTOR inhibitors OR IMDH inhibitors OR IMDH inhibitor OR monoclonal antibodies OR immunotherapy OR immunotherapies OR immunodeficiency* OR immune deficienc* OR anti-CD38 OR anti-CD20 OR calcineurin inhibitor OR calcineurin inhibitors OR disease-modifying OR DMT OR DMTs OR cytotoxic.

Reviewing these tagged items generated a further 54 relevant titles. Furthermore, the following bibliographic databases were searched: Medline (OVID), EMBASE, and Cochrane Controlled trials register to ensure no studies were missed.

Study Selection Criteria

English-language, peer-reviewed sources and sources published ahead-of-print before peer review were included. The types of studies that were eligible to be considered in this rapid review included Interventional trials, cohort, case-control, or before after studies. Case series were also included provided they included at least 100 participants for efficacy and safety and at least 10 for immunogenicity

After a pilot test, two reviewers independently screened titles as potentially eligible and all studies that at least one reviewer considered eligible was formally assessed. This was again be done by two independent reviewers according to eligibility criteria and any disagreements were resolved by the senior lead.

Data Extraction

Data relevant to the research question, such as study design, setting, location, population characteristics, interventions or exposure and outcomes were extracted when reported.

Data were extracted by one reviewer and the second reviewer verified key elements related to the outcomes of interest after pilot testing. Data that were extracted included, setting, countries, population (type of immunocompromised patients), intervention (stratified by vaccine platform (e.g. mRNA, viral vector), vaccine product, dose: after 1 dose and/or 2 doses of a 2-dose series; 3rd dose (booster dose), interval between dose 1 and 2 of a 2-dose series (manufacture-recommended interval vs extended interval), and interval between completed vaccination series and additional booster dose.

Data Synthesis

We synthesized the results narratively due to the variation in methodology and outcomes for the included studies.

We synthesized data calculating relative risk (for comparative studies) and synthesizing with a random effects model. Case series data were presented as rates and again were synthesized with a random effects model.

Appraisal of Evidence Quality

We evaluated the quality of included evidence using critical appraisal tools as indicated by the study design below. Quality assessment was completed by one reviewer and verified by a second reviewer. Conflicts were resolved through consensus.

The Grading of Recommendations, Assessment, Development and Evaluations (GRADE) (Schünemann et al., 2013) approach was used to assess the certainty in the findings based on eight key domains.

In the GRADE approach to quality of evidence, observational studies, as included in this review, provide low quality evidence, and this assessment can be further reduced based on other domains:

- High risk of bias
- Inconsistency in effects
- Indirectness of interventions/outcomes
- Imprecision in effect estimate
- Publication bias

and can be upgraded based on:
• Large effect
• Dose-response relationship
• Accounting for confounding.

The overall certainty in the evidence for each outcome was determined taking into account the characteristics of the available evidence (observational studies, some not peer-reviewed, unaccounted-for potential confounding factors, different tests and testing protocols, lack of valid comparison groups). A judgement of 'overall certainty is very low' means that the findings are very likely to change as more evidence accumulates.

Risk of Bias Assessment

The tools used for assessing risk of bias were the Cochrane Risk of Bias (ROB 2) for randomized controlled trials and the Cochrane ROBINS-I tool for observational studies.

Completed quality assessments for each included study are available on request.

Results

There were 370 titles screened (1-370). Of these, 161 studies were excluded (62 were excluded for being too small, 52 were duplicate or interim, in 41 the population or data were not relevant, and 6 other reasons). The remaining 209 titles were eligible to be included in the review. A list of included and excluded studies are given in Tables 1 and 2.

Figure 1: Flow Diagram of Study Selection

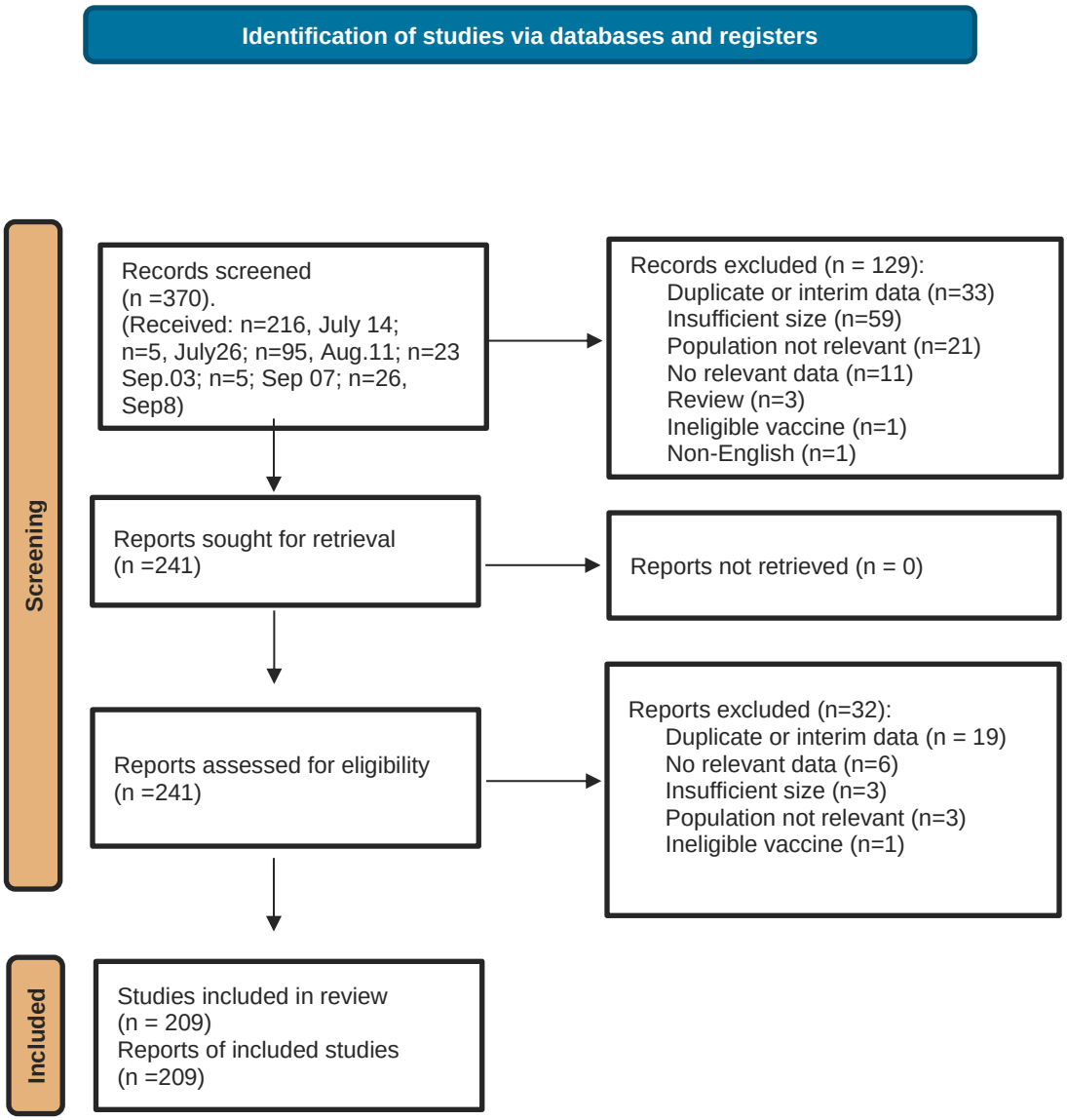


Table 1. Ineligible studies

Reference	Author	Reasons for exclusion
1	Gerber 2021	Insufficient size
2	Lee E-J 2021	Population not relevant and insufficient size
5	Goupil 2021	Duplicate of 106
6	Kanji 2021	Population not relevant
8	Konstantinidis 2021	Population not relevant
11	Manekis 2021	Duplicate of 137
12	Monin-Aldama 2021	Duplicate of 143
14	Shinde 2021	Duplicate of 34
16	Thakkar 2021	Duplicate of 28
17	Palich 2021	Duplicate of 41
21	Capetti 2021	No relevant data
25	Addeo 2021	Duplicate of 46
26	Spencer 2021	No relevant data
30	Aleman 2021	Insufficient size
33	Pacifico 2021	Insufficient size
34	Shinde 2021	Ineligible vaccine
35	Wong 2021	Duplicate of 15
36	Anand 2021	Duplicate of 32
37	Dailey 2021	No relevant data
39	Albach 2021	Insufficient size
42	Zee 2021	Population not relevant
43	Cherian 2021	Population not relevant
44	Achiron 2021	Duplicate of 45
48	Agrita 2021	Insufficient size
50	Ali 2021	Insufficient size
52	Au 2021	Insufficient size
55	Basic-Jukic 2021	Insufficient size
61	Boekel 2021	Duplicate of 229
62	Bonelli 2021	Insufficient size
64	Botwin 2021	Duplicate 63
65	Boyarsky 2021	population not relevant
66	Boyarsky 2021	Duplicate of 13
67	Boyarsky 2021	Duplicate of 23

68	Boyarsky 2021	Duplicate of 66
69	Boyarsky 2021	Duplicate of 66
70	Braun-Moscovici 2021	Duplicate of 71
72	Buttari 2021	Insufficient size
73	Caillard 2021	Insufficient size
74	Ceccarelli 2021	Insufficient size
76	Chilimuri 2021	review
77	Chodick 2021	Duplicate of 79
79	Cohen 2021	Duplicate of 81
80	Cohen 2021	Duplicate of 79
82	Connolly 2021	Duplicate of 23
83	Damiani 2021	Insufficient size
86	Del Bello 2021	Insufficient size
88	Dolff 2021	Insufficient size
89	Donadio 2021	Insufficient size
92	Elder 2021	Insufficient size
93	Eifer 2021	No outcome of interest
96	Crick 2021	Narrative review of a study
98	Frater 2021	Duplicate of 99
101	Furer 2021	Population not relevant and insufficient size
102	Gallo 2021	Insufficient size
103	Garcia 2021	Insufficient size
111	Haberman 2021	Duplicate of 110
115	Harrington 2021	Duplicate of 118
117	Harrington 2021	Duplicate of 116
123	Jalali 2021	Insufficient size
124	Kamar 2021	Duplicate of 259
125	Kennedy 2021	Duplicate of 7
126	Keshavarz 2021	Insufficient size
127	Kahyat-Khoei 2021	Insufficient size
128	Kahyat-Khoei 2021	Duplicate of 127
129	Konstantinidis 2021	Duplicate of 8
133	Lim 2021	No relevant data
134	Lim 2021	Duplicate of 133
136	Lustig 2021	No relevant data
137	Maneikis 2021	Duplicate of 11
142	Mitsunaga 2021	Population not relevant and insufficient size

144	Montoya 2021	Insufficient size
148	Narasimhan 2021	Duplicate of 147
149	Nawimana 2021	Insufficient size
150	Basic-Jukic 2021	No relevant data
152	Ogbebor 2021	Insufficient size
155	Petersen 2021	Insufficient size
159	Riad 2021	Population not relevant
160	Rimar 2021	Insufficient size
162	Rincon-Arevalo 2021	Duplicate of 161
168	Rusk 2021	Insufficient size
170	Sattler 2021	Duplicate of 169
176	Simon 2021	Duplicate of 175
177	Simon 2021	Insufficient size
179	Sindhi 2021	Insufficient size
181	Steber 2021	Insufficient size
183	Terpos 2021	Duplicate of 330
185	Terracina 2021	Insufficient size
187	Touizer 2021	Insufficient size
189	Vyhmeister 2021	Insufficient size
190	Wadei 2021	Insufficient size
192	Watad 2021	Insufficient size
193	Weinstock-Guttman 2021	Insufficient size
197	Yi 2021	Population not relevant
202	Tenforde 2021	Duplicate of 230
206	Hansen 2021	Population not relevant
208	Tsapepas 2021	Insufficient size
210	Iannone 2021	Insufficient size
212	Papasavvas 2021	Insufficient size
213	Mostafa 2021	Insufficient size
214	Greenhall 2021	Insufficient size
220	Re 2021	Duplicate of 218
222	Massa 2021	Duplicate of 217
223	Frantzen 2021	Duplicate of 219
224	Re 2021	Duplicate of 220
231	Tano 2021	Insufficient size
232	Romano 2021	Insufficient size

234	Abe 2021	Insufficient size
235	Marinelli 2021	Insufficient size
241	Cook 2021	No relevant data
249	Mehta 2021	Insufficient size
250	Lin 2021	Duplicate of 7
254	Chang 2021	Insufficient size
255	Atanackovic 2021	Insufficient size
258	Parry 2021	Duplicate of 153
260	Cserep 2021	Insufficient size
262	Hill 2021	Insufficient size
265	Anjan 2021	No relevant data
266	Malinis 2021	Duplicate of 216
270	Drulovic 2021	Ineligible vaccine
273	Huzly 2021	No relevant data
277	Squire 2021	Insufficient size
281	Benotmane 2021	Duplicate of 221
285	Manni 2021	Insufficient size
292	Kastritis 2021	Population not relevant
294	Golding 2021	Insufficient size
304	Xu 2021	No relevant data
307	Brosh-Nissimov 2021	No relevant data
311	Lotan 2021	No relevant data
312	Loconsole 2021	Insufficient size
317	Damiani 2021	Insufficient size
318	Allen-Philbey 2021	Population not relevant
319	Kuter 2021	Population not relevant
321	Callejas Rubio 2021	Non-English
322	Rosman 2021	Population not relevant
323	von Csefalvay 2021	Population not relevant
326	Ishay 2021	Population not relevant and insufficient size
329	Felten 2021	Population not relevant
331	Rzymski 2021	Insufficient size
333	Sotiriou 2021	Population not relevant
339	Rabinovitch 2021	Population not relevant
341	Boekel 2021	No relevant data
345	Ravanan 2001	Duplicate of 340
346	Speer 2001	Duplicate of 342

347	Dhakal 2021	Duplicate of 343
348	Veenstra 2021	Duplicate of 344
350	Ramirez 2021	Insufficient size
351	Salviani 2021	Insufficient size
353	Boekel 2021	Duplicate of 341
354	Connolly 2021	No relevant data
355	O'Nions 2020	Population not relevant
356	Lubetzky 2021	Population not relevant
357	Butt 2021	Population not relevant
359	Mado 2021	Insufficient size
360	Komaba 2021	Insufficient size
361	Wolf 2021	Insufficient size
362	Westhoff 2021	No relevant data
363	Ferguson 2021	Insufficient size
365	Chung 2021	Population not relevant
366	Benucci 2021	Duplicate of 332
367	Chow 2021	Systematic review
368	Malinis 2021	Duplicate of 266

Note: Some studies have more than one excluded reason and we chose the first applicable one in our assessment form. Duplicate data could be preliminary / interim data, early or duplicate publications. Insufficient size includes case reports.

Table 2. Eligible studies

Reference	Author	Outcome assessed
3	Attias 2021	Immunogenicity
4	Billany 2021	Immunogenicity
7	Kennedy 2021	Immunogenicity
9	Lacson 2021	Immunogenicity
10	Mahid 2021	Immunogenicity
13	Ou 2021	Safety
15	Wong 2021	Immunogenicity
18	Scurr 2021	Immunogenicity
19	Nadesalingam 2021	Immunogenicity
20	Miele 2021	Immunogenicity
22	Cucchiari 2021	Immunogenicity
23	Ruddy 2021	Immunogenicity
24	Chan 2021	Immunogenicity

27	Husain 2021	Immunogenicity
28	Thakkar 2021	Immunogenicity
29	Schmidt 2021	Immunogenicity
31	al-Janabi 2021	Immunogenicity
32	Anand 2021	Immunogenicity
38	Ben-Dov 2021	Immunogenicity
40	Broseta 2021	Immunogenicity
41	Palich 2021	Immunogenicity
45	Achiron 2021	Immunogenicity
46	Addeo 2021	Immunogenicity
47	Agha 2021	Immunogenicity
49	Agur 2021	Immunogenicity
51	Apostolidis 2021	Immunogenicity
53	Barda 2021	Final Immunogenicity
54	Barriere 2021	Immunogenicity
56	Benotmane 2021	Immunogenicity
57	Benotmane 2021	Immunogenicity
58	Bertrand 2021	Immunogenicity
59	Bigaut 2021	Immunogenicity
60	Bird 2021	Immunogenicity
63	Botwin 2021	Safety
71	Braun-Moscovici 2021	Immunogenicity
75	Chavarot 2021	Immunogenicity
78	Chodick 2021	Efficacy and safety
79	Cohen 2021	Immunogenicity
84	Danthu 2021	Immunogenicity
85	Depaak 2021	Immunogenicity
87	Diefenback 2021	Immunogenicity
90	Duarte 2021	Immunogenicity
91	Ducloux 2021	Immunogenicity
94	Salinas 2021	Immunogenicity
95	Firket 2021	Immunogenicity
97	Frantzen 2021	Immunogenicity
99	Frater 2021	Immunogenicity
100	Furer 2021	Immunogenicity
104	Giesen 2021	Immunogenicity
105	Ghione 2021	Immunogenicity

106	Giopil 2021	Immunogenicity
107	Grupper 2021	Immunogenicity
108	Grupper 2021	Immunogenicity
109	Guerrieri 2021	Immunogenicity
110	Haberman 2021	Immunogenicity
112	Hadi 2021	Efficacy
113	Hagin 2021	Immunogenicity
114	Haider 2021	Immunogenicity
116	Harrington 2021	Immunogenicity
118	Harrington 2021	Immunogenicity
119	Havlin 2021	Immunogenicity
120	Herishanu 2021	Immunogenicity
121	Ben Zadok 2021	Immunogenicity
122	Jahn 2021	Immunogenicity
130	Korth 2021	Immunogenicity
131	Lesny 2021	Immunogenicity
132	Levy 2021	Immunogenicity
135	Longlune 2021	Immunogenicity
138	Marinaki 2021	Immunogenicity
139	Marion 2021	Immunogenicity
140	Massarweh 2021	Immunogenicity
141	Mazzola 2021	Immunogenicity and safety
143	Monin 2021	Immunogenicity and safety
145	Monzo 2021 (Broseta 2021)	Immunogenicity
146	Nadesalingam 2021	Immunogenicity
147	Narasimhan 2021	Immunogenicity
151	van Oekelen 2021	Immunogenicity
153	Parry 2021	Immunogenicity
154	Peled 2021	Immunogenicity
156	Pimpinelli 2021	Immunogenicity
157	Rabinowich 2021	Immunogenicity
158	Ram 2021	Immunogenicity and safety
161	Rincon-Arevalo 2021	Immunogenicity
163	Rodriguez-Espinosa 2021	Immunogenicity
164	Roeker 2021	Immunogenicity
165	Rozen-Zvi 2021	Immunogenicity
166	Rubbert-Roth 2021	Immunogenicity
167	Ruddy 2021	Immunogenicity

169	Sattler 2021	Immunogenicity
171	Schrezenmeier 2021	Immunogenicity
172	Shostak 2021	Immunogenicity
173	Shroff 2021	Immunogenicity
174	Shrotri 2021	Immunogenicity
175	Simon 2021	Immunogenicity
178	Simon 2021	Immunogenicity
180	Spiera 2021	Immunogenicity
182	Stengert 2021	Immunogenicity
184	Terpos 2021	Immunogenicity
186	Torreggiani 2021	Immunogenicity
188	Tzarfati 2021	Immunogenicity
191	Waissengrin 2021	Safety
194	Werbel 2021	Immunogenicity and safety
195	Yanay 2021	Immunogenicity
196	Yau 2021	Immunogenicity
198	Yi 2021	Immunogenicity
199	Young-Xu 2021	Efficacy and safety
200	Chevallier 2021	Immunogenicity, efficacy and safety
201	Espi 2021	Immunogenicity
203	Moyon 2021	Immunogenicity
204	Mahil 2021	Immunogenicity, efficacy and safety
205	Holden 2021	Immunogenicity
207	Goshen-Lago 2021	Immunogenicity and safety
209	Khan 2021	Efficacy
211	Iacono 2021	Immunogenicity
215	Ben-Tov 2021	Efficacy and safety
216	Malinis 2021	Efficacy
217	Massa 2021	Immunogenicity
218	Re 2021	Immunogenicity
219	Frantzen 2021	Immunogenicity
221	Benotmane 2021	Immunogenicity
225	Labriola 2021	Immunogenicity
226	Hadjadj 2021	Immunogenicity
227	Chemaitelly 2021	Immunogenicity
228	Cao 2021	Immunogenicity
229	Boekel 2021	Immunogenicity

230	Tenforde 2021	Efficacy
233	Prendecki 2021	Immunogenicity
236	Liao 2021	Immunogenicity
237	Lacson 2021	Immunogenicity
238	Izmirly 2021	Immunogenicity
239	Hall 2021	Immunogenicity
240	Ghandili 2021	Immunogenicity
242	Benda 2021	Immunogenicity
243	Garcia 2021	Immunogenicity
244	Connolly 2021	Safety
245	Abo-Helo 2021	Immunogenicity
246	Zitt 2021	Immunogenicity
247	Rashidi-Alavijeh 2021	Immunogenicity
248	Midtvedt 2021	Immunogenicity
251	Heudel 2021	Efficacy
252	Guglielmelli 2021	Immunogenicity
253	Di Meo 2021	Immunogenicity
256	Stampfer 2021	Immunogenicity
257	Pimpinelli 2021	Immunogenicity
259	Del Bello 2021	Immunogenicity
261	Aslam 2021	Efficacy
263	Gurion 2021	Immunogenicity
264	Benjamini 2021	Immunogenicity
267	Re 2021	Immunogenicity
268	Qin 2021	Efficacy
269	Hod 2021	Immunogenicity
271	Stumpf 2021	Immunogenicity
272	Ramanathan 2021	Immunogenicity
274	Charmetant 2021	Efficacy
275	Caocci 2021	Immunogenicity
276	Woldemeskel 2021	Immunogenicity
278	Madelon 2021	Immunogenicity
279	Herrera 2021	Immunogenicity
280	Easdale 2021	Immunogenicity
282	Weigert 2021	Immunogenicity
283	Stefanski 2021	Immunogenicity
284	Sormani 2021	Immunogenicity

286	Kaiser 2021	Immunogenicity
287	Mrak 2021	Immunogenicity
288	Gavriatopoulou 2021	Immunogenicity
289	Espi 2021	Immunogenicity
290	Boyarsky 2021	Immunogenicity
291	Schrezenmeier 2021	Immunogenicity
293	Rotondo 2021	Safety
295	Fox 2021	Immunogenicity
296	Ali 2021	Safety
297	Ammitzbøll 2021	Immunogenicity
298	Ruddy 2021	Immunogenicity
299	Redjoul 2021	Immunogenicity
300	Prendecki 2021	Immunogenicity
301	Lemieux 2021	Immunogenicity
302	Clarke 2021	Immunogenicity
303	Benotmane 2021	Immunogenicity
305	Schramm 2021	Immunogenicity
306	Revon-Riviere 2021	Immunogenicity
308	Ehmsen 2021	Immunogenicity
309	Greenberger 2021	Immunogenicity
310	Hall 2021	Immunogenicity
313	Scoccianti 2021	Safety
314	Buttiron Webber 2021	Immunogenicity
315	Firinu 2021	Immunogenicity
316	Whitaker 2021	Efficacy
320	Shenoy 2021	Immunogenicity
324	Fong 2021	Immunogenicity
325	Blazquez-Navarro 2021	Immunogenicity
327	Lotan 2021	Safety
329	So 2021	Safety
330	Terpos 2021	Immunogenicity
332	Benucci 2021	Immunogenicity
334	Polewska 2021	Safety
335	Talamonti 2021	Safety
336	Tylicki 2021	Immunogenicity
337	Tallantyre 2021	Immunogenicity
338	Henriquez 2021	Immunogenicity and efficacy

340	Ravanan 2021	Efficacy
342	Speer 2021	Immunogenicity
343	Dhakal 2021	Immunogenicity
344	Veenstra 2021	Immunogenicity
349	Song 2001	Efficacy
352	Bardazzi 2021	Safety
358	Butt 2021	Efficacy
364	Connolly 2021	Immunogenicity
369	Skroza 2021	Safety
370	Stumpf 2021	Immunogenicity

Efficacy of COVID-19 vaccination in preventing SARS-CoV2 infection in the immunocompromised

There were three cohort studies (53, 78, 316) evaluating 7,283,329 participants that developed 20,087 SARS-CoV2 infections during follow up. In addition, there were two case-control studies (199, 230) evaluating 498,203 negative and 15,997 positive SARS-CoV2 tests. The summary and results of these studies is given in Tables 3 and 4.

Table 3. General summary of observational studies evaluating SARS-CoV2 vaccination in the general population

Author	Country and Population	Vaccine	Overall number vaccinated	Number immuno-compromised vaccinated	Overall number un-vaccinated	Number immuno-compromised unvaccinated	Matching /Adjustment
Cohort studies							
Barda et al. (53)	Israel, data from Clalit Health Services, largest of 4 integrated health organizations representing 4.7 million (53% population)	BNT162b2	596,618	16,615	596,618	16,318	Matched for age, sex, sector (General Jewish, Arab, Ultra-Orthodox Jewish), number of CDC risk factors, number of influenza vaccinations over previous 5 years

Chodick et al. (78)	Israel, data from Maccabi Health Services representing 2.6 million (25% population)	BNT162b2	872,454	25,459 (immunosuppression) 95,935 (cancer)	1,178,597*	27,822* (immunosuppression) 90,512* (cancer)	Adjusted for age, sex, sector (General Jewish, Arab, Ultra-Orthodox Jewish), chronic illness, calendar period
Whitaker et al. (316)	UK, data extracted from computerized medical record, Oxford-Royal College of General Practitioners Research and Surveillance Centre involving 718 general practices covering 7.2 million	BNT162b2 or ChAdOx1	2,221,473	84,234	1,817,569	7,325	Adjusted for region, age, sex, ethnicity, household size, income, GP consultation quartile, respiratory disease risk status and smoking
Case-control studies							
Author	**Country and population**	**vaccine**	**Overall negative tests**	**Immunocompromised negative tests**	**Overall positive tests**	**Immunocompromised positive tests**	**Matching/Adjustment**
Young-Xu et al. (199)	US, data from Veterans Health Administration Corporate Data Warehouse– 171 medical centres, caring for 6.2 million veterans	BNT162b2 or mRNA-1273	497,584	96,783 – IMM 40,710 - cancer	15,404	2,324 – IMM 992 - cancer	Age, sex, race, rurality, BMI, congestive heart failure, chronic kidney disease, diabetes mellitus, hypertension, VA priority level
Tenforde et al. (230)	US, surveillance activity across IVY network of 18 academic medical	BNT162b2 or mRNA-1273	619	155	593	99	Age, sex, region, race, calendar time, number of chronic medical conditions, >

	centres in 16 states						one hospitalization in a year, smoking, education level, mask wearing, indoor gathering

*Infections from the first 7 days of the 1st vaccination (assumed to be similar risk as unvaccinated)

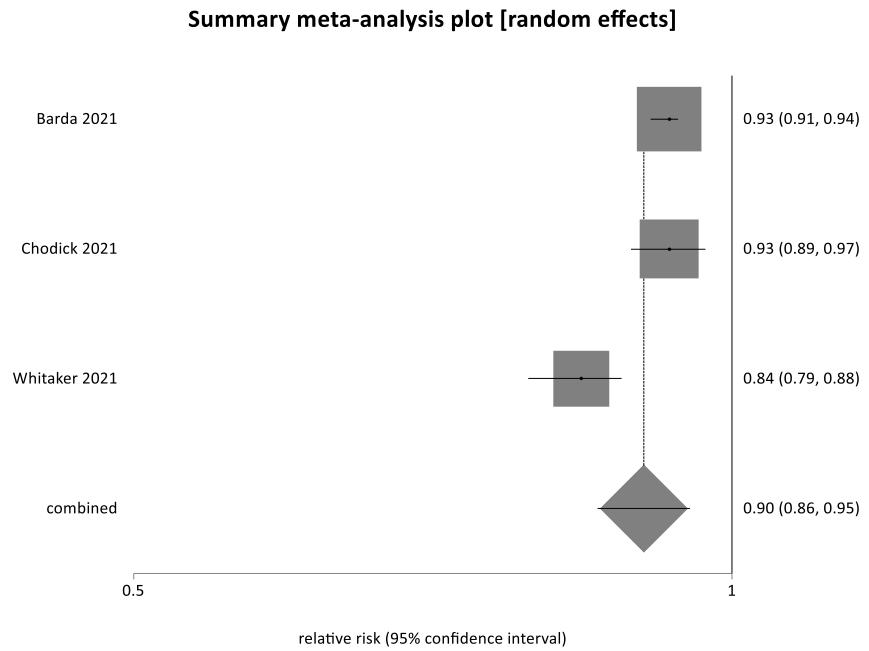
Table 4. Summary of results of general population observational studies

Author	Overall no. COVID-19 cases	Duration of follow up	Time after second vaccine considered protected	Overall vaccine protection (95% confidence interval)	Vaccine protection in immunocompromised (95% confidence interval)
Cohort studies					
Barda et al. (53)	10561 infections 5996 symptoms 369 hospitalized 41 deaths	Mean 15 days (IQR = 5 to 25)	7 days	93% (91 to 94) - infection 96% (94 to 97) – symptom 92% (85 to 97) - hospital	90% (49 to 100) - infection 84% (19 to 100) – symptom 100% (2 vs 0) - hospital
Chodick et al. (78)	5242 infections 3444 symptoms	7-27 days	7 days	93% (89-97)* - infection	79% (66-94)* – IMM 88% (80-97)* - cancer 85% (77-93) - combined
Whitaker et al. (316)	4284 infections	unclear	14 days	84% (79-88) - infection	74% (48-87)
Case-control studies					
Author	**Proportion vaccinated in positive cases**	**Proportion vaccinated in negative cases**	**Time after second vaccine considered protected**	**Overall vaccine protection (95% confidence interval)**	**Vaccine protection in immunocompromised (95% confidence interval)**
Young-Xu et al. (199)	4%	17%	7 days	94% (92-95) - infection	88% (82-92) – IMM 84% (73-91) - cancer
Tenforde et al. (230)	9%	44%	14 days	91% (86-95%) - hospital	63% (21-83)

*Calculated by pooling protection from the two calendar periods outlined in supplementary table 2.

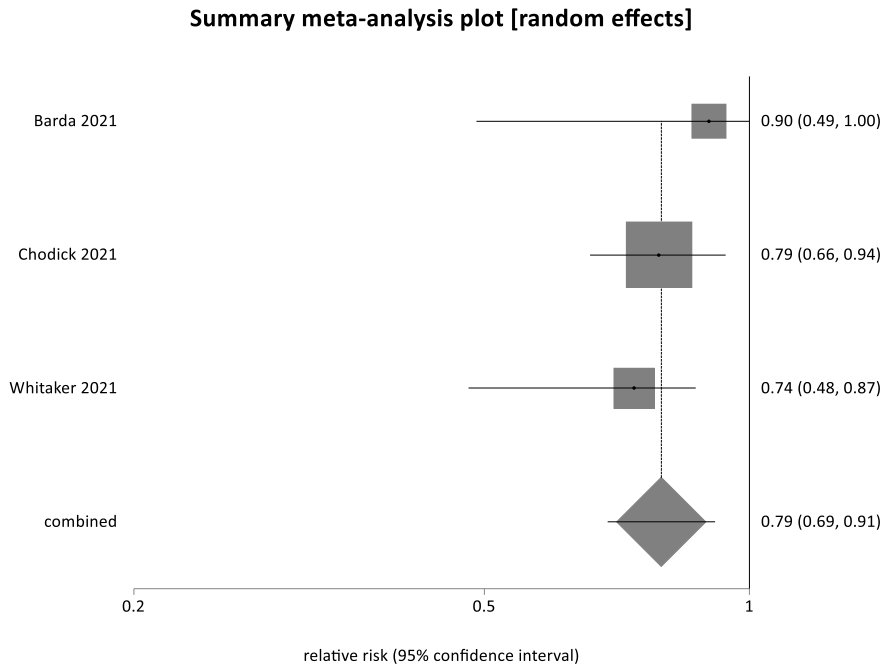
The three ((53, 78, 316) cohort studies reported a pooled vaccine efficacy in the general population of 90% (95% CI = 86 to 95%) with significant heterogeneity between studies (I^2 = 84%, χ^2 = 12.7, p = 0.002) driven by the UK study giving a lower efficacy than the two Israeli studies (Figure 2). These population studies contained 177,773 participants that were immunocompromised although none of the studies stated how this was defined. The vaccine efficacy in the immunocompromised population was 79% (95% CI = 69 to 91%) with no statistically significant heterogeneity between studies (I^2 = 0%, χ^2 = 0.69, p = 0.71) (Figure 3). One cohort study (78) described the vaccine efficacy in 186,447 cancer patients and reported 88% (95% CI = 80-97%) protection in those vaccinated.

Figure 2. Vaccine efficacy in the general population in cohort studies



x-axis refers to the summary statistic used to calculate vaccine effectiveness

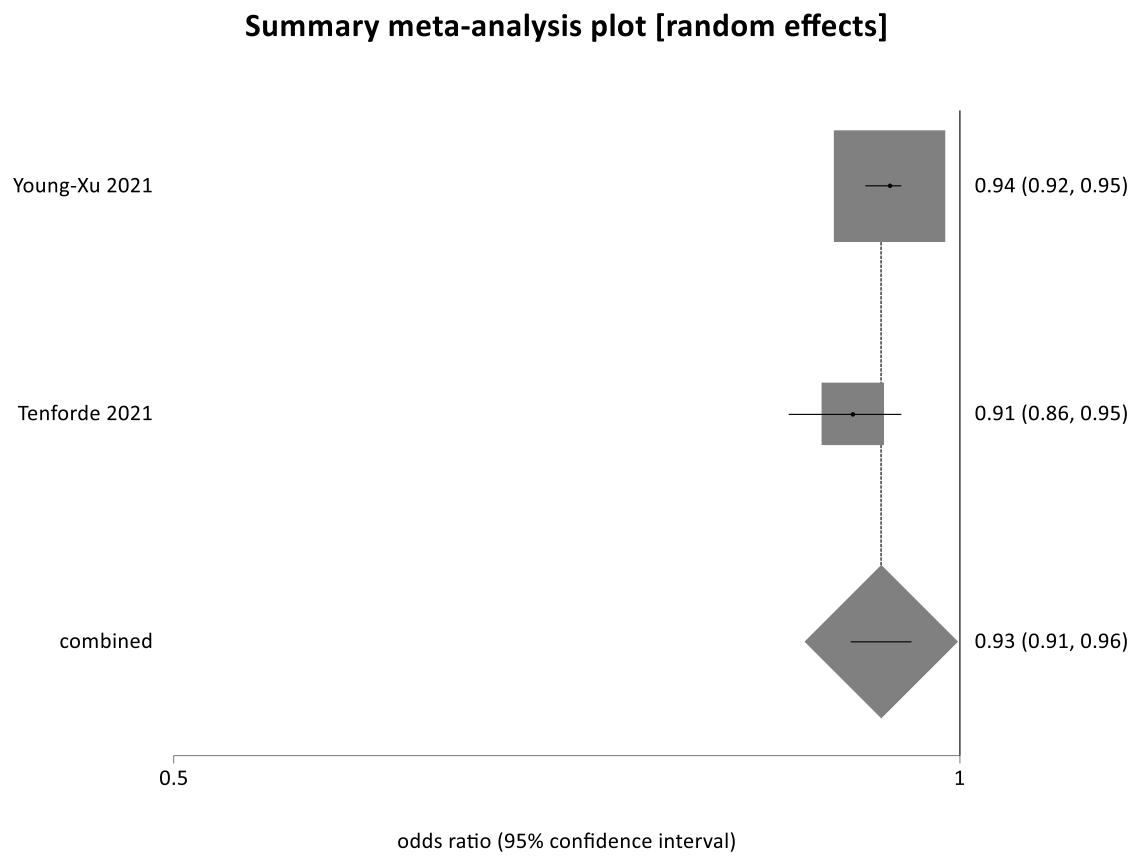
Figure 3. Vaccine efficacy in the immunocompromised population in cohort studies



x-axis refers to the summary statistic used to calculate vaccine effectiveness

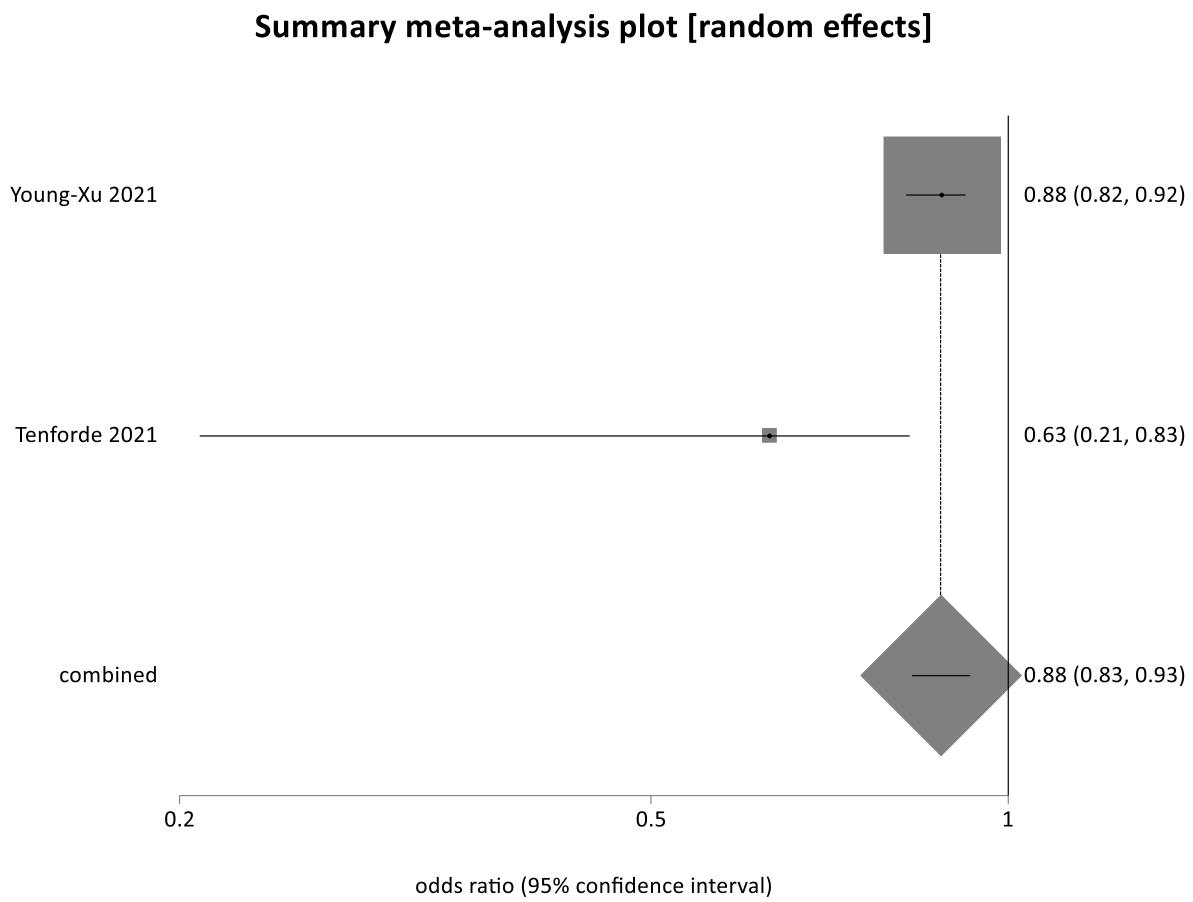
The two (199, 230) case control studies reported a pooled vaccine efficacy in the general population of 93% (95% CI = 91 to 96%) with mild heterogeneity between studies (I^2 = 32%, χ^2 = 1.48, p = 0.22) (Figure 4). Case-control studies are more prone to bias and confounding than cohort studies and calculating the vaccine efficacy assumes that the odds ratio approximates to the relative risk which is not the case if the disease is common. It is therefore reassuring that these two US case-controls studies gave similar results to the cohort studies above. These population studies contained 99,355 participants that were immunocompromised although none of the studies stated how this was defined. The vaccine efficacy in the immunocompromised population was 88% (95% CI = 83 to 93%) with no statistically significant heterogeneity between studies (I^2 = 0%, χ^2 = 0.90, p = 0.34) (Figure 5). One case control study (199) described the vaccine efficacy in 41,632 cancer patients and reported 84% (95% CI = 73-91%) protection in those vaccinated.

Figure 4. Vaccine efficacy in the general population in case-control studies



x-axis refers to the summary statistic used to calculate vaccine effectiveness

Figure 5. Vaccine efficacy in the immunocompromised population in case-control studies



x-axis refers to the summary statistic used to calculate vaccine effectiveness

There are also four studies (227, 251, 261, 340) that reported vaccine efficacy in specific immunocompromised populations comparing those that are vaccinated with those that are unvaccinated. Heudel et al. (251) reported COVID-19 symptoms and a positive SARS-CoV2 test developing in 1503 cancer patients undergoing active treatment over a median of 44 days (range 1-130 days) during a vaccination program. 1203 (80%) had solid tumors and the remaining hematological malignancy and 75% received BNT162b2 with 21% mRNA-1273 and 4% ChAdOx1. 4/1091 (0.4%) of the fully vaccinated developed symptomatic COVID-19 compared to 20/412 (5%) that had a single dose. The vaccine efficacy was not reported in this paper but can be calculated as 92% (95% CI = 78 to 97%). This is a similar vaccine efficacy to the general population and also compatible with an efficacy slightly lower than the general population described in the two population studies above (78, 199).

Another study (261) reported on vaccine efficacy in 2151 solid organ transplant patients 912 fully vaccinated, 88 partially vaccinated and 1151 unvaccinated controls. 70% received the

mRNA-1273 vaccine. There were 65 cases of COVID-19 during a mean of 144 days of follow up in the vaccinated versus 691 days in the unvaccinated group. Adjusting for different durations of follow up gives a vaccination efficacy of 81% (95% CI = 50 to 95%). In contrast, a cohort study of 782 kidney transplant patients in Qatar (227) found that the vaccine effectiveness only 47% (95% CI 0-74%) 14 days after the 2nd vaccination (either BNT162b2 or mRNA-1273) when compared with the unvaccinated. This increased to 74% (95% CI = 33-90%) 56 days after the second vaccine. A final study (340) evaluated SARS-CoV-2 infections in vaccinated and unvaccinated solid organ transplant recipients linking the UK transplant registry, Public Health England, National Health Service Digital and National Immunisation Management Services records. 39,727 (82%) had been vaccinated, 6748 (14%) unvaccinated and the remainder had one vaccine. There were 3473/6748 that were SARS-CoV-2 positive in the unvaccinated group compared to 143/39727 positive cases in the fully vaccinated group. In those that were positive case fatality was 438/3473 (12.6%) in unvaccinated group compared to 11/143 (7.7%) in the fully vaccinated group.

There were also four studies (216, 268, 274, 349) that gave uncontrolled information on COVID-19 risk in fully vaccinated transplant patients. Only one of these studies (274) described the duration of follow up and none had a meaningful comparator group, so results are difficult to interpret. The proportion developing breakthrough COVID-19 varied between 0.65% (216) and 2% (274) with a pooled proportion of 1% (95% CI = 0.6 to 2%) in 19790 solid organ transplant patients.

Hadi et al. (112) described efficacy of vaccination in 864,575 participants with 5,562 having inflammatory bowel diseases (IBD). Risk of developing COVID-19 was similar in the IBD group compared to the general population (0.36% versus 0.28%), relative risk = 0.95 (95% CI = 0.51 to 1.78) after adjusting for confounding factors. Adverse events were also similar in both groups. Over 50% of patients with IBD were taking immunosuppressive therapy and although there were not data given on this group, the authors did state that immunosuppressive therapy was not associated with an increased risk of developing COVID-19. A similar outcome was reported by Ben-Tov et al. (215) although this used the same database as Chodick et al. (78) and so some of the participants are likely to be common to both studies. Nevertheless, Ben-Tov et al. (215) reported no increase in COVID-19 infections in 12,231 fully vaccinated IBD patients compared with 36,254 matched vaccinated participants without IBD. COVID-19 infection risk was similar in both groups (0.19% in IBD and 0.15% in controls) RR = 1.21 (95% CI = 0.74 to 1.97). No increase in risk was seen in those taking immunosuppressive therapy.

Immunogenicity of COVID-19 vaccination in the immunocompromised and dialysis patients

Studies addressing the immune response in the immunocompromised were subdivided into persons living with the human immunodeficiency virus (HIV), malignancy, immunosuppressive therapy, transplant patients and those with primary immune deficiencies. Studies evaluated anti-Spike protein antibodies, neutralizing antibodies and T cell responses. Almost all studies evaluated anti-Spike protein antibodies, and we use these antibodies when reporting seroconversion (manufacturer's definitions used as cut-off values).

Immunogenicity in persons living with Human Immunodeficiency Virus

Overall, there were seven studies (10, 99, 114, 132, 174, 276, 298) that evaluated COVID-19 vaccination in persons living with HIV (PLWH) summarized in Table 5.

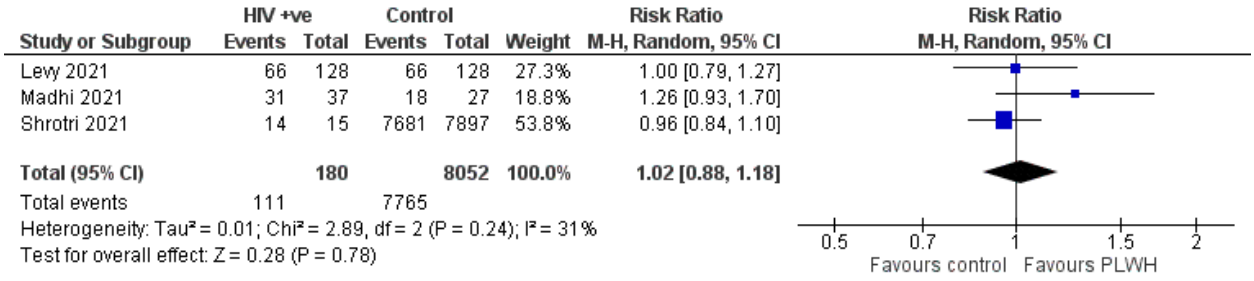
Table 5. Summary of persons living with HIV studies

Author	Design	Country	Case description	Control description	Vaccine	Titre measured	Duration between 1st and 2nd vaccine
Madhi (10)	cohort	Sth Africa	HIV +ve that were COVID naïve. Age = 43 Female = 46%	HIV -ve controls that were COVID naïve Age = 31 Female = 84%	ChAdOx1	anti-RBD IgG	28 days
Frater (99)	cohort	UK	HIV +ve on ART Age = 42.5 Female = 0%	group 5d of COV002 study (RCT of AZ vaccine in healthy volunteers) Age = 38.5 Female = 48%	ChAdOx1	anti-S IgG	28 days
Haidar (114)	cohort	US	HIV +ve (all CD4>200) treated over last 12 months across the University of Pittsburgh Health System Age = 57.1 Female = 8%	health care workers employed across the same health care system Age = 43.7 Female = 72%	BNT162b2 (41%), mRNA-1273 (59%) or Ad26.COV2.S	anti-RBD IgG Beckman Coulter platform	unclear

Levy (132)	cohort	Israel	HIV +ve all on antiviral, 18.2% had AIDS, 7 malignancies and two organ transplants. Mean time since diagnosis 13.2 years Age = 49.8 Female = 8%	health care workers not on immunosuppression Age = N/R Female = N/R	BNT162b2	anti-RBD IgG	21 days
Shrotri (174)	Cohort	UK	HIV +ve Age = N/R Female = N/R	general data for patients not on IMM Age = N/R Female = N/R	BNT162b2 or ChAdOx1	anti-RBD IgG (Roche Elecsys)	4-12 weeks
Woldemeskel (276)	Cohort	US	HIV +ve, 11 black no prior COVID, 3 had low level viremia despite ART Age = 52 Female = 58%	healthy donors no prior COVID Age = 41 Female = 41%	BNT162b2	anti-S IgG (Euroimmun)	unclear
Ruddy (298)	Case series	US	persons with HIV (PWH) Age = 62 Female = 7%	N/A	5 BNT162b2, 9 mRNA-1273	anti -RBD (IgM, IgG) , a critical target of neutralizing antibodies within the spike protein	4 weeks

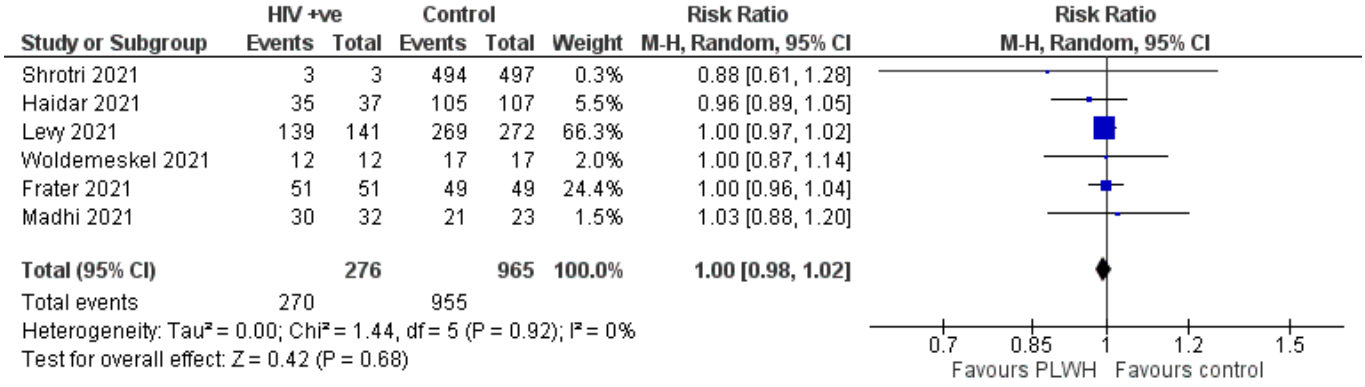
Three cohort studies (10, 132, 174) compared the immunogenicity of COVID-19 vaccination in PLWH and controls 15-28 days after the first vaccination in 8,232 participants. There was no statistically significant difference between PLWH and controls in the proportion seroconverting (RR = 1.02; 95% CI = 0.88 to 1.18) with mild heterogeneity between studies (I^2 = 31%, χ^2 = 2.89, p = 0.24) (Figure 6).

Figure 6. Seroconversion in people living with HIV and controls after first vaccination



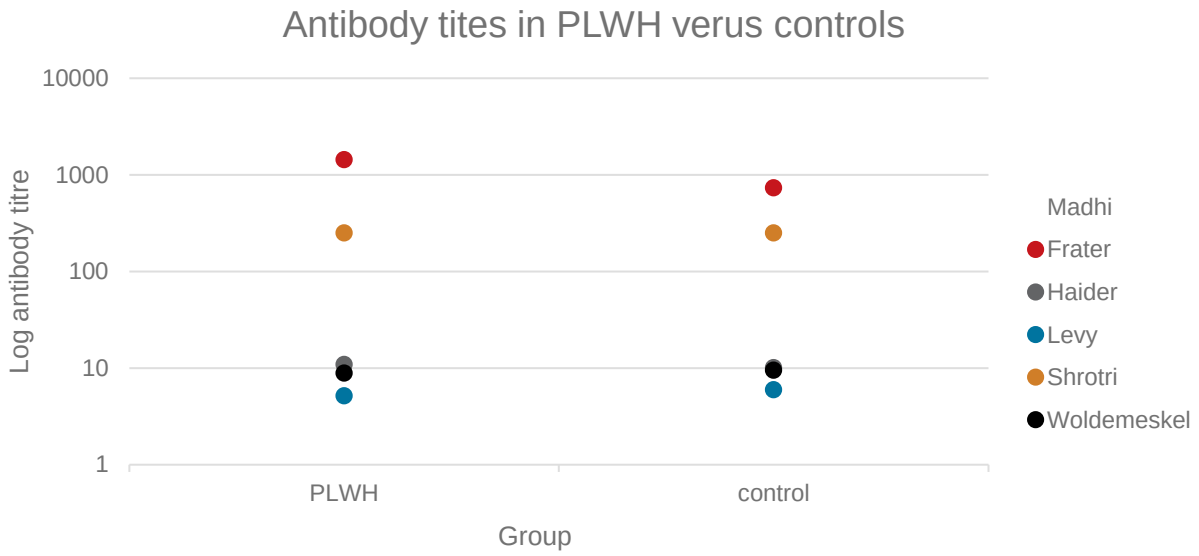
Six cohort studies (10, 99, 114, 132, 174, 276) compared the immunogenicity of COVID-19 vaccination in PLWH and controls 14-75 days after the second vaccination in 1,241 participants. There was no statistically significant difference between PLWH and controls in the proportion seroconverting (RR = 1.00; 95% CI = 0.98 to 1.02) with 98% seroconverting in PLWH and 99% in the control arm with no heterogeneity between studies ($I^2 = 0\%$, $\chi^2 = 1.44$, $p = 0.92$) (Figure 7).

Figure 7. Seroconversion in people living with HIV and controls after second vaccination



Most of the six cohort studies described median and interquartile ranges for antibody titres, which cannot be accurately synthesized. However, the median/mean antibody titres were similar in both groups (Figure 8).

Figure 8. Median/mean antibody titres for PLWH and controls



There was also one case series (298) reporting on 14 PLWH with no control group. Seroconversion was reported in 10/10 cases 14-27 days after the first vaccine and 14/14 28 days after the second vaccine. Participants had either BNT162b2 or mRNA-1273 and results were not presented separately for each type of vaccine.

Immunogenicity in patients taking immunosuppressive therapy

Drugs that suppress the immune system are used for a variety of autoimmune diseases and might also be expected to impact of the immunogenicity of COVID-19 vaccines. There were 40 studies (3, 7, 15, 23, 31, 37, 45, 51, 71, 85, 104, 106, 109, 110, 114, 145, 166, 174, 180, 204, 226, 229, 233, 236-238, 271, 272, 278, 282-284, 287, 297, 315, 320, 332, 337, 344, 364) included in this rapid review that addressed this question and these are summarized in Table 6. The control groups used in these studies were either those with the disease but not treated with immunosuppressive therapy or healthy volunteers. These were analyzed separately but gave similar results, so these control groups are combined in the data synthesis.

Table 6. Summary of patients taking immunosuppressive therapy studies

Author	Design	Country	Case description	Control description	Vaccine	Titre measured	Duration between 1st and 2nd vaccine
Billany (3)	Case series	UK	maintenance hemodialysis, 10% IMM 20% previous COVID Age = 62.1 Female = 40%	maintenance hemodialysis patients not on IMM	BNT162b2 (82%) or ChAdOx1 (18%)	anti-RBD IgG (Siemens ADVIA Centaur Xp/XPT assay)	N/A
Kennedy (7)	Cohort	UK	IBD patients receiving infliximab (8.7% prior covid) Age = 41.1 Female = 50%	IBD patients receiving vedoluzimab (9.2% prior covid) Age = 49.6 Female = 47%	BNT162b2 (46%) or ChAdOx1 (54%)	anti-S IgG (Roche, Elecsys)	N/R
Wong (15)	Cohort	US	IBD cases on anti-TNF, ustekinumab, vedoluzimab or no therapy - selected the anti-TNF and ustekinumab patients Age = 49 Female = 52%	health care workers (14) and healthy volunteers (29) Age = 34 Female = 43%	BNT162b2 (48%) or mRNA-1273 (52%)	anti-RBD total and IgG (Siemens Healthineers)	unclear
Ruddy (23)	Case series	US	rheumatological disorders all taking IMM Age = 44 Female = 95%	N/A	BNT162b2 (51%) or mRNA-1273 (49%)	anti-RBD total Ig (Roche, Elecsys)	27 days (21-28 IQR)
Al-Janabi (31)	Case series	UK	patients with RA, psoriasis, IBD on a biologic/immunomodulator Age = 53	N/A	BNT162b2 (50%) or ChAdOx1 (50%)	anti-RBD total Ig (Roche, Elecsys) (and anti-S1	N/R

			Female = 41%			IgG (Siemens))	
Dailey (37)	Case series	US	Case series of pediatric IBD patients but created cohort study out of those on vedolizumab versus other biologic (demographic data not available on this subset) Age = N/R Female = N/R	N/A	BNT162b2 or mRNA-1273 (n=28), d26.COV2.S (n=5)	anti-RBD IgG (Acro Biosystems)	unclear
Achiron (45)	Cohort	Israel	MS for median 13 years treated with IMM (cladribine, fingolimod or ocrelizimab) Age = 48 Female = 53%	healthy volunteers and MS w/o IMM Age = 54.3 (healthy); 50.5 (MS w/o IMM Female = 94% (healthy); 49% (MS w/o IMM	BNT162b2	anti-S IgG (Quantivac, Euroimmun)	21 days
Apostolidis (51)	Cohort	US	MS patients on anti-CD20 therapy Age = 40.4 Female = 75%	healthy controls w/in University of Pennsylvania system Age = 35.2 Female = 60%	BNT162b2 (62%) or mRNA-1273 (38%)	anti-S IgG (and anti-RBD IgG)	unclear
Braun-Moscovici (71)	Cohort	Israel	Case series of consecutive autoimmune patients receiving first vaccine (mean disease duration 11 years) – patients on IMM Age = 57.6 Female = 75%	Case series of consecutive autoimmune patients receiving first vaccine but not on IMM Age = N/R Female = N/R	BNT162b2	anti-S IgG (Abbott, ARCHITECT IgG Quant test)	21 days
Deepak (85)	Cohort	US	Patients with chronic inflammatory disease (100 on MMX, 33 on none, ASA, vedoluzimab) Age = 45.5 Female = 74%	Faculty & staff of Washington University, BJC (St Louis) &UCSF Age = 43.4 Female = 55%	BNT162b2 or mRNA-1273	anti-S IgG	28 days
Giesen (104)	Cohort	Germany	patients w/ chronic inflammatory disease on immunosuppression (one on sulphasalazine only which is not immunosuppressive but rest on IMM) Age = 50.5 Female = 65%	health care workers, non-infected with COVD-19 Age = 37.5 Female = 69%	BNT162b2 or mRNA-1273 (n=5)	anti-S IgG (Quantivac, Euroimmun)	35 days

Guerrieri (109)	Case series	Italy	Patients with MS either on fingolimod or ocrelizumab (16 of each) Age = 42.9 Female = 69%	N/A	BNT162b2 (30) or mRNA-1273 (2)	anti-S Ig	21 days
Haberman (110)	Cohort	US	Patients with immune mediated inflammatory disease (predominantly psoriatic & RA) on IMM Age = 56 Female = 61%	healthy controls Age = 49 Female = 68%	BNT162b2	anti-S1 IgG (Quantivac, Euroimmun)	unclear
Haidar (114)	Cohort	US	various autoimmune disease (50% IBD, 50% rheumatological) treated over last 12 months across the University of Pittsburgh Health System Age = 54.2 Female = 70%	health care workers employed across the same health care system Age = 43.7 Female = 72%	BNT162b2 (41%), mRNA-1273 (59%) or d26.COV2.S	anti-RBD IgG Beckman Coulter platform	unclear
Broseta (145)	Cohort	Spain	hemodialysis, mean of 67.9 months (5% on IMM) all seronegative at baseline Age = 70.9 Female = 33%	Hemodialysis patients not on IMM	BNT162b2 (43%) or mRNA-1273 (57%)	anti-S1 IgG (Siemens)	21-28 days
Goupil (106)	Cohort	Canada	Hemodialysis patients COVID naïve on IMM Age = 70 Female = 34% (Also COVID +ve group)	Hemodialysis patients COVID naïve not on IMM	BNT162b2	anti-RBD IgG	N/R
Mahil (204)	Cohort	UK	consecutive patients with psoriasis receiving methotrexate or targeted biological monotherapy Age = 44 Female = 44%	healthy controls (Consecutive volunteers without psoriasis and not receiving IMM) Age = 34 Female = 47%	BNT162b2	anti-S IgG	28 days
Spiera (180)	Case series	US	adult patients with rheumatic diseases from one rheumatology practice who received at least one dose of a COVID-19 vaccine (30 treated with rituximab, 35 taking more than one	N/A	BNT162b2 (57%), mRNA-1273 (43%)	anti-SARS-CoV2 IgG (Roche, Elecsys)	N/R

			antirheumatic medication) Age = 61.3 Female = 76%				
Shrotri (174)	Cohort	UK	large prospective community cohort, Virus Watch reported data for all vaccinated participants, also data for individual diseases & immunocompromised intervention patients Age = 65 Female = N/R	general data for patients not on IMM Age = N/R Female = N/R	ChAdOx1 n=5342 and BNT162b2 n=3009, other 40, missing =36	anti-RBD IgG (Roche Elecsys)	between 4-12 weeks
Rubbert-Roth (166)	Cohort	Switzerland	consecutive patients with RA on disease-modifying anti-rheumatic drug treatment (were enrolled in RECOVER observational trial) Age = 64.6 Female = 55%	Healthy controls Age = 44.8 Female = 70%	mRNA-1273 (9 vs 0), BNT162b2 (44 vs 20)	anti-S1 Ig (Roche Elecsys)	3-4 weeks
Hadjadj (226)	Cohort	France	Patients with systemic inflammatory diseases on IMM, COVID naïve observational trial) Age = 52 Female = 75%	immunocompetent health care workers from the same hospital, COVID naïve Age = 56 Female = N/R	BNT162b2	anti-S IgG	4 weeks
Boekel (229)	Cohort	Holland	Patients with autoimmune disease (80% were on IMM) Age = 63 Female = 67%	patients asked to recruit a healthy control with same sex and comparable age Age = 63 Female = 67%	ChAdOx1 (54%), BNT162b2 (38%) or mRNA-1273 (8%)	anti-RBD IgG (in house)	12 weeks for ChAdOx1, 6 weeks for BNT162b2 and 4 weeks mRNA-1273
Prendecki (233)	cohort	UK	patients receiving IMM for autoimmune rheumatic or glomerular diseases COVID naïve (also reported prior COVID) Age = 52.3 Female = 46%	health care workers Age = 41.4 Female = 59% 46%	ChAdOx1 (29%) and BNT162b2 (71%)	anti-S IgG (Abbott)	32 days for ChAdOx1 and 30 days BNT162b2

Liao (236)	Case series	US	patients in National Jewish Health, a pulmonary specialty outpatient clinic with chronic medical condition (subset on IMM) Age = 62 Female = 62%	N/A	BNT162b2 (66%), mRNA-1273 (34%)	anti-S IgG (Euroimmun)	unclear
Lacson (237)	Cohort study	US	Dialysis Clinic, Inc. (DCI) that assessed antibody response following administration of SARS-CoV-2 messenger RNA (mRNA) vaccines (30 clinics in 8 states) on IMM Age = 68 Female = 38%	Dialysis Clinic, Inc. (DCI) that assessed antibody response following administration of SARS-CoV-2 messenger RNA (mRNA) vaccines (30 clinics in 8 states) not on IMM	BNT162b2 (90%) or mRNA-1273 (10%)	anti-S1 IgG	Manufacturer recommendation
Izmirly (238)	Cohort study	US	Patients attending SLE clinics Age = 45.5 Female 88%	Healthy controls Age = 45.3 Female = 60%	BNT162b2 (68%), mRNA-1273 (27%), d26.COV2.S (5%)	anti-RBD IgG	Manufacturer recommendation
Stumpf (271)	Cohort study	Germany	hemodialysis (95%) and peritoneal dialysis (5%) for a mean of 5.7 years on IMM	hemodialysis (95%) and peritoneal dialysis (5%) for a mean of 5.7 years not on IMM	BNT162b2 (18%) or mRNA-1273 (82%)	anti-S1 IgG or IgA (Euroimmun)	28 days
Ramanathan (272)	Cohort study	US	autoimmune disease treated with antimetabolites or biologics Age = 67 Female = 53%	Health care workers Age = 42 Female = 62.5%	BNT162b2 (41%) or mRNA-1273 (59%)	anti-S1 IgG (Euroimmun)	N/R
Madelon (278)	Cohort study	US	MS or rheumatic disease treated with anti-CD20 (ocerlizumab or rituximab) (2 prior COVID) - some had other IMM in addition Age = 49 Female = 57%	immunocompetent healthy controls (3 prior COVID) Age = 54.5 Female = 68%	BNT162b2 (22%) or mRNA-1273 (78%)	anti-RBD total Ig (Roche, Elecsys)	28 days

Weigert (282)	Cohort study	Portugal	Chronic hemodialysis patients without COVID with median dialysis duration of 46 months on IMM	Chronic hemodialysis patients without COVID with median dialysis duration of 46 months not on IMM	BNT162b2	anti-S IgG (Roche, Elecsys)	21 days
Stefanski (283)	Cohort study	Germany	RA and autoimmune patients on rituximab (RTX) and RA patients on other IMM Age = 58 (RTX) 68 (RA) Female = 74%	Healthy controls Age = 57 Female = 50%	ChAdOx1, BNT162b2 or mRNA-1273	anti-S IgG	N/R
Sormani (284)	Case series	Italy	MS for a median of 9.4 years treated with disease modifying therapies 87 (11%) had no treatment - 7.8% had prior COVID Age = 45.8 Female = 66%	N/A	BNT162b2 (76%) or mRNA-1273 (23%)	anti-RBD total Ig (Roche, Elecsys)	N/R
Mrak (287)	Cohort study	Austria	Patients under rituximab treatment for RA, vasculitis, connective tissue diseases for a mean of 6.9 months. 57% had other disease modifying agents Age = 61.7 Female = 77%	sex and aged matched healthy controls	BNT162b2 (82%) or mRNA-1273 (18%)	anti-RBD total Ig (Roche, Elecsys)	N/R
Ammitzbøll (297)	Case series	Denmark	systemic lupus erythematosus (SLE; n = 61) and rheumatoid arthritis (RA; n = 73) from the COPANARD cohort on IMM Age = 70 Female = 67%	N/A	BNT162b2	SARS-CoV- 2 spike S1 protein	N/R
Firinu (315)	Cohort study	Italy	IMM for 1) AS, psoriasis, psoriatic arthritis (PsA); 2) RA 3) systemic lupus erythematosus; 4)miscellaneous systemic disorders 5) IBD 6) MS Age = 56 Female = 68%	Health care workers Age = 51 Female = 68%	BNT162b2	anti-RBD IgG (Snibe Diagnostics)	21 days

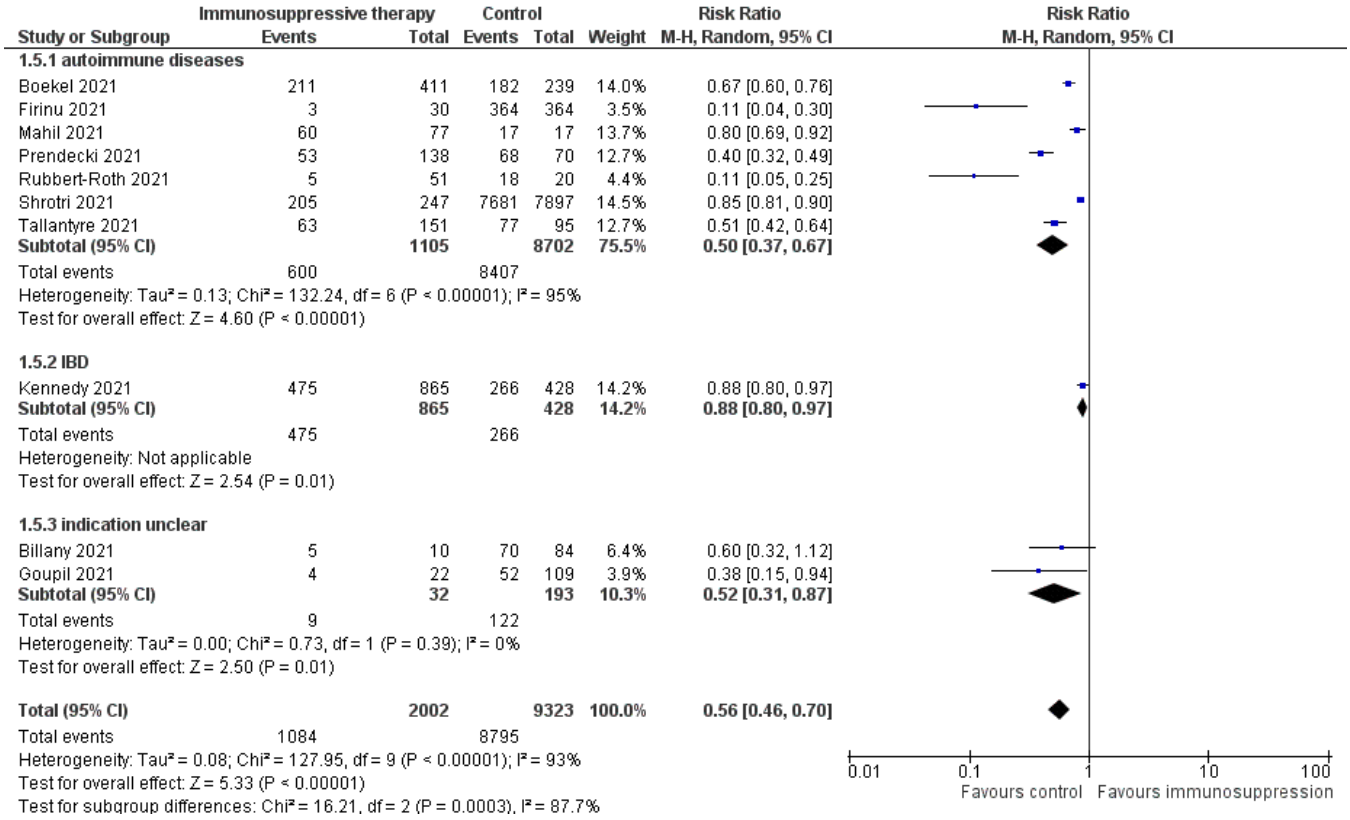
Shenoy (320)	Cohort study	India	Patients with autoimmune rheumatoid disease. 57% on methotrexate, 10% on tofacitinib, 22% on other IMM, 27% on steroids (some in combination with other IMM) Age = 52 Female = 79.4%	Healthy controls Age = 43.6 Female = 7.3%	ChAdOx1 and BVV152 (this was excluded from analysis)	Anti-S IgG	N/R
Benucci (332)	Case series	Italy	RA patients treated with rituximab Age = 57.4	N/A	BNT162b2	anti-RBD IgG (FEIA ThermoFisher, Sweden)	3 weeks
Tallantyre (337)	Cohort study	UK	MS patients on disease modifying therapies Age = 52.2 Female = 73% (Demographics available for whole cohort only)	MS patients not on disease modifying therapies	ChAdOx1 (47%) and BNT162b2 (38.5%) Unknown (14.4%)	anti-RBD-IgG (Kantaro Biosciences ,USA)	10 weeks
Veenstra (344)	cohort	US	Various autoimmune disease patients on IMM Age: 55.9 Female: 87.5%	Vaccinated healthy controls Age: 38.1 Female: NR	BNT162b2 or mRNA-1273	anti-RBD IgG (Kantaro and BioTechne, USA)	4 weeks
Connolly (364)	Case series	US	Patients with anti-neutrophil cytoplasmic antibody (NACA) associated vasculitis (AVV) - 91.1% taking rituximab and all on IMM. Age: 69 Female: 35.4%	N/A	BNT162b2 (40%) or mRNA-1273 (52%) or d26.COV2.S (8%)	anti-S IgG (Roche, Elecsys) or (Euroimmun)	N/R

Immunogenicity of the first vaccination in patients taking immunosuppressive therapy

There were 12 cohort or case series studies (3, 7, 31, 51, 104, 106, 174, 166, 229, 233, 315, 337) evaluating 2139 patients taking immunosuppressive therapy that reported on the proportion seroconverting after their first vaccination. Overall, the seroconversion rate after the first vaccination was 47% (95% CI = 35 to 59%) (Figure S1). There were 10 cohort studies (3, 7, 104, 106, 174, 166, 229, 233, 315, 337) involving 11,325 participants that compared seroconversion after the first vaccination in patients taking immunosuppressive therapy with

controls. The relative risk of seroconversion in patients taking immunosuppressive therapy was 0.56 (95% CI = 0.46 to 0.70) with major heterogeneity between studies (I^2 = 93%, χ^2 = 127.95, p<0.0001) (Figure 9).

Figure 9. Seroconversion in patients taking immunosuppressive therapy compared with controls after the first vaccination



Immunogenicity of the second vaccination in patients taking immunosuppressive therapy

There were 36 cohort or case series studies (7, 15, 23, 37, 45, 51, 71, 85, 104, 109, 110, 114, 145, 166, 174, 180, 226, 229, 233, 236-238, 271, 272, 278, 282-284, 287, 297, 315, 320, 332, 337, 344, 364) evaluating 3585 patients taking immunosuppressive therapy that reported on the proportion seroconverting after their second vaccination. Overall, the seroconversion rate after the second vaccination was 76% (95% CI = 70 to 82%) (Figure S2) although there was funnel plot asymmetry (Figure S3) suggesting this result was driven by smaller studies giving lower seroconversion rates so this pooled result may be an underestimation of the rate. There were 28 cohort studies (7, 15, 45, 51, 71, 85, 104, 109, 110, 114, 145, 166, 174, 226, 229, 233, 237, 238, 271, 272, 278, 282, 283, 287, 315, 320, 337, 344) involving 5,644 participants that compared seroconversion after the second vaccination in patients taking immunosuppressive therapy with controls. The relative risk of seroconversion in patients taking immunosuppressive therapy was 0.78 (95% CI = 0.72 to 0.85) with major heterogeneity between studies (I^2=91%, χ^2 = 301.8, p<0.0001) (Figure 10). Most studies reported that the antibody titres were lower in patients taking immunosuppressive therapy compared to controls even in those that had seroconverted (Figure 11).

Figure 10. Seroconversion in patients taking immunosuppressive therapy compared with controls after the second vaccination

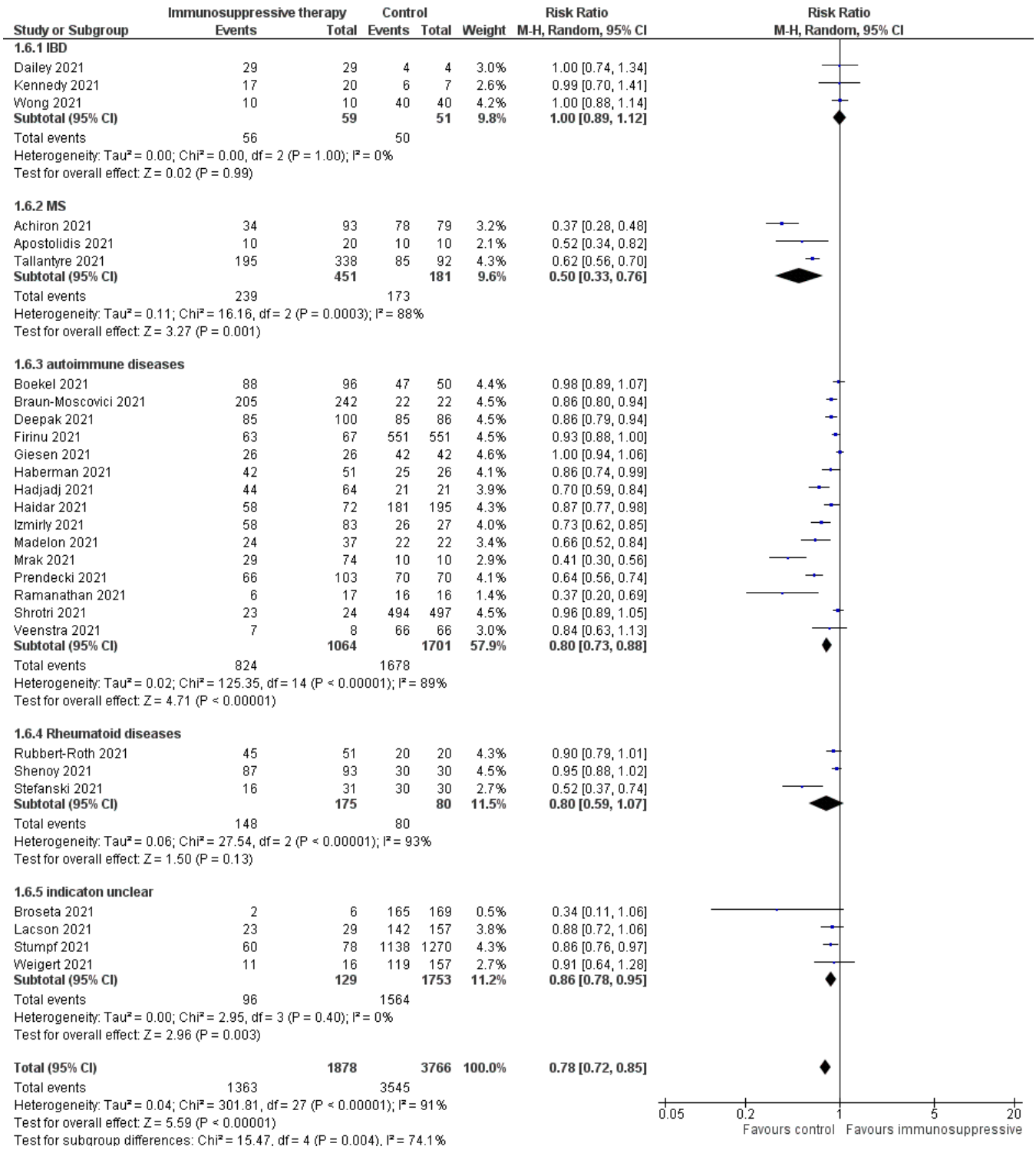
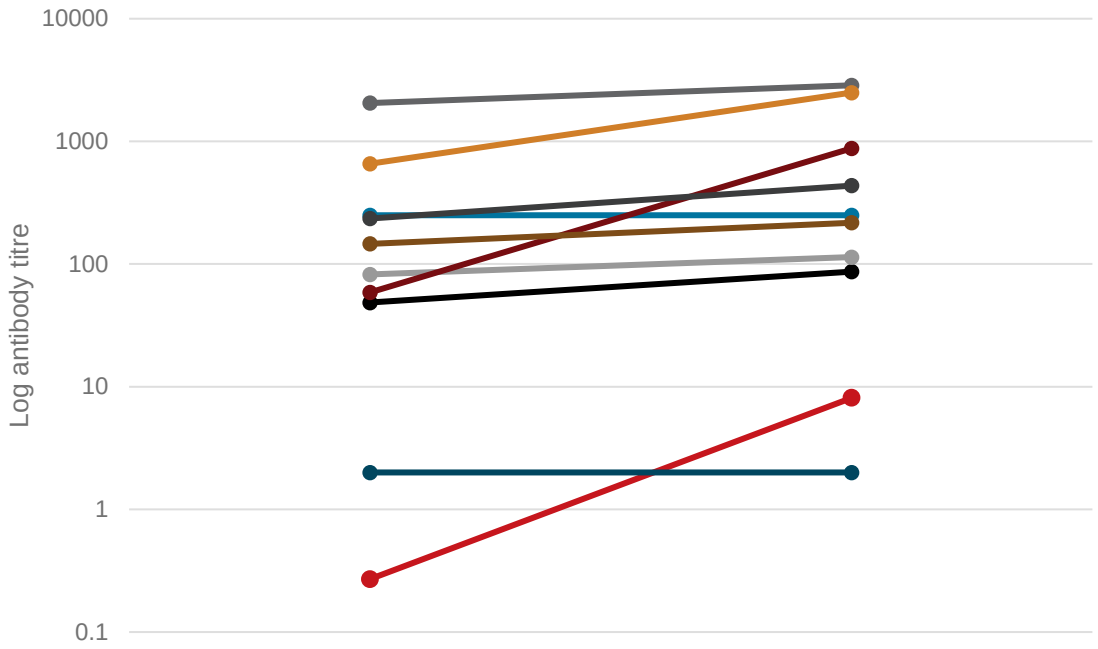


Figure 11. Median/mean antibody titres for patients taking immunosuppressive therapy and controls



Immunogenicity in patients with malignancy

Therapy to treat malignancy can suppress the immune system and the disease itself can have a negative impact, particularly in the case of hematological malignancy. Given the differences in impact on the immune system, solid and hematological malignancies were evaluated separately as predefined subgroups. A summary of the eligible studies is given in Tables 7 and 8. One study (324) recruited patients with both types of malignancy (Table 7) and compared seroconversion in COVID-19 naïve patients with those that had prior infection. This did not separate seroconversion in solid or hematological malignancy and the overall seroconversion in this case series after the 2nd vaccine was 132/154 (86%) in those that were COVID-19 naïve.

Table 7. Characteristics of eligible studies evaluating immunogenicity in patients with solid malignancy

Author	Design	Country	Case description	Control description	Vaccine	Titre measured	Duration between 1st and 2nd vaccine
Palich (41)	Cohort	France	breast, lung, gyn, prostate = main types (58% having chemo at time of vaccination). None had prior exposure to COVID 19 Age = 67 Female = 64%	health care workers Age = 55 Female = 37%	BNT162b2	anti-S total Ig (Roche, Elecsys) and anti-S IgG (Abbott Infinity)	21 days
Scurr (18)	Cohort	UK	solid cancer patients Age = 52.6 Female = 63%	staff and students Cardiff University Age = 35.6 Female = 69%	BNT162b2 or ChAdOx1	anti-RBD IgG in house	N/R
Barriere (54)	Cohort	France	solid tumor patients no priori COVID, 86% treated w/ chemo Age = 69.5 Female = 48%	healthy volunteers no prior COVID Age = 53 Female = N/R	BNT162b2	anti-RBD total Ig (Roche, Elecsys)	21 days
Haidar (114)	Cohort	US	various solid malignancies treated over last 12 months across the University of Pittsburgh Health System (majority receiving systemic therapy) Age = 63.1 Female = 71%	health care workers employed across the same health care system Age = 43.7 Female = 72%	BNT162b2 (41%), mRNA-1273 (59%) or Ad26.COV2.S	anti-RBD IgG Beckman Coulter platform	unclear

Addeo (46)	Case series	US	81% solid, 19% hematological - 37% clinical surveillance 63% chemo or immunotherapy. All COVID naïve (although report on 9 patients that had prior COVID). Demographics are for whole case series as did not separate out the two. Age = 63 Female = 45%	N/A	BNT162b2 (29%) or mRNA-1273 (71%)	anti-S IgG (Roche, Elecsys)	3 weeks Pfizer, 4 weeks Moderna
Thakar (16)	Case series	US	67% solid and 33% hematological, 75% active, 56% active chemo. Demographics for all as did not separate Age = 67 Female = 58%	N/A	BNT162b2 (58%), mRNA-1273 (31%) and Ad26.COV2.S (10%)	anti-RBD IgG (Abbott)	21 days
Terpos (184)	Cohort	Greece	solid and hematological malignancies under several systemic therapies, that receiving Immune Checkpoint Inhibitors (table s1, all solid cancer) Age = 66 Female = 39%	matched healthy volunteers Age = 64 Female = N/R	BNT162b2 (70%), mRNA-1273 (25%) and AZD1222 (5%) vaccine	SARS-CoV-2 neutralzing antibody detection kit (GeneScript, NJ)	N/R
Shroff (173)	Cohort	US	Patients with Solid Tumors on Active, Immunosuppressive Cancer Therapy Age = 63.3 Female = 81%	control cohort that also received the Pfizer/BioNTech vaccine Age = 41.4 Female = 66%	BNT162b2/BioNTech	anti-RBD IgG and anti-S IgG (Genscript and Sino Biological)	N/R
Monin (143)	Cohort	UK	95 patients with solid cancer and 56 patients with hematological cancer Age = 73 Female = 48%	healthy controls (mostly health-care workers) Age = 73 Female = 48%	BNT162b2	anti-S IgG	21 days (some had been scheduled to delayed vaccine 12 weeks)
Massarweh (140)	Cohort	Israel	adult patients with solid tumors undergoing active intravenous anticancer treatment at least 12 days before enrollment	healthy controls - taken from a convenience sample of the patients' family/ caregivers who	BNT162b2	anti-S IgG (Abbott, ARCHITECT IgG Quant test)	N/R

			Age = 66 Female = 43%	accompanied them to treatment Age = 62 Female = 68%			
Benda (242)	Case series	Switzerl and	both hematological and solid malignancy - hematological MM (34%) CLL (38%), other (26%) Age = 65.1 Female = 42%	N/A	BNT162b 2	anti-RBD IgG (Elecsys)	21 days
Shrotri (174)	Cohort	UK	solid malignancy Age = N/R Female = N/R	general data for patients not on IMM Age = N/R Female = N/R	BNT162b 2 or ChAdOx1	anti-RBD IgG (Roche Elecsys)	4-12 weeks
Iacono (211)	Cohort	Italy	outpatients (≥80 years), solid (72.2%) or hematological malignancies (27.3%) Age = 82 Female = 58%	A group of health care workers, >66 years, 1:2 Age = N/R Female = N/R	BNT162b 2	anti-S IgG	20 days
Goshen-Lago (207)	Cohort	Israel	patients with solid organ cancer Age = 68 Female = 43%	healthy, age-matched health care workers Age = 64 Female = 55%	BNT162b 2	anti-S IgG (Diasorin, Liaison)	N/R
Webber (314)	case series	UK	291 cancer patients on active treatment, most were solid cancer-29 had previous infection Age = 68.2 Female = N/R	patients who ended treatment >6 between 6-12 months on active surveillance	BNT162b 2	SARS-CoV-2 spike, IgG <25 AU = poor seroconversion	21 days
Fong (324)	Case series	Austria	cancer patients with or without prior COVID (64% solid, 36% hematological - did not separate data) Age: 66 Female: 49%	N/A	BNT162b 2	anti-S IgG (Abbott, ARCHITECT IgG Quant test)	N/R

Table 8. Characteristics of eligible studies evaluating immunogenicity in patients with hematological malignancy

Author	Design	Country	Case description	Control description	Vaccine	Titre measured	Duration between 1st and 2nd vaccine
Agha (47)	Case series	US	HM seen UPMC Hillman Cancer Center, 45% undergoing treatment, 55% observation Age = 71 Female = 48%	N/A	BNT162b2 (51%) or mRNA-1273 (42%), 7% not recorded	anti-RBD total Ig Beckman Coulter platform	unclear
Bird (60)	Case series	UK	MM (48 with v. good response to Rx) Age = 67 Female = 41%	N/A	BNT162b2 (52%) or ChAdOx1 (48%)	anti-S1 IgG	N/R
Cohen (79)	Case series	Israel	vaccinated patients with HM attending whole body PET; 54 had serology (had lymphoma or myeloma) Age = 68.8 Female = 47%	N/A	BNT162b2	anti-S IgG (Roche, Elecsys)	unclear
Diefenbach (87)	Case series	US	NHL, HL or CLL Age = 63 Female = 47%	N/A	BNT162b2 (77%), mRNA-1273 (23%)	anti-RBD Ig (Sino Biological)	unclear
Ghione (105)	Cohort	US	lymphoma and were having or have had B cell depleting therapies priori COVID excluded Age = N/R Female = N/R	health care workers and volunteers from nursing home no prior COVID Age = N/R Female = N/R	BNT162b2, mRNA-1273, Ad26.COV2.S	anti-S IgG or IgA	unclear
Haidar (114)	Cohort	US	hematological malignancies treated over last 12 months across the University of Pittsburgh Health System Age = 66.3 Female = 51%	health care workers employed across the same health care system Age = 43.7 Female = 72%	BNT162b2 (41%), mRNA-1273 (59%) or Ad26.COV2.S	anti-RBD IgG Beckman Coulter platform	unclear
Harrington (115)	Case series	UK	CML Age = 45.6 Female = 25%	N/A	BNT162b2	anti-S IgG	N/R
Harrington (116)	Case series	UK	variety (e.g. myelofibrosis,	N/A	BNT162b2	anti-S IgG	N/R

			polycythemia (not CML so no duplication) Age = N/R Female = 67%				
Herishanu (120)	Cohort	Israel	CLL Age = 71 Female = 33%	age and sex matched healthy controls Age = 68 Female = N/R	BNT162b2 or mRNA-1273	anti-RBD IgG (Roche, Elecsys)	3-4 weeks
Lim (133)	Cohort	UK	lymphoma and were having or have had B cell depleting therapies prior COVID excluded Age = 66 Female = 37%	healthy controls Age = 52	BNT162b2 (77) or ChAdOx1 (51)	anti-S IgG (MesoScale Discovery)	N/R
Addeo (46)	Case series	US	81% solid, 19% hematological - 37% clinical surveillance 63% chemo or immunotherapy. All COVID naïve (although report on 9 patients that had prior COVID). Demographics are for whole case series Age = 63 Female = 45%	N/A	BNT162b2 (29%) or mRNA-1273 (71%)	anti-S IgG (Roche, Elecsys)	3 weeks (Pfizer) or 4 weeks (Moderna)
Thakar (16)	Case series	US	67% solid and 33% hematological, 75% active, 56% active chemo. Demographics are for whole case series. Age = 67 Female = N/R	N/A	BNT162b2 (58%), mRNA-1273 (31%) and Ad26.COV2.S (10%)	anti-RBD IgG (Abbott, ARCHITECT IgG Quant test)	21 days
Tzarfati (188)	Cohort	Israel	patients with HM with prior COVID excluded Age = 71 Female = 56%	subjects with no HM paired for age, gender, comorbidities and time from vaccination to serology assay were analyzed Age = 69 Female = 44%	BNT162b2	anti-S1/S2 IgG (Diasorin, Liaison)	N/R
Terpos (330)	Cohort	Greece	myeloma age >18 years; presence or smoldering myeloma (n=38) or active MM (n=213) or	Healthy controls vaccinated at the same centre matched for age and sex	BNT162b2 (78%) ChAdOx1 (22%)	SARS-CoV-2 neutralizing antibody detection kit	21 days

			monoclonal gammopathy (n=25) Age = 74 Female = 45%	Age = NR Female = NR		(GeneScript, NJ)	
Roeker (164)	Case series	US	patients with CLL Age = 71 Female = 48%	N/A	BNT162b2 (n=25) or mRNA-1273 (n=19)	anti-S1/S2 IgG (Diasorin, Liaison)	N/R
Pimpinelli (156)	Cohort	Italy	42 patients with MM and 50 with myeloproliferative malignancies (20 CML and 30 myeloproliferative neoplasms), on active anti-cancer treatment Age = 73 Female = 47%	36 elderly controls not suffering from cancer Age = 81 Female = 50%	BNT162b2	anti-S1/S2 IgG (Diasorin, Liaison)	N/R
Parry (153)	Cohort	UK	patients with CLL or small lymphocytic leukemia (SLL) Age = 69 Female = 47%	age-matched healthy donors from local primary care networks Age = N/R Female = N/R	BNT162b2 (n=154), ChadOx1 (n=145)	anti-S total Ig (Roche, Elecsys)	3 weeks
van Oekelen (151)	Cohort	US	patients with MM, with and without previously documented COVID-19 (60/320 had COVID-19 prior to immunization) Age = 68 Female = 42%	healthy controls- selected from an ongoing observational study -serological data from a subgroup selected to best match the demographics and age of the MM patient population Age = N/R Female = N/R	69.1% BNT162b2, 27.2% mRNA-1273, 3.8% unknown	anti-S IgG (SeroKlir Kantaro)	N/R
Monin (143)	Cohort	UK	151 (95 patients with solid cancer and 56 patients with hematological cancer) Age = 73 Female = 26%	healthy controls (mostly health-care workers)54 then excluded 17 had been exposed- not as a control cohort for patients with cancer (who were mostly older in age), but to facilitate comparisons of vaccine	BNT162b2	anti-S IgG	21 days (some had been scheduled to delayed vaccine 12 weeks)

				immunogenicity and safety Age = 73 Female = 70%			
Maneikis (137)	Cohort	Lithuania	885 patients with HM had received both vaccine doses. (Main analysis: 857 patients anti-S1 IgG seronegative at baseline. Age-matched comparison consist of 315 pts HM aged 18–60) Age = 65 Female = 53%	healthy health-care workers had received both vaccine doses age 18-60. Age = 40 Female = 84%	BNT162b2	anti-RBD IgG (Abbott, ARCHITECT IgG Quant test)	median 21 days (IQR 21–21)
Ghandili (240)	Case series	Germany	patients with multiple myeloma and related plasma cell dyscrasias, COVID naïve Age = 67.5 Female = 40%	N/A	BNT162b2, mRNA-1273 (both 77%) ChAdOx1 (23%)	anti-S IgG (Liaison)	N/R
Benda (242)	Case series	Switzerland	both hematological and solid malignancy - hematological MM (34%) CLL (38%), other (26%) Age = 65.1 Female = 42%	N/A	BNT162b2	anti-RBD IgG (Roche Elecsys)	21 days
Guglielmelli (252)	Cohort	Italy	Patients with myelofibrosis, essential thrombocythemia, polycythemia vera Age = 59 Female = 67%	healthy volunteers Age = N/R Female = N/R	mRNA-1273 (83%), BNT162b2 (17%)	anti-RBD IgG	N/R
Stampfer (256)	Cohort	US	Patients with MM Age = 68 Female = 41%	contemporaneous aged matched healthy controls Age = 61 Female = 61%	mRNA-1273 or BNT162b2	anti-S IgG (Sino Biological)	21-28 days
Pimpinelli (257)	Case series	Italy	Patients with myelofibrosis, essential thrombocythemia, polycythemia vera Age = 72 Female = 52%	N/A	BNT162b2	anti-S IgG	21 days
Gurion (263)	Case series	Israel	Patients with lymphoma (Hodgkins (12%) and NHL (88%)) Age = 65 Female = 45%	N/A	BNT162b2	anti-S IgG (Abbott)	21 days

Benjamin (264)	Case series	Israel	Patients with CLL, median times since diagnosis 6.9 years Age = 70 Female = 40%	N/A	BNT162b2	anti-S IgG (Liaison)	21 days
Re (267)	Case series	France	HM (NHL, 46, MM 23, CLL 10, myeloproliferative disorder 10) Age = 75.5 Female = 33%	N/A	BNT162b2 (93%) or mRNA-1273 (7%)	anti-S total Ig	manufacturers recommendations
Ramanathan (272)	Cohort	US	hematological malignancy Age = 60 Female = 26%	health care workers Age = 42 Female = 63%	BNT162b2 (55%), mRNA-1273 (44%)	anti-S1 IgG (Euroimmun)	unclear
Caocci (274)	Case series	Italy	myelofibrosis with or without ruxolitinib therapy Age = 66 Female = N/R	N/A	BNT162b2	anti-S IgG (Liaison)	21 days
Shrotri (174)	Cohort	UK	hematological malignancy Age = N/R Female = N/R	general data for patients not on IMM Age = N/R Female = N/R	BNT162b2 or ChAdOx1	anti-RBD IgG (Roche Elecsys)	4-12 weeks
Gavriatopoulou (288)	Cohort	Greece	Patients with Waldenstrom Macroglobulinemia, CLL, NHL Age = 75 Female = 52%	volunteer controls of similar age and gender Age = 75 Female = 53%	BNT162b2 (76%), ChAdOx1 (24%)	Neutralizing antibodies (ELISA cPASS, GenScript)	N/R
Greenberger (309)	Case series	US	Patients with hematologic malignancies, excluded prior covid exposure Age = 68 Female = 62%	N/A	mRNA-1273 652, BNT162b2 793	anti-spike with a positive cutoff of at least 0.8 U/mL	26 days (median)
Ehmsen (308)	case series	Denmark	patients with HM (n= 323) and solid (n=201) Age = 72 Female = 37%	N/A	BNT162b2 (303), mRNA-1273 (19)	anti-SARS-CoV-2 spike (anti-S) IgG antibody	N/R
Fox (295)	Case series	UK	patients with B cell malignancies, either receiving active treatment or had received treatment within the last 24 months and solid (n=201)	N/A	BNT162b2 (n=41) or ChAdOx1 (n=14)	anti-RBD IgG (Roche Elecsys)	1 month

			Age = 60 Female = 100%				
Iacono (211)	Cohort	Italy	outpatients (≥80 years), solid (72.2%) or hematological malignancies (27.3%) Age = 82 Female = 58%	A group of health care workers, >66 years, 1:2 Age = N/R Female = N/R	BNT162b2	anti-S IgG	N/R
Henriquez (338)	Cohort	France	MM patients undergoing treatment or treatment within one year (11 had prior Covid) Age = 69.9 Female = 49%	Health care giver from same hospital Age = NR Female = NR	BNT162b2	Neutralizing antibodies (S-Fuse cells and reporter assay)	21 days

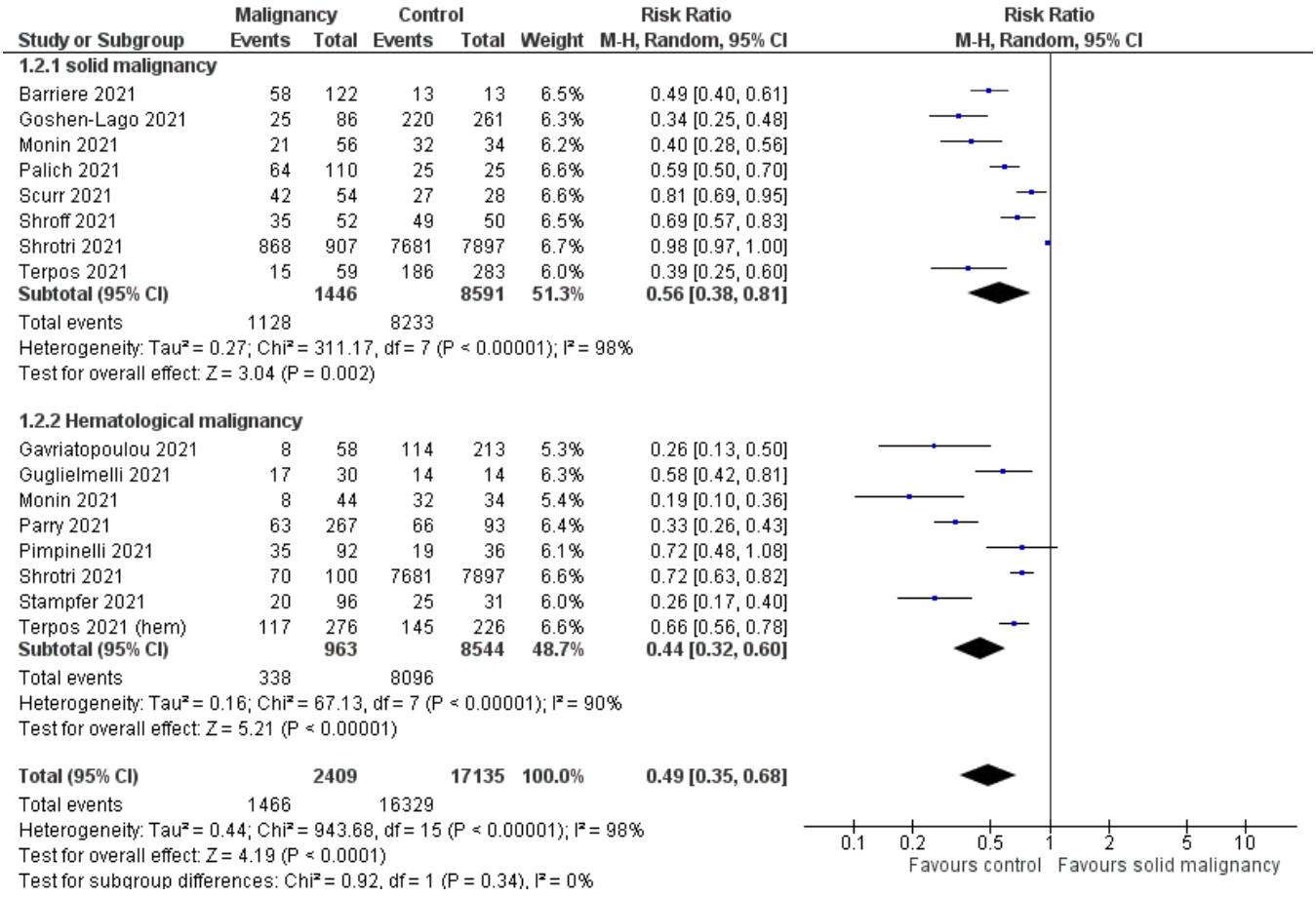
Immunogenicity of the first vaccination in solid malignancy patients

There were 10 cohort or case series studies (18, 41, 46, 54, 143, 173, 174,184, 207, 242) evaluating 1670 patients with solid malignancy that reported on the proportion seroconverting after their first vaccination. Overall, the seroconversion rate after the first vaccination was 60% (95% CI = 38 to 80%) (Figure S4). There were 8 cohort studies (18, 41, 54, 143, 153, 173, 174, 184, 207) involving 10,037 participants that evaluated seroconversion after the first vaccination in patients with solid malignancy compared to controls. The relative risk of seroconversion in patients with solid malignancy was 0.56 (95% CI = 0.38 to 0.81) with major heterogeneity between studies (I^2=98%, χ^2 = 311.2, p<0.0001) (Figure 12).

Immunogenicity of the first vaccination in hematological malignancy patients

There were 15 cohort or case series studies (46, 60, 115, 116, 143, 153, 156, 174, 240, 242, 252, 256, 288, 295, 330) evaluating 1367 patients with hematological malignancy that reported on the proportion seroconverting after their first vaccination. Overall, the seroconversion rate after the first vaccination was 43% (95% CI = 34 to 53%) (Figure S5). There were 8 cohort studies (143, 153, 156, 174, 252, 256, 288, 330) involving 9507 participants that evaluated seroconversion after the first vaccination in patients with hematological malignancy compared to controls. The relative risk of seroconversion in patients with hematological malignancy was 0.44 (95% CI = 0.32 to 0.60) with major heterogeneity between studies (I^2 = 98%, χ^2 = 67.1, p<0.0001) (Figure 12). There was no statistically significant difference between solid and hematological malignancy (χ^2 for subgroup difference = 0.92, p = 0.34) (Figure 12) in seroconversion after first vaccination.

Figure 12. Seroconversion in patients with solid and hematological malignancy compared with controls after the first vaccination



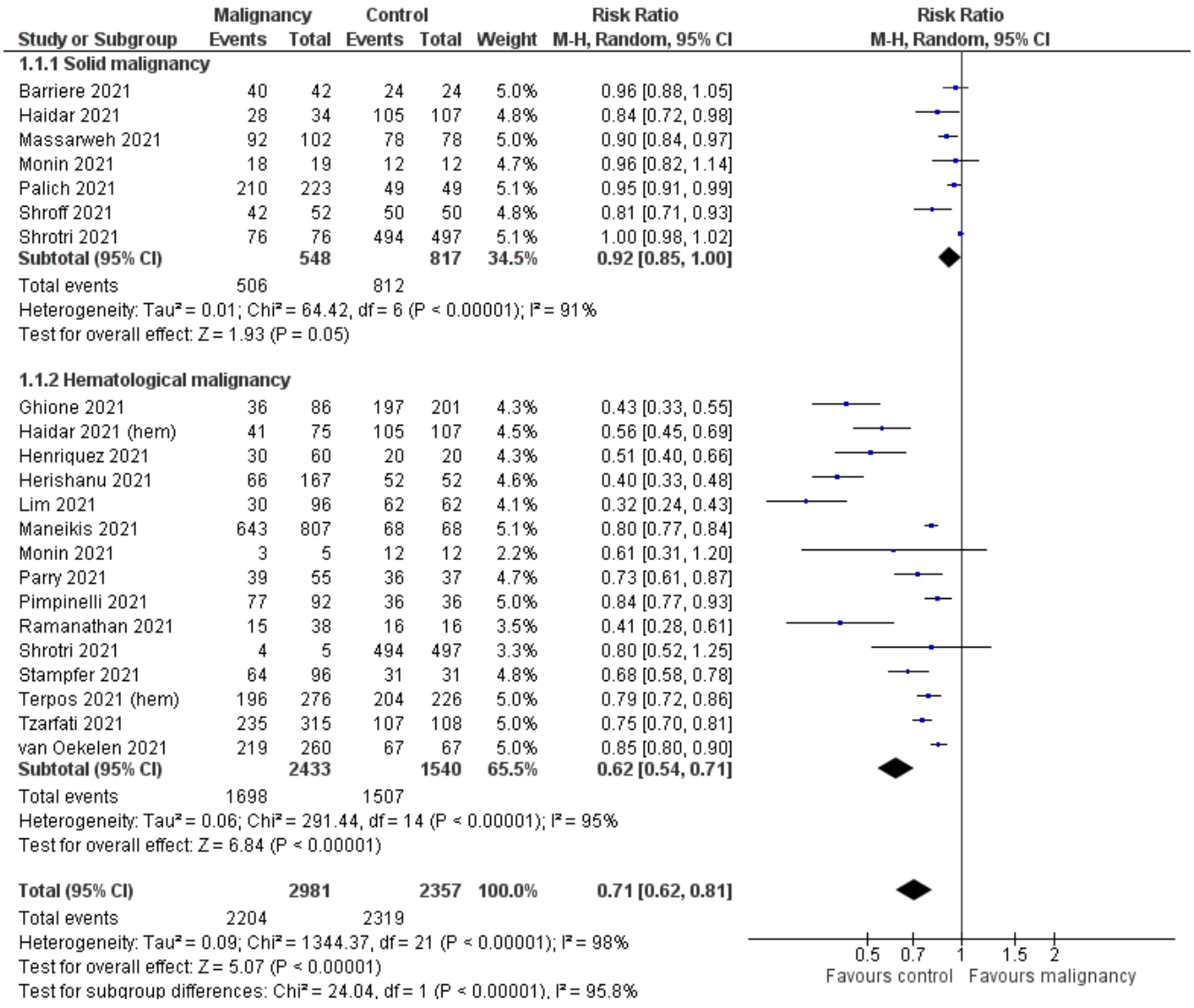
Immunogenicity of the second vaccination in solid malignancy patients

There were 13 cohort or case series studies (16, 41, 46, 54, 114, 140, 143, 173, 174, 207, 211, 242, 314) evaluating 1445 patients with solid malignancy that reported on the proportion seroconverting after their second vaccination. Overall, the seroconversion rate after the second vaccination was 93% (95% CI = 89 to 96%) (Figure S6). There were 7 cohort studies (41, 54, 114, 140, 143, 173, 174) involving 1365 participants that evaluated seroconversion after the second vaccination in patients with solid malignancy compared to controls. The relative risk of seroconversion in patients with solid malignancy was 0.92 (95% CI = 0.85 to 1.00) with major heterogeneity between studies (I^2 = 91%, χ^2 = 64.4, p<0.0001) (Figure 13).

Immunogenicity of the second vaccination in hematological malignancy patients

There were 31 cohort or case series studies (16, 46, 47, 79, 87, 105, 114, 120, 133, 137, 143, 151, 153, 156, 164, 174, 188, 211, 242, 256, 257, 263, 264, 267, 272, 274, 295, 308, 309, 330, 338) evaluating 5366 patients with hematological malignancy that reported on the proportion seroconverting after their second vaccination. Overall, the seroconversion rate after the second vaccination was 61% (95% CI = 55 to 67%) (Figure S7). There were 15 cohort studies (105, 114, 120, 133, 137, 143, 151, 153, 156, 174, 188, 256, 272, 30, 338) involving 3973 participants that evaluated seroconversion after the second vaccination in patients with hematological malignancy compared to controls. The relative risk of seroconversion in patients with hematological malignancy was 0.62 (95% CI = 0.54 to 0.71) with major heterogeneity between studies (I^2 = 95%, χ^2 = 291.4, p<0.0001) (Figure 13). There was a statistically significant difference between solid and hematological malignancy (χ^2 for subgroup difference = 24.0, p<0.0001) (Figure 13) in seroconversion after the second vaccination, with hematological malignancies having a lower seroconversion than solid malignancies.

Figure 13. Seroconversion in patients with solid and hematological malignancy compared with controls after the second vaccination



Immunogenicity in transplant patients

The more profound immunosuppression that is required to prevent transplant rejection may have an impact on response to SARS-CoV2 vaccination. There were 45 studies (20, 22, 27, 29, 38, 56, 58, 75, 84, 95, 107, 114, 119, 121, 130, 138, 139, 141, 148, 154, 157, 158, 161, 165, 170, 172, 198, 200, 205, 228, 239, 247, 248, 253, 259, 269, 271, 272, 279, 280, 290, 296, 299, 300, 305) that evaluated the immunogenicity of SARS-CoV2 vaccination in transplant patients and these are summarized in Table 9.

Table 9. Characteristics of eligible studies evaluating immunogenicity in transplant patients

Author	Design	Country	Case description	Control description	Vaccine	Titre measured	Duration between 1st and 2nd vaccine
Miele (20)	Cohort	Italy	solid organ transplant (5 kidney, 5 lung, 4 liver, 2 heart) median 9 years from transplant Age = 57 Female = 19%	staff that were immunocompetent Age = 44 Female = 57%	BNT162b2	anti-S IgG (Diasorin, Liaison)	Unclear
Cucchiari (22)	Case series	Spain	kidney transplant (15 eligible also had pancreas) - mean 1.65 years from transplant Age = 57.6 Female = 29%	N/A	mRNA-1273	anti-S IgG or IgM	4 weeks
Husain (27)	Case series	US	kidney transplants - median 8 years since transplant Age = 66 Female = 39%	N/A	BNT162b2 (57%) or mRNA-1273 (43%)	anti-S IgG (Diasorin, Liaison) (n=5) or anti-S IgG (Roche, Elecsys) (n=23)	unclear
Schmidt (51)	Cohort	Germany	solid organ transplants with no COVID history, 90% kidney, median 6.5 years transplantation Age = 54.5 Female = 45%	immunocompetent controls Age = 50.6 Female = 70%	BNT162b2 (20%), mRNA-1273 (7%) or ChAdOx1 (73%)	anti-S IgG (Quantivac, Euroimmun)	N/R
Benotmane (56)	Case series	France	kidney transplants - median 6.4 years all naïve to COVID Age = 57.5 Female = 35%	N/A	mRNA-1273	anti-S IgG (Abbott, ARCHITECT IgG Quant test)	
Bertrand (58)	Cohort	France	kidney transplants - median 6.9 years Age = 63.5 Female = 49%	hemodialysis patients with median duration of 3.1 years	BNT162b2	anti-S IgG (Abbott, ARCHITECT IgG	21 days

				Age = 71.2 Female = N/R		Quant test) and (Beijing Wantai Biological Pharmacy Ent Co)	
Chavarot (75)	Case series	France	kidney transplants - median 6.4 years all naïve to COVID Age = 64 Female = 33%	N/A	BNT162b2	anti-S IgG (Abbott, ARCHITECT IgG Quant test)	28 days
Danthu (84)	Cohort	France	kidney transplants - median 6.4 years - no prior COVID Age = 64.8 Female = 41%	hemodialysis patients with median duration of 5.1 years no prior COVID Age = 73.5 Female = 41%	BNT162b2	anti-S IgG (Diasorin, Liaison)	N/R
Firket (95)	cohort	Belgium	kidney transplant - 8.3 years post-transplant Age = 51.2 Female = 55%	Controls Age = 48.2 Female = 35%	BNT162b2	anti-S IgG (Diasorin, Liaison)	21 days
Grupper (107)	Cohort	Israel	kidney transplant patients (22 in the last 12 months) Age = 58.6 Female = 18%	health care workers from institution that Rx patients Age = 52.7 Female = 68%	BNT162b2	anti-S IgG (Diasorin, Liaison)	21 days
Haidar (114)	Cohort	US	various solid organ transplants, 87 kidney, heart 35, 33 liver, 18 lung treated over last 12 months across the University of Pittsburgh Health System Age = 61.2 Female = 40%	health care workers employed across the same health care system Age = 43.7 Female = 72%	BNT162b2 (41%), mRNA-1273 (59%) or Ad26.COV2.S	Anti-RBD IgG Beckman Coulter	unclear
Havlin (119)	Cohort	Czech Republic	Lung transplants - 4.25 years after transplant Age = 52.1 Female = 40%	healthy volunteers Age = N/R Female = N/R	BNT162b2	anti-S IgG (Diasorin, Liaison)	unclear
Ben Zadock (121)	Case series	Israel	heart transplant - median 9.2 years from transplant Age = 61 Female = 17%	N/A	BNT162b2	anti-S IgG (Abbott, ARCHITECT IgG Quant test)	N/R
Korth (130)	Cohort	Germany	kidney transplant - no prior COVID, mean time	Health care workers Age = 44.4	BNT162b2	anti-S IgG (Diasorin, Liaison)	21 days

			after transplant = 11.4 years Age = 57.7 Female = 52%	Female = 61%			
Holden (205)	Case series	Denmark	80 solid organ transplant (SOT) recipients (≥ 18 years of age) Age = 58.9 Female = 45%	N/A	all but one BNT162b2	anti-S1 IgG (Quantivac, Euroimmun)	N/R
Chevallier (200)	Cohort	France	Allo-HSCT, with no active graft-versus-host disease and more than 3 months after transplant (underline Myeloid and Lymphoid) Age = 57 Female = 40%	26 healthy controls from the Hematology Department staff Age = N/R Female = N/R	BNT162b2	anti-RBD IgG (Roche, Elecsys)	N/R
Yi (198)	Cohort	US	Kidney transplant recipients Lymphoid) Age = N/R Female = N/R	Kidney waitlist patients Age = N/R Female = N/R	BNT162b2 or mRNA-1273	anti-S total Ig	N/R
Shostak (172)	Case series	Israel	lung or heart-lung transplant recipients who received the BNT162b2 vaccine, who had received two doses between Dec 20, 2020, and Feb 8, 2021 Age = 60.5 Female = 33%	N/A	BNT162b2-BioNTech	anti-S IgG (Abbott, ARCHITECT IgG Quant test)	N/R
Sattler (170)	Cohort	Germany	39 age-matched kidney transplant recipients treated with standard immunosuppressive medication, Age = 57.4 Female = 28%	39 healthy controls (majority encompassed health care professionals) + 26 with kidney failure on hemodialysis (HD) Age = 53 Female = 43%	BNT162b2	anti-S IgG or IgA (Quantivac, Euroimmun)	21 days
Rozen-Zvi (165)	Case series	Israel	consecutive kidney transplant recipients - for a median 7.08 years Age = 57.5 Female = 36%	N/A	BNT162b2	anti-S IgG (Abbott, ARCHITECT IgG Quant test)	21 days
Rincon-Arevalo (161)	Cohort	Germany	Mixed: dialysis patients (DP) n=44 (40 maintenance hemodialysis+4 peritoneal dialysis),	healthy controls (HC)mainly health care workers n=25 Age = 41 Female = 40%	BNT162b2-BioNTech	anti-S1 IgG (Quantivac, Euroimmun)	N/R

			kidney transplant recipients (KTR) n=40 Age = DP 69.0, PD 70.5, KTR 62.5 Female = 36%				
Rabinowich (157)	Cohort	Israel	liver transplant recipients Age = 60 Female = 30%	healthy volunteers-healthcare workers with no major comorbidities Age = 52.7 Female = 68%	BNT162b2-BioNTech	anti-S1 IgG (Diasorin, Liaison)	3 weeks
Peled (154)	Cohort	Israel	stable adult heart transplant recipients Age = 62 Female = 35%	A healthy control group of 136 subjects Age = 63 Female = 63%	BNT162b2-BioNTech	anti-RBD IgG	N/R
Narasimhan (148)	Cohort	US	lung Transplant Recipients vaccinated for SARS-CoV-2 with 2D (with one previously infected case) Age = 65 Female = 36%	2D-vaccinated LT naïve (non-transplanted and non-exposed to COVID-19) Age = N/R Female = N/R	Pfizer-BioNTech (n=48) and mRNA-1273 (n=25)	anti-S IgG (Abbott, alinity)	N/R
Mazzola (141)	Cohort	France	Solid organ transplant-recipients without previous COVID-19 Age = 61 Female = 31%	healthy volunteers-healthcare workers with no major co-morbidities Age = 55 Female = 72%	BNT162b2	anti-RBD IgG (Abbott, alinity)	28 days
Marion (139)	Case series	France	Recipients of solid organ transplant (heart, kidney, liver, or pancreas) Age = 58 Female = 37%	N/A	BNT162b2 (942), mRNA-1273 (8)	anti-S Ig (Beijing Wantai Biological Pharmacy Ent Co)	28 days
Marinaki (138)	Cohort	Greece	Solid organ transplant (SOT) recipients (10 kidney and 24 heart) Age = 60 Female = 21%	age- and sex-matched health-care workers (HCW) Age = N/R Female = N/R	BNT162b2	anti-RBD IgG (Abbott, ARCHITECT IgG Quant test)	N/R
Cao (228)	Cohort	US	lung (16), kidney (13), heart (6), lung (1), heart lung (1) Age = 64 Female = 27%	immunocompetent controls (also had past COVID controls) Age = 66 Female = 80%	BNT162b2 or mRNA-1273	anti-S1 IgG	21 days (IQR 19-25)

Ram (158)	Case series	Israel	patients undergoing immune cell therapy: allo-HCT (n=66) or after CD19-based CART therapy (n=14) Age = 65 Female = 45%	N/A	BNT162b2	anti-RBD IgG (Roche, Elecsys)	21 days (range, 17-36)
Hall (239)	Case series	Canada	patients from transplant program, Lung (26%), kidney (24%), kidney-pancreas (22%), heart (14%), liver (12%) - median 2.96 years from transplant Age = 66.2 Female = 31%	N/A	mRNA-1273	anti-RBD IgG (Elecsys Roche)	N/R Rashid-Alavijeh
Rashid-Alavijeh (247)	cohort	Germany	liver transplant recipients for a median of 8 years Age = 57 Female = 40%	health care workers Age = N/R Female = 55%	BNT162b2	anti-S IgG (Liaison)	26 days
Midtvedt (248)	Case series	Norway	kidney transplant recipients for a mean of 11.7 years without history of COVID Age = 67.4 Female = 44%	N/A	BNT162b2	anti-RBD IgG in house	28 days
Di Meo (253)	cohort	Canada	solid organ transplant recipients Age = 61 Female = 3%	health care workers Age = 44 Female = 70%	BNT162b2 or mRNA-1273 (50%)	anti-S total Ig (Abbott)	35-39 days
Del Bello (259)	Case series	France	consecutive solid organ transplants, 277 kidney, 69 liver, 34 lung/heart, 6 pancreas, 10 combined - median 7 years Age = 59 Female = 35%	N/A	BNT162b2	anti-S IgG (Beijing Wantai Biological Pharmacy Enterprise) (228) or other assay (168)	28 days
Hod (269)	Cohort	Israel	Stable renal transplant patients with no prior COVID, mean timre from transplant 5.8 years Age = 59.7 Female = 20%	immunocompetent health care workers Age = 57 Female = 70%	BNT162b2	anti-RBD-IgG	unclear
Stumpf (271)	cohort	Germany	kidney transplant recipients for mean of	kidney transplant recipients for mean of 9.9 years	BNT162b2 (28%) or mRNA-	anti-S1 IgG or IgA	28 days

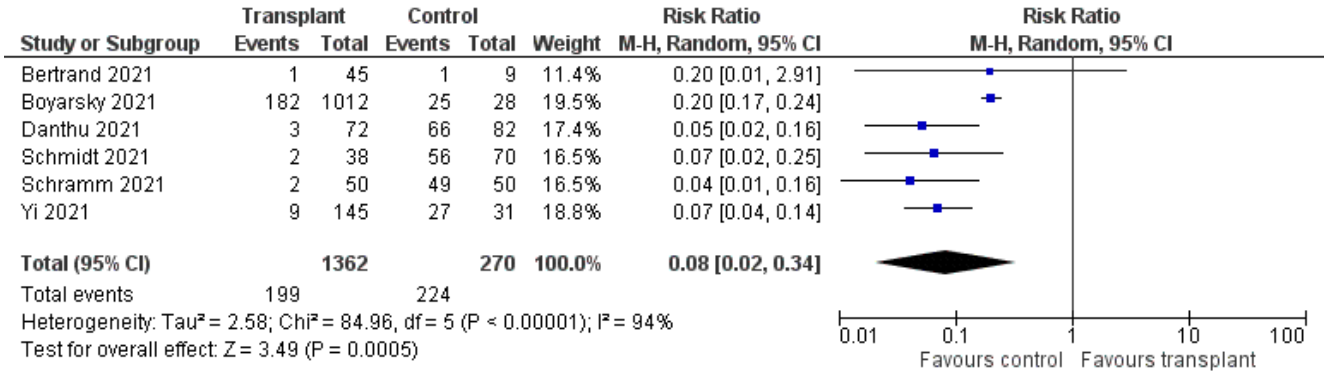
			9.9 years priori COVID excluded Age = 57.3 Female = 35%	priori COVID excluded Age = 48 Female = 76%	1273 (72%)	(Euroimmun)	
Ramanathan (272)	Cohort	US	solid organ transplant (71% kidney, 24% liver, 5% heart) Age = 39 Female = 52%	health care workers Age = 42 Female = 63%	BNT162b2 (62%), mRNA-1273 (38%)	anti-S1 IgG (Euroimmun)	unclear
Herrera (279)	Case series	Spain	Heart (46) and liver (58) transplants after median of 5.4 years with no prior COVID Age = 61 Female = 30%	N/A	mRNA-1273	anti-RBD IgG or IgM (Siemens)	28 days
Easdale (280)	Case series	UK	Allo-HCST at least 3 months post-transplant Age = 50 Female = 38%	N/A	BNT162b2 or ChAdOx1	anti-S1 IgG if neg total (Ortho Clincial Diagnostics)	N/R
Boyarsky (290)	Cohort	US	solid organ transplants COVID naïve (47% kidney, 21% liver, 14% heart, 11% lung) - median 6.2 years since transplant Age = 60 Female = N/R	SOT prior COVID Age = 56.6 Female = N/R	mRNA-1273	anti-S IgG (Roche) or anti-RBD IgG (Euroimmun)	N/R
Schramm (305)	Cohort	Germany	cardiothoracic transplant recipients, none had previous infection Age = 55 Female = 36%	50 healthy staff members Age = 47 Female = N/R	BNT162b2	anti-SARS-CoV-2 spike protein (S), also reported Neutralizing antibodies against SARS-CoV-2	N/R
Benotmane (303)	Cohort	France	41 immunocompromised kidney transplant recipients (KTRs) who had who were already seropositive at baseline because of previous exposure to SARS-CoV- 2. median between infection and vaccination was	22 health- care workers with a history of COVID-19 who received either the BNT162b2 (n = 19) or the mRNA-1273 vaccine (n = 3). Age = 47 Female = 77%	mRNA-1273 in cases	anti-S- IgG (Abbott, ARCHITECT IgG II Quant test)	N/R

			306 days [IQR]: 171−316 days) Age = 59 Female = 37%				
Prendecki (300)	Cohort	UK	920 kidney transplantation recipients Age = 59 Female = 34%	65 health care workers Age = 38 Female = N/R	BNT162b2 (n=490), ChAdOx1 (n=430) in cases, 55 BNT162b2 and 15 ChAdOx1 in controls	(Abbott, ARCHITECT IgG II Quant test)	74 days
Redjoul (299)	Case series	France	HSCT recipients- (184 allogeneic HSCT recipients and 134 autologous HSCT recipients) Age = 59 Female = 13%	N/A	BNT162b2	spike glyco protein-specific IgG receptor-binding domain (IgG[S-RBD]	4 weeks
Ben-Dov (38)	Cohort	Israel	Kidney transplant patients – median of 4 years from transplant Age = 53.5 Female = 84%	Nephrology health case team healthy controls Age = 43.6 Female = 46%	BNT162b2 (n=49) mRNA-1273 (n=64)	Anti-S IgG (Abbot, ARCHITECT IgG II Quant test).	21 days

Immunogenicity of the first vaccination in transplant patients

There were 12 cohort or case series studies (29, 58, 75, 84, 107, 121, 172, 198, 239, 259, 290, 305) evaluating 2323 transplant patients that reported on the proportion seroconverting after their first vaccination. Overall, the seroconversion rate after the first vaccination was 8% (95% CI = 4 to 14%) (Figure S8). There were 6 cohort studies (29, 58, 84, 198, 290, 305) involving 1632 participants that compared seroconversion after the first vaccination in transplant patients with controls. The relative risk of seroconversion in transplant patients compared to controls was 0.08 (95% CI = 0.02 to 0.34) with major heterogeneity between studies (I^2 = 94%, χ^2 = 85.0, p<0.0001) (Figure 14).

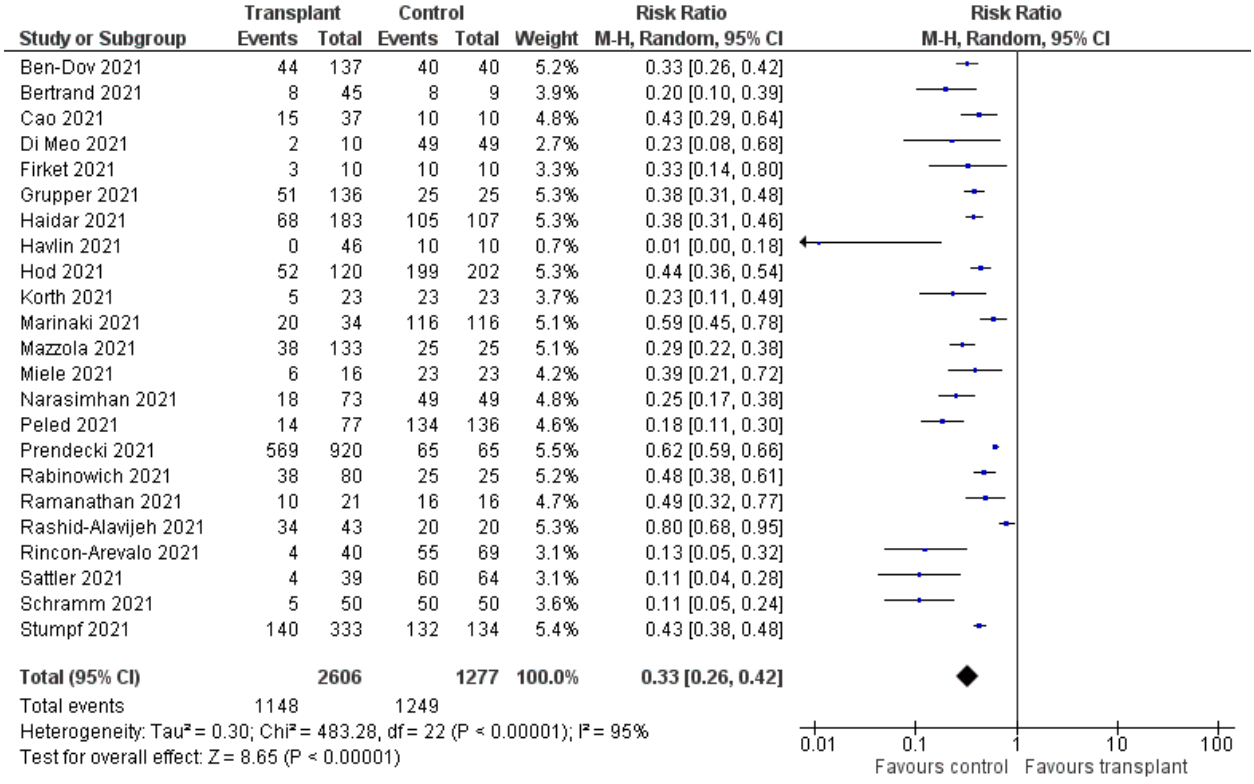
Figure 14. Seroconversion in transplant patients compared with controls after the first vaccination



Immunogenicity of the second vaccination in transplant patients

There were 33 cohort or case series studies (20, 22, 27, 38, 58, 75, 95, 114, 119, 121, 130, 138, 139, 141, 148, 154, 157, 161, 165, 170, 172, 205, 228, 239, 247, 248, 253, 259, 269, 271, 272, 300, 305) evaluating 4257 transplant patients that reported on the proportion seroconverting after their second vaccination. Overall, the seroconversion rate after the second vaccination was 31% (95% CI = 25 to 37%) (Figure S9). There were 23 cohort studies (20, 38, 58, 95, 107, 114, 119, 130, 138, 141, 148, 154, 157, 161, 170, 228, 247, 253, 269, 271, 272, 300, 305) involving 3883 participants that compared seroconversion after the second vaccination in transplant patients with controls. The relative risk of seroconversion in transplant patients was 0.33 (95% CI = 0.26 to 0.42) with major heterogeneity between studies (I^2 = 95%, χ^2 = 483.3, p<0.0001) (Figure 15).

Figure 15. Seroconversion in transplant patients compared with controls after the second vaccination



In addition, there were four studies evaluating seroconversion in patients undergoing bone marrow transplant. Seroconversion after the first vaccine was seen in 55% in one study (200) and 53% in another (280) involving a total of 167 patients. Seroconversion was observed in 67.5% after the second vaccine in one study involving 77 patients (158) and in 60% in another involving 130 patients (343).

Immunogenicity in patients with a primary immune deficiency

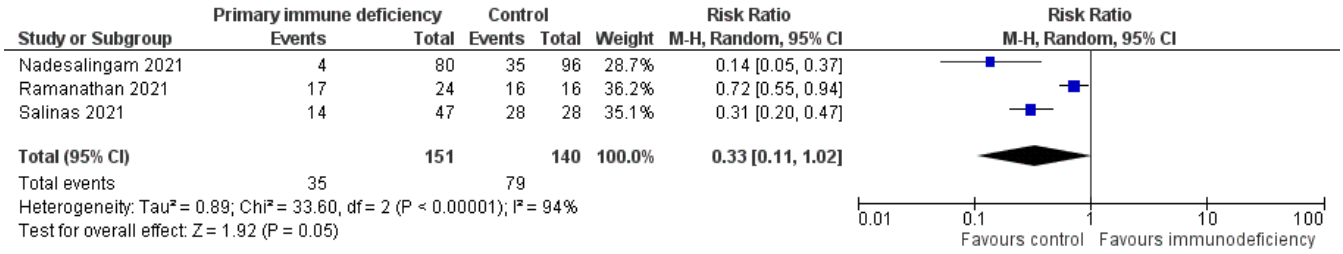
There were four studies (94, 113, 146, 272) that described the immunogenicity of SARS-CoV2 vaccination in patients with a variety of primary immune deficiencies although the majority had combined variable immune deficiency (Table 10).

Table 10. Characteristics of eligible studies evaluating immunogenicity in patients with primary immune deficiency

Author	Design	Country	Case description	Control description	Vaccine	Titre measured	Duration between 1st and 2nd vaccine
Salinas (94)	cohort	Italy	Patients with CVID (n=41) and XLA (n=6). Age and sex N/R	Healthy age matched health care workers. Age and sex N/R	BNT162b2	Anti-S and anti-RBD	21 days
Hagin (113)	case series	Israel	Patients with inborn errors of immunity 18/26 receive immunoglobulins. Age = 48.5, 61.5% female	N/A	BNT162b2	Anti-RBD (Abbott ARCHITECT IgG Quant test)	N/R
Nadesalingam (146)	cohort	UK	Patients with various immune deficiency disorders. Age and sex NR	Health care workers from same tertiary care centre as cases. Age and sex NR	BNT162b2 or ChAdOx1	Detectable neutralizing antibodies	N/A
Ramanathan (272)	cohort	US	Primary immune deficiencies (54% CVID, 46% other). Age = 48, 66.6% female	Health care workers. Age = 42, 62.5% female	BNT162b2 (66%) or mRNA-1273 (34%)	Anti-S IgG (Euroimmun)	N/R

One cohort study (146) described seroconversion after the first vaccination with 4/80 (5%) having detectable neutralizing antibodies to the B.1.1.7 strain in the primary immune deficiency group compared to 41/94 (44%) in healthy controls. There were three cohort or case series studies (94, 113, 272) in 97 patients with primary immune deficiency that described the proportion seroconverting after the second vaccination. The pooled rate was 56% (95% CI = 28 to 82%) (Figure S10). Given the paucity of data the three cohort studies (94, 146, 272) (291 participants) that compared seroconversion in primary immune deficiency with healthy controls for either the first or the second vaccine were pooled (Figure 16). The relative risk of seroconversion in the primary immune deficiency group compared to controls was 0.33 (95% CI = 0.11 to 1.02) with major heterogeneity between studies (I^2 = 94%, χ^2 = 33.6, p<0.0001) (Figure 16).

Figure 16. Seroconversion in primary immune deficiency patients compared with controls after either the first or second vaccination



Immunogenicity in dialysis patients

Dialysis patients are not classified as being immunocompromised, but reports suggest that patients undergoing dialysis mount less of an immune response to SARS-CoV2 vaccination than healthy controls (161). There were 38 studies (3, 4, 24, 32, 38, 40, 49, 58, 84, 90, 91, 97, 106, 108, 122, 131, 135, 145, 161, 163, 171, 175, 182, 186, 195, 196, 225, 237, 243, 246, 271, 282, 286, 289, 302, 325, 336, 342) that evaluated SARS-CoV2 vaccination in dialysis patients, and these are summarized in Table 11.

Table 11. Characteristics of eligible studies evaluating immunogenicity in dialysis patients

Author	Design	Country	Case description	Control description	Vaccine	Titre measured	Duration between 1st and 2nd vaccine
Attias (3)	Case series	France	maintenance hemodialysis Age = N/R Female = 20%	N/A	BNT162b2	anti-S1 IgG antibodies	28 days
Billany (4)	case series	UK	maintenance hemodialysis, 10% immunosuppression, 20% previous COVID Age = 62.1 Female = 40%	N/A	BNT162b2 or ChAdOx1	anti-RBD IgG (Siemans ADVIA Centaur Xp/XPT assay)	
Chan (24)	Case series	US	maintenance hemodialysis Age = 70 Female = 5%	N/A	mRNA-1273	anti-RBD IgG	28 days
Agur (49)	Case series	Israel	hemodialysis and PD, patients with prior COVID or immunosuppression excluded	N/A	BNT162b2	anti-S IgG antibodies (Abbott)	21 days

			Age = 71.5 Female = 34%				
Anand (32)	Case series	US	patients on dialysis who were COVID -ve prior to being vaccinated provide much larger numbers who were assessed but outcome data on only a subset Age = N/R Female = N/R	N/A	BNT162b2 (34%), mRNA-1273 63%), Ad26.COV2.S (3%)	anti-RBD IgG (Siemens)	N/R
Ben-Dov (38)	Cohort	Israel	Dialysis patients – median of 2.8 years Age = 65.1 Female = 70%	Nephrology health case team healthy controls Age = 43.6 Female = 46%	BNT162b2 (n=49) mRNA-1273 (n=64)	Anti-S IgG (Abbot, ARCHITECT IgG II Quant test).	21 days
Broseta (40)	Case series	Spain	hemodialysis, mean of 67.9 months (5% on immunosuppressive therapy) all sero -ve at baseline Age = 70.9 Female = 33%	N/A	BNT162b2 (43%) or mRNA-1273 (57%)	anti-S1 IgG (Siemens)	21-28 days
Bertrand (58)	case series	France	hemodialysis patients with median duration of 3.1 years Age = 71.2 Female = 34%	N/A	BNT162b2	anti-S1 IgG levels (Abbott)	21 days
Danthu (84)	Cohort	France	hemodialysis patients with median duration of 5.1 years Age = 73.5 Female = 41%	Health care workers Age = 51.6 Female = 43%	BNT162b2	anti-S1 IgG levels (Abbott)	N/R
Duarte (90)	Case series	Portugal	hemodialysis patients-35 months; Age = 75.1 Female = N/R 25 Peritoneal dialysis - 18 months Age = 60.5 Female = N/R	N/A	BNT162b2	anti-S1 IgG antibodies	21 days
Ducloux (91)	Case series	France	45 hemodialysis COVID naïve who had 3 doses Age = unclear Female = unclear	N/A	BNT162b2	anti-S1 IgG levels (Abbott)	unclear
Frantzen (97)	Case series	France	Hemodialysis patients attending dialysis Marseille clinic (1 on immunosuppressive	N/A	BNT162b2	anti-S IgG antibodies (Elecsys)	21 days

			therapy, 13% previous COVID infection) Age = 71 Female = 30%				
Goupil (106)	Cohort	Canada	hemodialysis patients COVID naïve - mean duration 3.8 years; hemodialysis patients with previous COVID - mean duration 3.4 years Age = 70 Female = 34%	controls COVID naïve; controls previous COVID Age = 47 Female = 65%	BNT162b2	anti-RBD IgG	N/R
Grupper (108)	Cohort	Israel	hemodialysis patients - 3.25 years (1 patient on immunosuppression) Age = 74 Female = 25%	healthy volunteers from same academic institution Age = 57 Female = 73%	BNT162b2	anti-S IgG antibodies (Abbott)	21 days
Jahn (122)	Cohort	Germany	hemodialysis patients - 4.33 years (none had prior COVID) Age = 68 Female = 43%	health care workers vaccinated Age = 45.5 Female = 56%	BNT162b2	anti-S IgG antibodies (Liaison, Diarson, Italy)	N/R
Lesny (131)	Cohort	Germany	hemodialysis - for average 2.1 years or PD Age = 64 Female = 13%	health care workers Age = 54 Female = 93%	BNT162b2 (48%) or ChAdOx1 (52%)	anti-RBD IgG	N/R
Yau (196)	Cohort	Canada	142 in-centre hemodialysis patients (2 had covid at baseline) Age = 72 Female = 30%	35 health care worker controls (3 had covid at baseline) Age = 46 Female = 94%	BNT162b2	anti-S IgG and anti-RBD IgG	mean 21 days (range 19-28)
Yanay (195)	Cohort	Israel	chronic dialysis patients (127 hemodialysis and 33 peritoneal dialysis patients) who completed vaccination with BNT162b2 vaccine Age = 69 Female = 37%	hospital employees of all sectors who completed vaccination with BNT162b2 vaccine Age = 50.5 Female = 49%	BNT162b2	anti-S IgG antibodies (Liaison, Diarson, Italy)	21-35 days
Torreggiani (186)	Case series	France	All the chronic hemodialysis patients treated in the centre, those vaccinated Age = 69.9 Female = 41%	N/A	BNT162b2	anti-S IgG antibodies (Elecsys)	3 weeks
Stengert (182)	Cohort	Germany	Patients with chronic renal insufficiency on	healthcare workers	BNT162b2	anti-S IgG antibodies	21 days

			intermittent hemodialysis Age = 69 Female = 42%	vaccinated at the same time points Age = 54.5 Female = 82%		and anti-RBD IgG	
Simon (145)	Cohort	Austria	Hemodialysis Patients Age = 67 Female = 28%	volunteer healthcare workers who had been vaccinated using the same regimen Age = 49 Female = 61%	BNT162b2 mRNA-1273	Elecsys® Anti-SARS-CoV-2 test, which measured the nucleocapsid (N) antibodies	21 days
Schrezenmeier (171)	Cohort	Germany	chronic kidney disease stage 5 before on dialysis Age = 74 Female = 26%	Vaccinated Non-Dialysis Controls with other Co-Morbidities (n = 44 control patients without dialysis) Age = 80 Female = 68%	BNT162b2	anti-S IgG antibodies (Euroimmun)	N/R
Rodriguez-Espinosa (163)	Case series	Spain	peritoneal dialysis patients Age = 61.5 Female = 63%	N/A	mRNA-1273	anti-S1 IgG (Siemens)	28 days
Longlune (135)	Case series	France	chronic dialysis patients (hemodialysis (n=85) or peritoneal dialysis (n= 24)) 5 had covid history at baseline Age = 64 Female = 31%	N/A	BNT162b2	anti-S1 IgG	28 days
Lobriola (225)	Cohort	Belgium	Nursing home residents on in-center hemodialysis at five hospitals from the UC Louvain network, Age = 81 Female = 56%	Non-dialysed nursing home resident matched for COVID history were controls Age = 88 Female = 64%	BNT162b2	anti-RBD (Roche Elecsys)	N/R
Lacson (237)	Case series	US	Dialysis Clinic, Inc. (DCI) dialysis clinics in the US that assessed antibody response following administration of mRNA vaccines (30 clinics in 8 states) Age = 68 Female = 47%	N/A	BNT162b2 (90%) or mRNA-1273 (10%)	anti-S1 IgG	manufacturers recommendations
Garcia (243)	Case series	US	dialysis at home or at a dialysis clinic Age = N/R Female = N/R	N/A	BNT162b2 (62%), mRNA-1273	total RCT-Ig	manufacturers recommendations

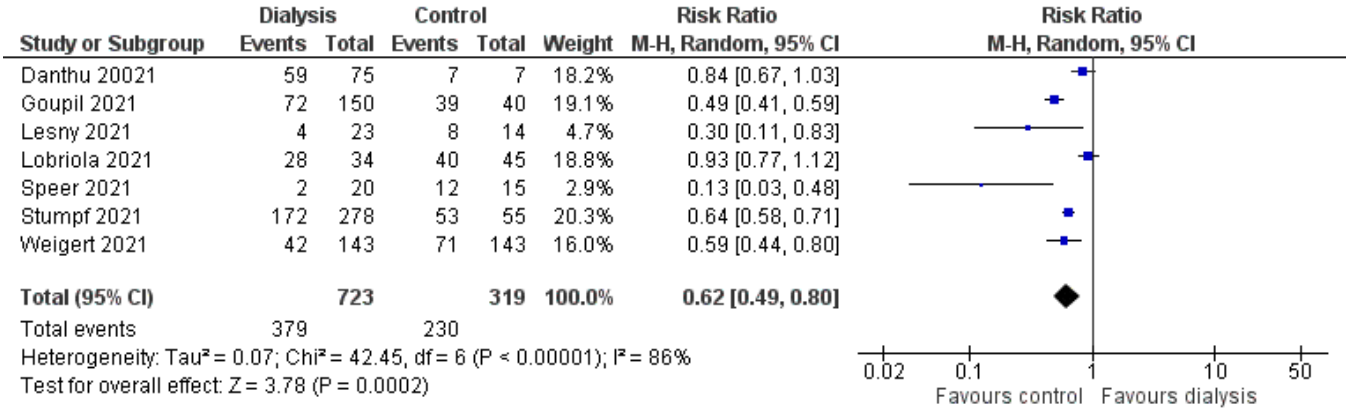
					(20%), Ad26.COV2.S (18%)		
Zitt (246)	case series	Austria	In-centre dialysis patients that were COVID naïve Age = 67.6 Female = 32%	N/A	BNT162b2	anti-RBD IgG (Liaison, Diarson, Italy)	21 days
Stumpf (271)	Cohort	Germany	hemodialysis (95%) and peritoneal dialysis (5%) for a mean of 5.7 years Age = 67.6 Female = 35%	health care workers prior COVID excluded Age = 48 Female = 76%	BNT162b2 (28%) or mRNA-1273 (72%)	anti-S1 IgG or IgA (Euroimmun)	28 days
Weigert (282)	Cohort	Portugal	Chronic hemodialysis patients without COVID with median dialysis duration of 46 months Age = 72 Female = 32%	random selection from a pool of health care workers and nursing home residents Age = 73 Female = 53%	BNT162b2	anti-S IgG (Roche, Elecsys)	21 days
Kaiser (286)	case series	Austria	hemodialysis patients for median 2.4 years Age = 66.6 Female = 39%	N/A	BNT162b2 (33.6%). mRNA-1273 (66.4%)	anti-RBD IgG (Abbott)	N/R
Espi (289)	Cohort	France	hemodialysis patients for 4.1 years Age = 64.9 Female = 35%	unmatched healthy volunteers Age = 46.6 Female = 53%	BNT162b2	anti-RBD IgG (Snibe Diagnostic, Shenzen, China))	3-5 weeks
Rincon-Arevalo (161)	Cohort	Germany	Mixed: dialysis patients (DP) n=44 (40 maintenance hemodialysis+4 peritoneal dialysis), kidney transplant recipients (KTR) n=40 Age = DP 69.0, PD 70.5, KTR 62.5 Female = N/R	healthy controls (HC) mainly health care workers n=25 Age = 41 Female = 40%	BNT162b2	anti-S1 IgG (Quantivac, Euroimmun)	3-4 weeks
Clarke (302)	Cohort	UK	hemodialysis patients (465/1021 (45.8%) had evidence of natural infection – were	65 health care workers were used as a control group	BNT162b2 (n=523), ChAdOx1 (n=498) in	anti-S1 IgG levels (Abbott)	63 days

			excluded from assessment of efficacy in general but included in the impact of prior COVID analysis Age = 67 Female = N/R	Age = 38 Female = N/R	cases, vs 50 BNT162b2 and 15 ChAdOx1 in control		
Sattler (170)	Cohort	Germany	26 with kidney failure on hemodialysis (HD) Age = 67.4 Female = 35%	39 healthy controls (majority health care professionals) Age = 53 Female = 49%	BNT162b2	anti-S IgG or IgA (Quantivac, Euroimmun)	21 days
Tylicki (336)	Case series	Poland	Patients with hemodialysis for mean of 3 years (28% prior COVID considered separately Age: covid naïve = 70, prior covid = 65 Female: covid naïve 38%, prior covid 34%	N/A	BNT162b2	anti-S IgG antibodies (Liaison, Diarson, Italy)	21 days
Blazquez-Navarro (325)	Case series	Germany	Hemodialysis patients Age: 67 Female: 36%	N/A	BNT162b2	anti-S IgG (Quantivac, Euroimmun)	N/R
Speer (342)	Cohort	Germany	Patients on long term hemodialysis median 5 years Age: 74 Female: 45%	Healthy controls Age: 48 Female: 59%	BNT162b2	anti-S1 IgG (Siemens, Germany)	19-22 days

Immunogenicity of the first vaccination in dialysis patients

There were 18 cohort or case series studies (3, 4, 40, 58, 84, 90, 106, 131, 135, 163, 171, 186, 196, 225, 246, 271, 282, 342) evaluating 1398 dialysis patients that reported on the proportion seroconverting after their first vaccination. Overall, the seroconversion rate after the first vaccination was 49% (95% CI = 39 to 59%) (Figure S11). There were 7 cohort studies (84, 106, 131, 225, 271, 282, 342) involving 1042 participants that compared seroconversion after the first vaccination in dialysis patients with controls. The relative risk of seroconversion in dialysis patients compared to controls was 0.62 (95% CI = 0.49 to 0.80) with major heterogeneity between studies ($I^2 = 86\%$, $\chi^2 = 42.4$, $p<0.0001$) (Figure 17).

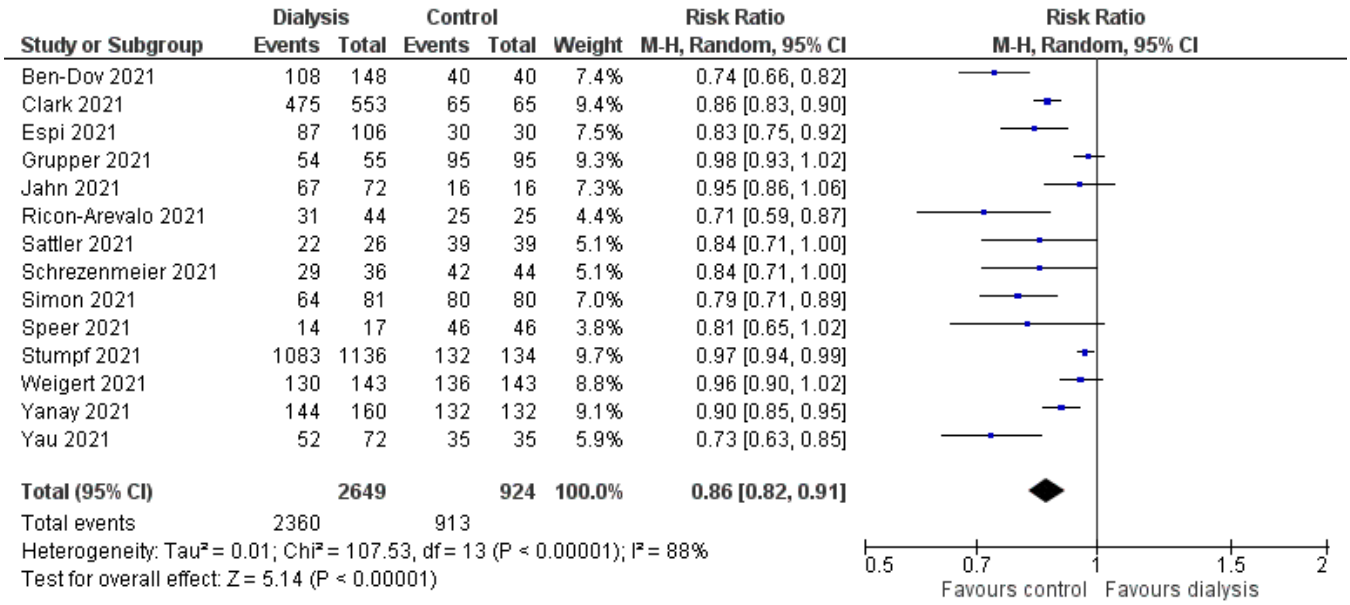
Figure 17. Seroconversion in dialysis patients compared with controls after the first vaccination



Immunogenicity of the second vaccination in dialysis patients

There were 32 cohort or case series studies (3, 24, 32, 38, 40, 49, 58, 90, 91, 97, 108, 122, 135, 161, 163, 170, 171, 175, 182, 195, 196, 237, 243, 246, 271, 282, 286, 289, 302, 325, 336, 342) evaluating 6142 dialysis patients that reported on the proportion seroconverting after their second vaccination. Overall, the seroconversion rate after the second vaccination was 89% (95% CI = 86 to 92%) (Figure S12). There were 14 cohort studies (38, 108, 122, 161, 170, 171, 175, 195, 196, 271, 282, 289, 302, 342) involving 3573 participants that compared seroconversion after the second vaccination in dialysis patients with controls. The relative risk of seroconversion in dialysis patients was 0.86 (95% CI = 0.82 to 0.91) with major heterogeneity between studies (I^2 = 88%, χ^2 = 107.5, p<0.0001) (Figure 18).

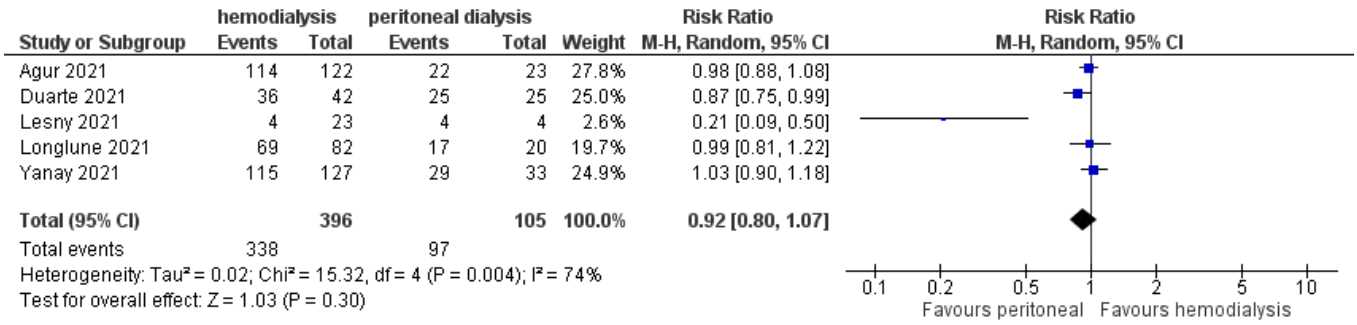
Figure 18. Seroconversion in dialysis patients compared with controls after the second vaccination



Comparison of hemodialysis and peritoneal dialysis

One study (131) reported that seroconversion was better in patients on peritoneal dialysis compared to hemodialysis. This hypothesis was tested in a *post-hoc* analysis of the studies. There were 5 cohort studies (49, 90, 131, 135, 195) evaluating 501 patients that compared the two types of dialysis. There was no statistically significant difference between hemodialysis and peritoneal dialysis (RR = 0.92; 95% CI = 0.80 to 1.07) with major heterogeneity between studies (I^2 = 74%, χ^2 = 15.3, p = 0.004) (Figure 19).

Figure 19. Seroconversion with SARS-CoV2 vaccination in hemodialysis compared to peritoneal dialysis



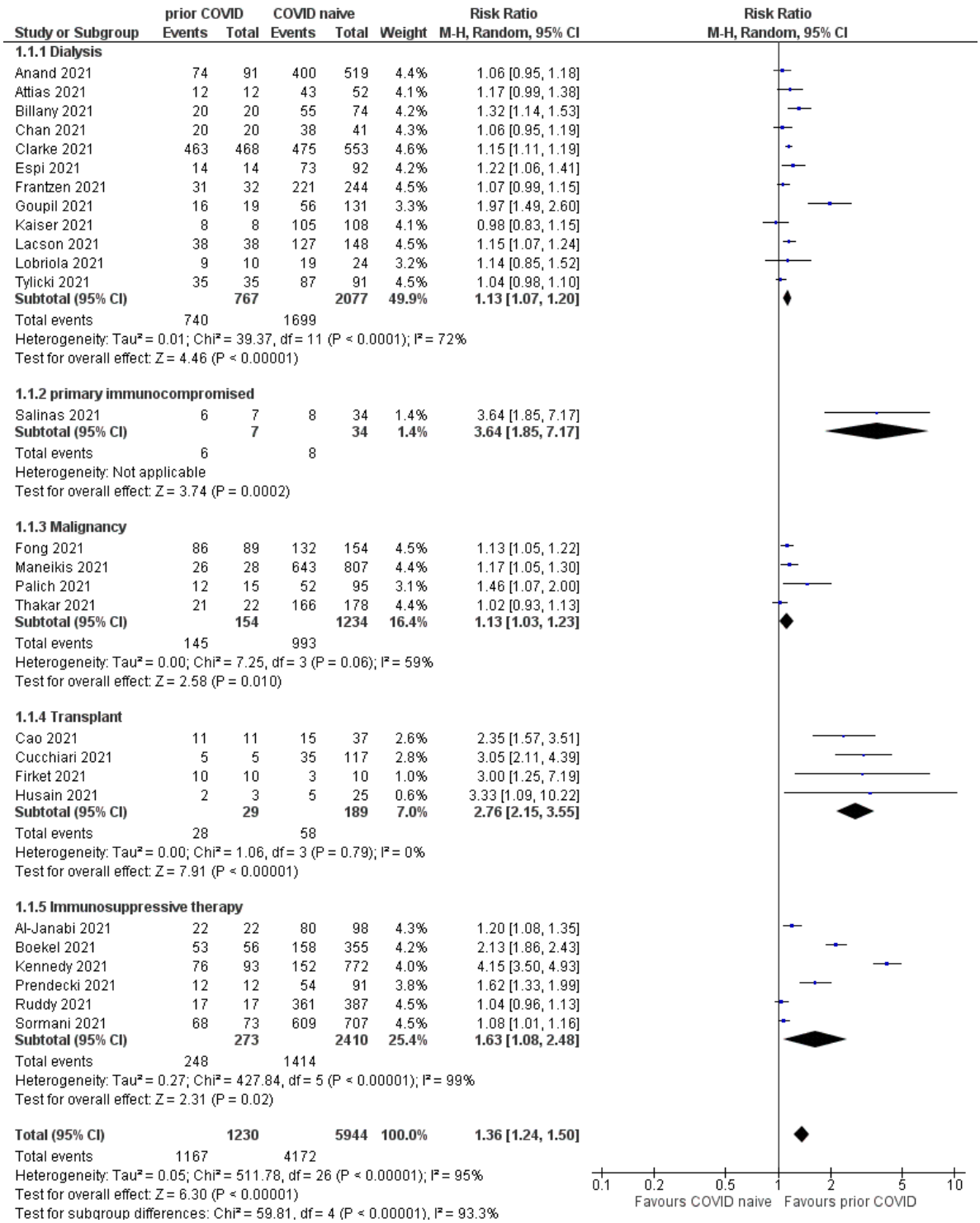
Influence of prior COVID in the immunogenicity of COVID-19 vaccination in the immunocompromised

Studies (106) have reported that the response to COVID-19 vaccination is more robust in patients that have had prior SARS-CoV2 infection. There were 27 studies (3, 4, 7, 16, 22-24, 27, 31, 32, 41, 94, 95, 97, 106, 137, 225, 228, 229, 233, 237, 284, 286, 289, 302, 324, 336) that described seroconversion in patients with prior COVID-19 compared to those that had not been infected in 7174 patients. Where possible, seroconversion after the 2nd vaccination was used. The proportion seroconverting was greater overall in those with prior COVID-19 with a relative risk of 1.36 (95% CI 1.24 to 1.50) with major heterogeneity between studies (I^2 = 95%, χ^2 = 511.8, p<0.0001) (Figure 20). This was, in part, driven by differences in the impact of prior infection on seroconversion depending on what was causing the patient to be immunocompromised. The impact of prior COVID-19 was larger in diseases that impact seroconversion more such as transplant and primary immune deficiency (Table 12).

Table 12. Summary of impact of prior COVID-19 according to disease group

Group	Number of studies	Number of patients	Relative risk (95% CI)
Dialysis	12	2844	1.13 (1.07 to 1.20)
Primary immune deficiency	1	41	3.64 (1.85 to 7.17)
Malignancy	4	1388	1.13 (1.03 to 1.23)
Transplant	4	218	2.76 (2.15 to 3.55)
Immunosuppressive therapy	6	2683	1.63 (1.08 to 2.48)
Overall	**27**	**7174**	**1.36 (1.24 to 1.50)**

Figure 20. The impact of prior COVID-19 on seroconversion with SARS-CoV2 vaccination in the immunocompromised



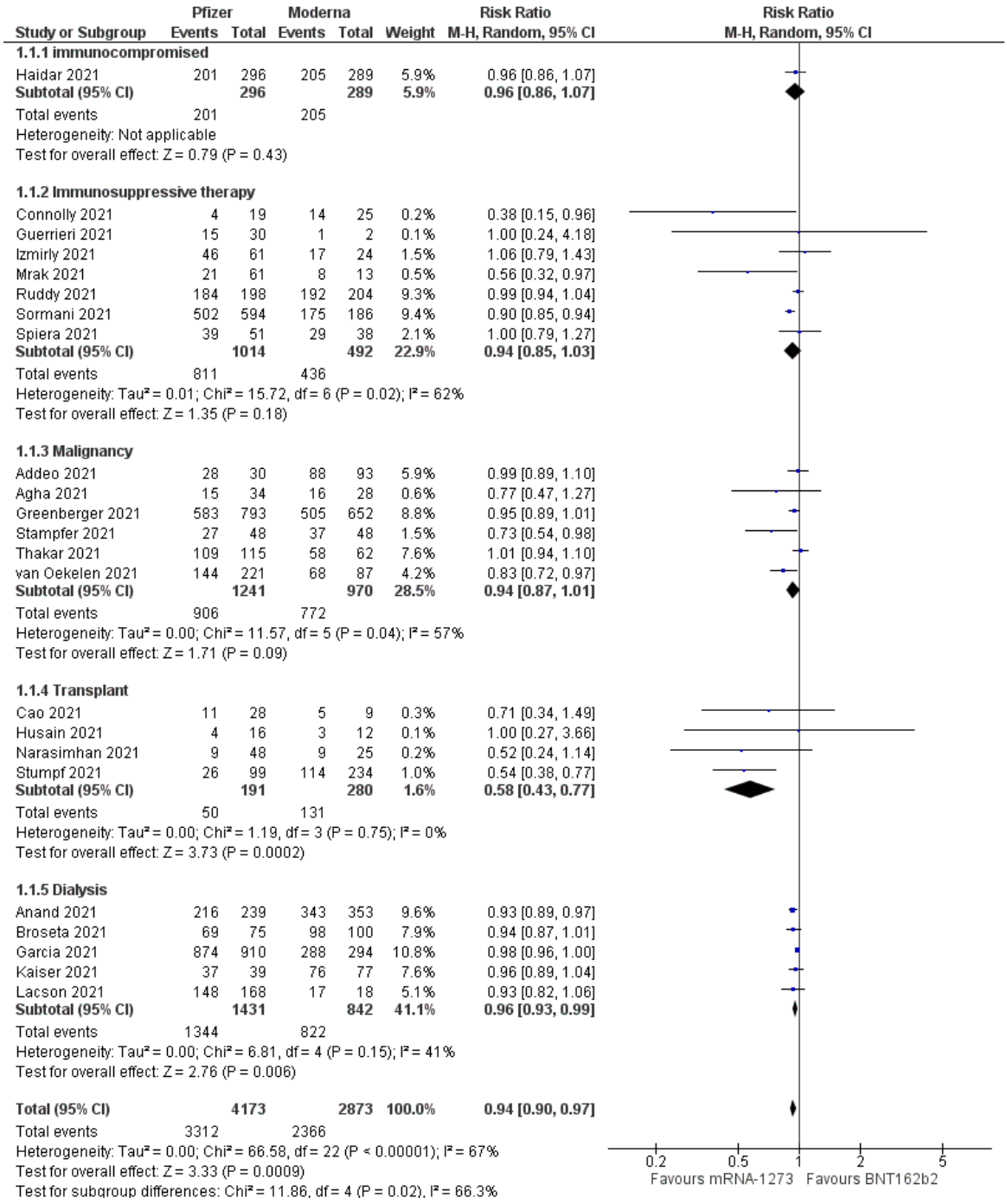
Efficacy of BNT162b2 versus mRNA-1273 for seroconversion in the immunocompromised

Recent observational data (371) from the US has suggested BNT162b2 may be slightly less effective at preventing COVID-19 infections than mRNA-1273. This study (371) was in the general population, and it is unclear whether the two vaccines have different seroconversion rates in the immunocompromised and dialysis populations. To address this question, we identified eligible studies described above that administered either the BNT162b2 or mRNA-1273 to the same population and reported seroconversion proportions by vaccine type after the second vaccination. There were 23 studies (16, 23, 27, 32, 40, 46, 47, 109, 114, 148, 151, 180, 228, 237, 238, 243, 256, 271, 284, 286, 287, 309, 364) evaluating 7046 patients that recorded the efficacy of BNT162b2 and mRNA-1273 in the same population (Figure 21). Overall, BNT162b2 had slightly lower rates of seroconversion than mRNA-1273 with relative risk of 0.94 (95% CI = 0.90 to 0.97) with moderate heterogeneity between studies (I^2 = 67%, χ^2 = 66.6, p<0.0001) (Figure 21). A proportion of this heterogeneity was due to BNT162b2 being particularly less effective in transplant patients (Table 13).

Table 13. Summary of seroconversion with BNT162b2 versus mRNA-1273 in the immunocompromised and dialysis populations

Group	Number of studies	Number of patients	Relative risk (95% CI)
Immunocompromised	1	585	0.96 (0.86 to 1.07)
Immunosuppressive therapy	7	1506	0.94 (0.85 to 1.03)
Malignancy	6	2211	0.94 (0.87 to 1.01)
Transplant	4	471	0.58 (0.43 to 0.77)
Dialysis	5	2273	0.96 (0.93 to 0.99)
Overall	**23**	**7046**	**0.94 (0.91 to 0.97)**

Figure 21. Seroconversion with BNT162b2 versus mRNA-1273 in the immunocompromised and dialysis populations



Immunogenicity of a third dose of COVID-19 vaccination

The reduced immunogenicity of COVID-19 vaccination in the immunocompromised and dialysis population has led some to suggest administering a third vaccine to increase seroconversion and augment antibody titres. There were 10 before after studies (91, 135, 194, 201, 217, 219-221, 259, 370) that addressed this hypothesis as well as one randomized controlled trial (310) and these are summarized in Table 14.

Table 14. Summary of studies evaluating immunogenicity of a 3rd vaccine dose

Author	Design	Country	Population description	Vaccine	Titre measured	Duration between 2nd and 3rd vaccine	Time after 3rd vaccine titre measured
Ducloux (91)	Before after	France	Hemodialysis patients that had not had previous COVID-19 infection (by history and serology) and had two BNT162b2 vaccinations	BNT162b2	anti-S1 IgG (Abbott)	N/R	1 month
Longlune (135)	Before after	France	Dialysis patients (88, hemodialysis, 24 peritoneal dialysis) that had two BNT162b2 vaccinations	BNT162b2	anti-S total Ig (Beijing Wantai Biological Pharmacy Ent)	1 month	1 month
Werbel (194)	Before after	US	Solid organ transplant patients that had two vaccinations (BNT162b2 (57%) or mRNA-1273 (43%))	BNT162b2 (16.6%) or mRNA-1273 (33.3%) or Ad26.COV2.S (50%)	anti-RBD total Ig (Roche, Elecsys) or anti-S1 IgG (Euroimmun)	67 days	14 days
Espi (201)	Before after	France	Maintenance hemodialysis patients from two centres that had received two BNT162b2 vaccinations and had not had COVID-19 within the last 3 months	BNT162b2	anti-RBD IgG (Snibe Diagnostic, Shenzen, China)	Within 3 months	10-14 days
Massa (217)	Before after	France	Consecutive kidney transplant patients from a single centre that had received two BNT162b2 vaccinations	BNT162b2	anti-RBD IgG (Abbott)	28 days	28 days

Frantzen (219)	Before after	France	Maintenance hemodialysis patients from two centres that had received two BNT162b2 vaccinations	BNT162b2 (58%), mRNA-1273 (31%) and Ad26.COV2.S (10%)	anti-S Ig (Roche, Elecsys)	At least one month	1 month
Re (220)	Before after	France	Patients with hematological malignancies (CLL, NHL and MM) that had received two BNT162b2 vaccinations	BNT162b2	anti-RBD total Ig (Roche, Elecsys)	N/R	3-4 weeks
Benotmane (221)	Before after	France	Kidney transplant patients from a single centre that had no history of prior COVID-19 and an anti-S IgG of less than 50 after receiving two BNT162b2 vaccinations	BNT162b2	anti-S IgG (Abbott, ARCHITECT IgG Quant test)	51 days	28 days
Del Bello (259)	Before after	France	Consecutive solid organ transplants (majority liver and kidney) that had received two BNT162b2 vaccinations	BNT162b2	anti-S IgG (Beijing Wantai Biological Pharmacy Ent) (58%), other anti-S IgG assay (42%)	59 days	28 days
Stumpf (370)	Before after	Germany	Kidney transplant recipients that received two BNT162b2 vaccinations	BNT162b2	Anti-RBD IgG (Euroimmun)	68 days	4 weeks
Hall (310)	RCT	Canada	Solid organ transplant recipients that had received two mRNA-1273 vaccinations randomized to receive third dose of mRNA-1273 or placebo	mRNA-1273	anti-RBD Ig (Roche, Elecsys)	2 months	4 weeks (± 1 week)

The one Canadian well conducted RCT by Hall et al. (310) involving 117 transplant patients was included with the ten before after studies as results were similar. The RCT (310) was low risk of bias and increased the GRADE assessment of the quality of the evidence. Overall, there were 11 studies that evaluated 2217 patients (91, 135, 194, 201, 217, 219-221, 259, 310, 370) with an overall increase in seroconversion of 14% (95% CI 7 to 22%) with major heterogeneity between studies (I^2 = 80%, χ^2 = 48.9, p<0.0001) (Figure 22). This heterogeneity was driven, in part, by differences in the benefit of a third vaccination in different groups. One study (220) evaluating hematological malignancy found no increase in seroconversion (although there was an increase in antibody titre in those that seroconverted after the second vaccine). Four studies (91, 135, 201, 219) involving 550 dialysis patients showed an increase in seroconversion of 5% (95% CI = 1 to 10%) with no heterogeneity between studies (I^2 = 0%, χ^2 = 0.4, p = 0.94) (Figure 22). Six studies (194, 217, 221, 259, 310, 370) involving 1551 transplant patients showed an increase in seroconversion of 23% (95% CI = 14 to 31%) with moderate heterogeneity between studies (I^2 = 55%, χ^2 = 11.2, p = 0.05) (Figure 22). This heterogeneity was driven by one study (221) that preselected patients to give a third vaccine based on the level of anti-S antibodies after the second vaccine. If that study (221) was excluded the increase in seroconversion was 26% (95% CI = 21 to 32%) with no heterogeneity between studies (I^2 = 0%, χ^2 = 2.96, p = 0.57). All studies that reported antibody titres found levels were increased after the third vaccine (Figure 23).

Figure 22. Increased proportion of seroconversion after a third COVID-19 vaccine in the immunocompromised and dialysis populations.

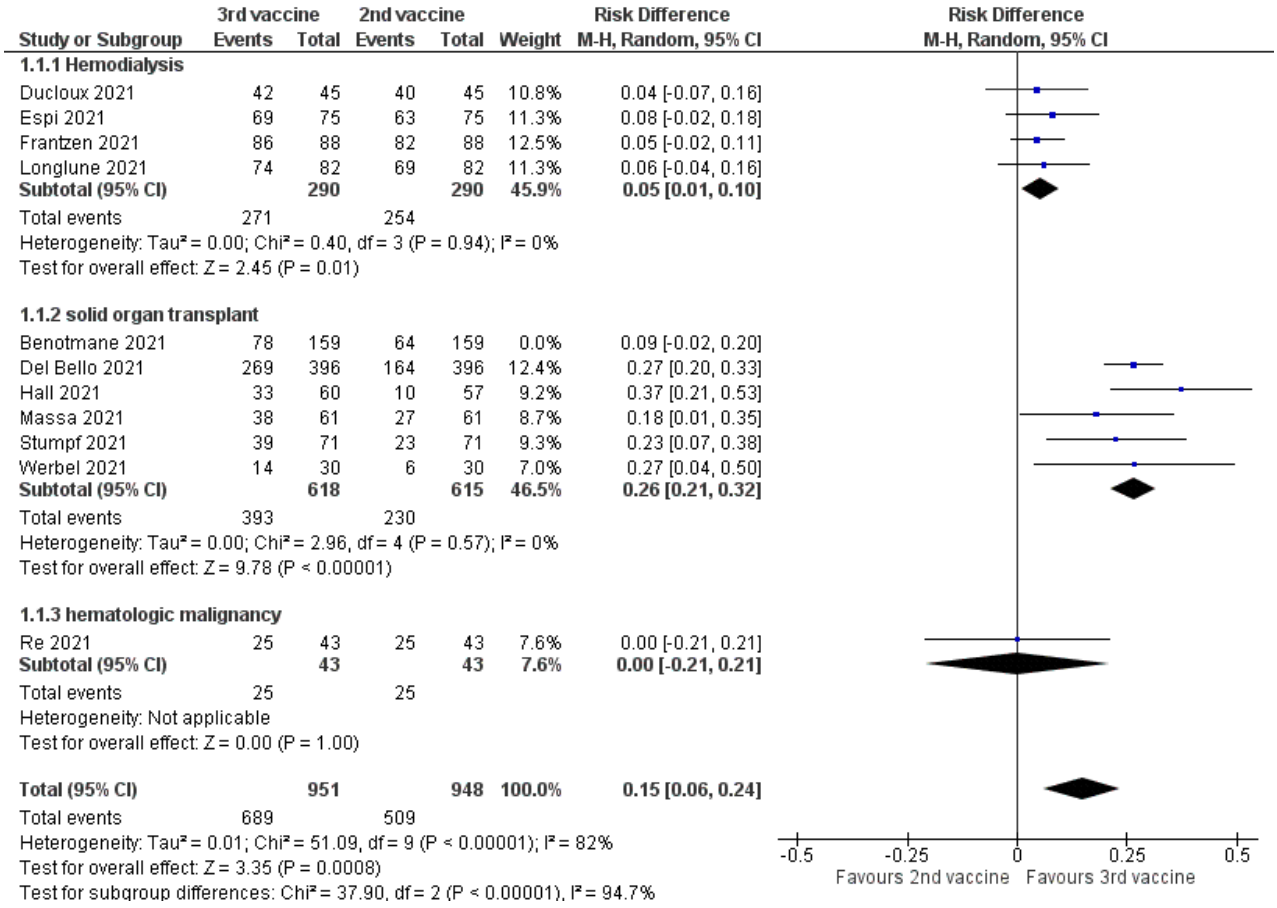
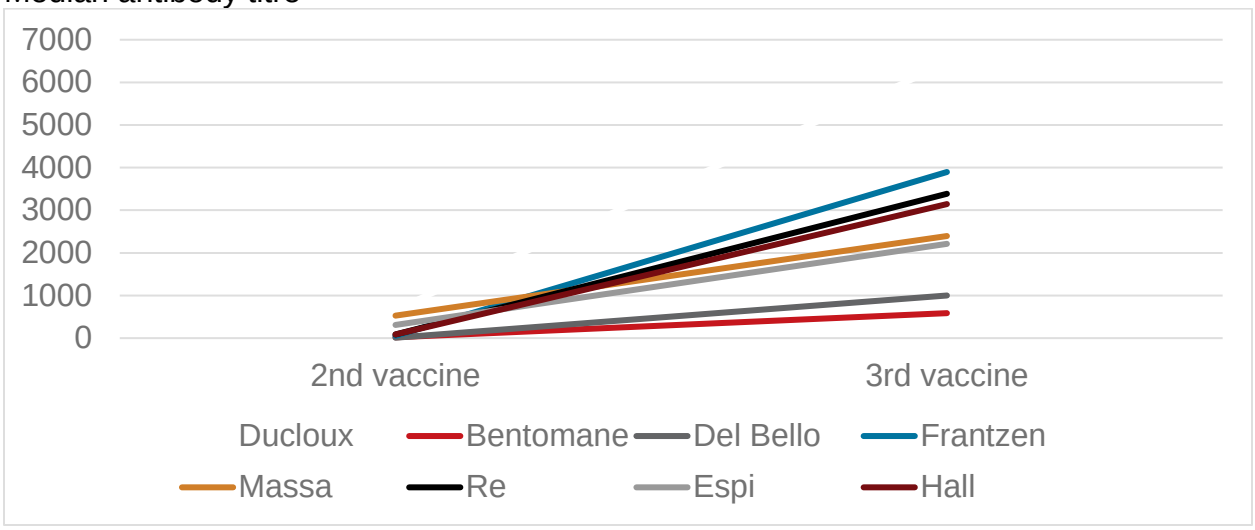


Figure 23. Increase in antibody titres after third vaccination



Safety of COVID-19 vaccination in immunocompromised and dialysis patients

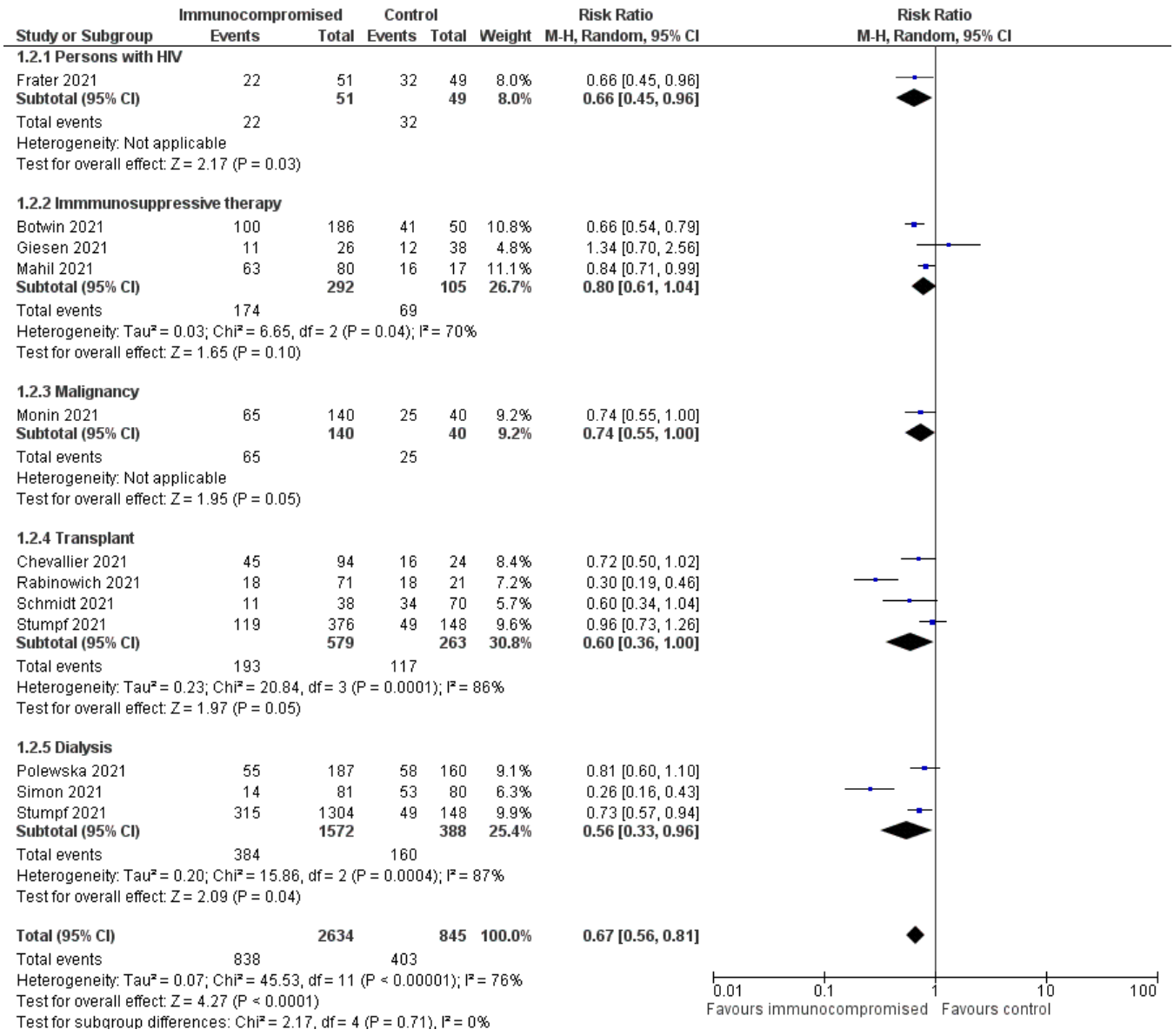
We narrowed the focus of evaluation to studies that compared immunocompromised or dialysis patients receiving the vaccine with healthy controls due to the time constraints of this rapid review. We extracted overall adverse events or overall systemic adverse events from both the first and second vaccination. If the study gave adverse events from both the first and second vaccination, we presented the second vaccination data unless there were more than 25% fall in numbers after the first vaccine. This latter rule only applied to one study (143) and the difference between malignancy and healthy control was greater after the second vaccination, but we reported data from the first vaccination to be conservative. Descriptions of these studies have been provided in the above sections.

There were 11 studies (29, 63, 99, 104, 143, 157, 175, 200, 204, 271, 334) evaluating 3479 participants with one study (271) providing information on adverse events for both transplant and dialysis patients. Adverse events were less common in the immunocompromised or dialysis patients compared with healthy controls (RR = 0.67; 95% CI = 0.56 to 0.81) with major heterogeneity between studies (I^2 = 76%, χ^2 = 45.5, p<0.0001) (Figure 24).

Individual adverse events such as myalgia, fatigue, fever, nausea, diarrhea or skin reaction were not more prevalent in immunocompromised patients, but we also assessed reactions that might be specific to this patient group. Ali et al. (296) reported 6/113 patients receiving allogenic hematopoietic stem cell transplantation developed new graft versus host disease (GVHD) 3-55 days after vaccination. Ram et al. (158) noted that 10% of patients receiving allogenic hematopoietic stem cell transplantation developed mild cytopenia after vaccination 3/77 developing an exacerbation of GVHD within a week of vaccination. A further study in this patient group (200) did not note any GVHD or cytopenia. This population is particularly at risk of developing GVHD and cytopenia so these uncontrolled observations are difficult to interpret but this should be studied further.

No adverse event signal was seen in solid organ transplants after two vaccines but there was one (194) case of biopsy proven anti-body mediated rejection in a heart transplant patient within a week of the third vaccine that did not require intervention and did not result in change in heart function.

Figure 24. Overall adverse events in immunocompromised and dialysis patients receiving COVID-19 vaccination compared to healthy controls

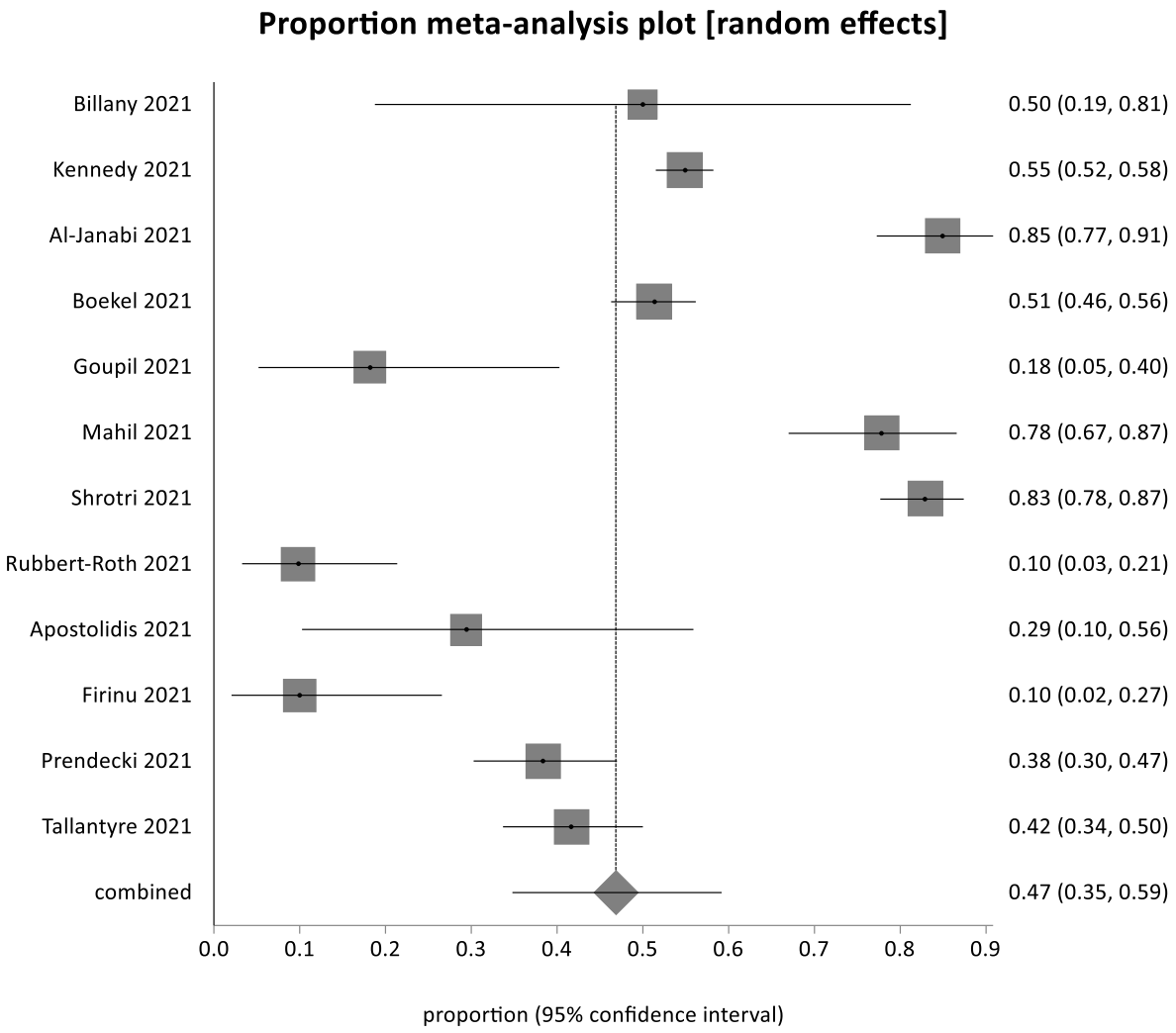


Conclusion

Population studies suggest COVID-19 vaccination has about an 80% efficacy in protecting against both COVID-19 infection and symptoms in the immunocompromised and cancer patients. This is slightly lower than the 90% protection seen in the healthy population. This observation is reflected in a modest reduction in seroconversion after vaccination in patients with solid malignancy, those taking immunosuppressive therapy and those on dialysis. A third vaccination can increase seroconversion by about 5% in these groups. Transplant patients are more severely impacted with only 31% seroconverting after the second vaccine. A third vaccination is more helpful in this group increasing the absolute seroconversion rate by over 20%. Prior COVID-19 infection increases seroconversion, again particularly in transplant patients. mRNA-1273 is slightly more effective than BNT162b2 in the immunocompromised and dialysis populations. There is no major safety concern with COVID-19 vaccination symptoms in the immunocompromised and dialysis patients and overall adverse events are less than in the healthy population.

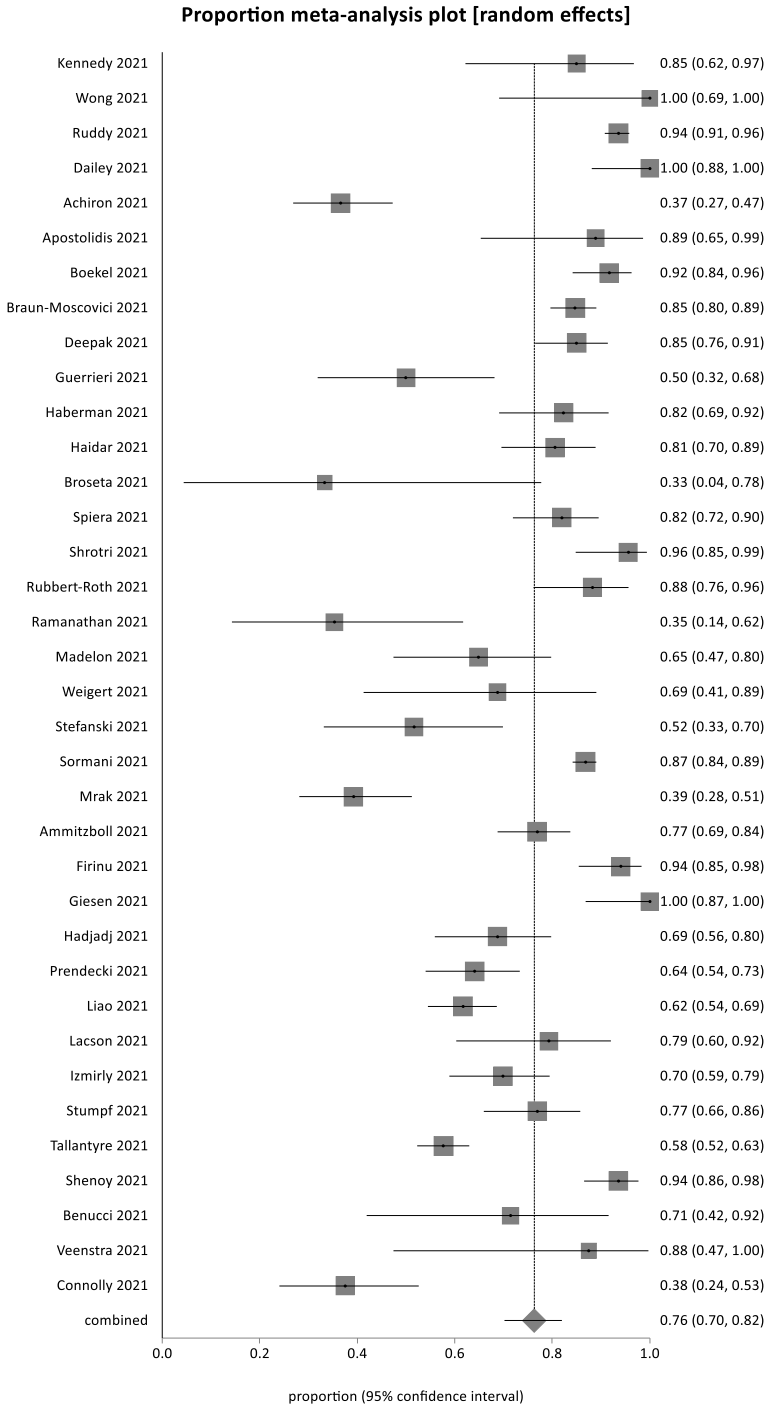
Appendix 1: Additional figures

Figure S1. Proportion of patients taking immunosuppressive therapy seroconverting after the first vaccination



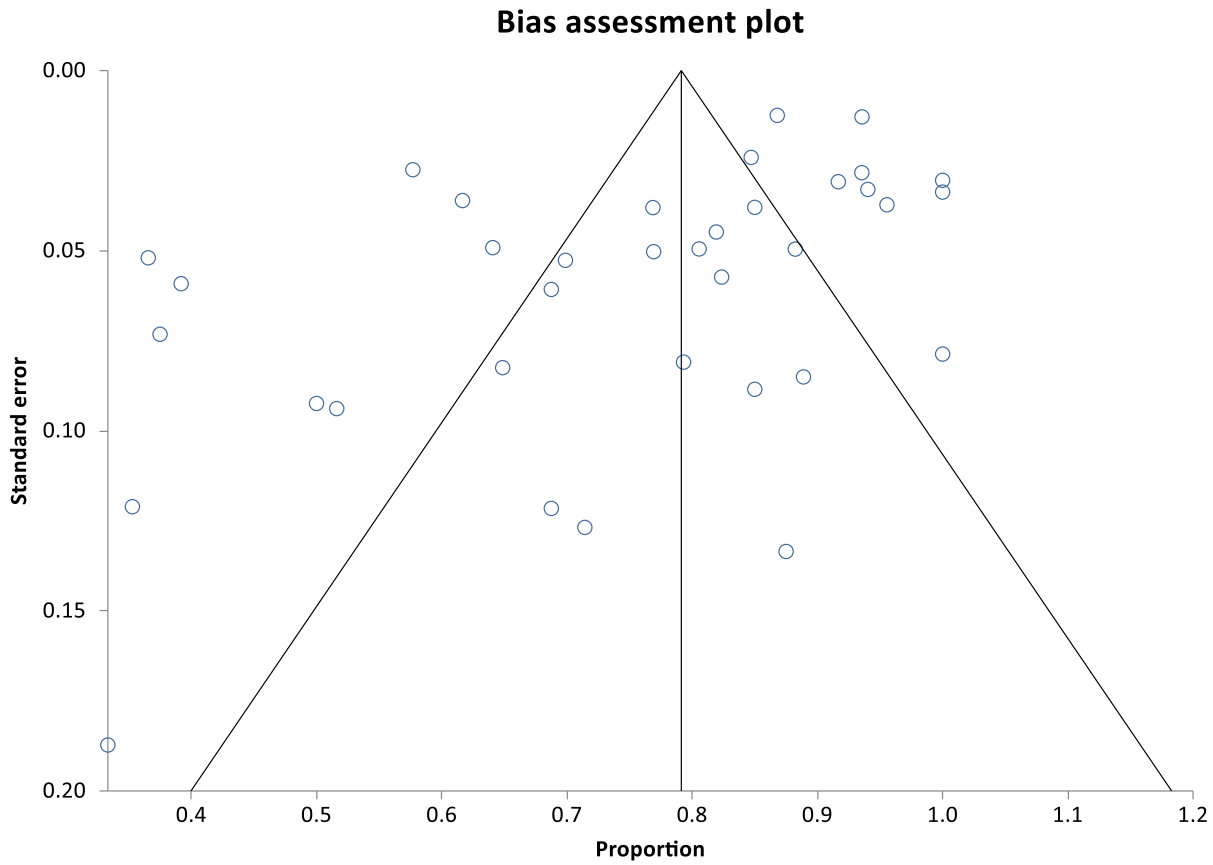
Non-combinability of studies
Cochran Q = 292.8 (df = 11) P < 0.0001
I^2 = 96.2% (95% CI = 95.2% to 97.0%)

Figure S2. Proportion of patients taking immunosuppressive therapy seroconverting after the second vaccination



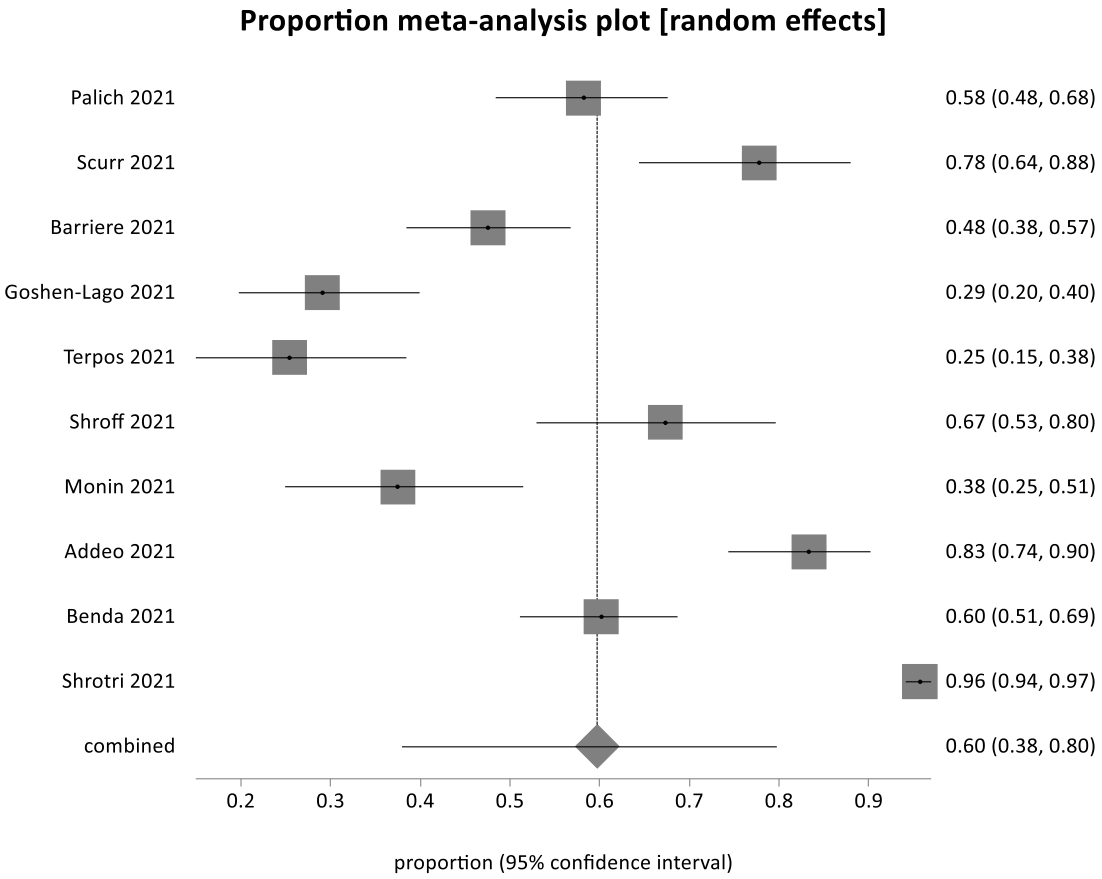
Non-combinability of studies
Cochran Q = 542.6 (df = 35) P < 0.0001
I^2 = 93.5% (95% CI = 92.3% to 94.5%)

Figure S3. Funnel plot of proportion of patients taking immunosuppressive therapy seroconverting after the second vaccination



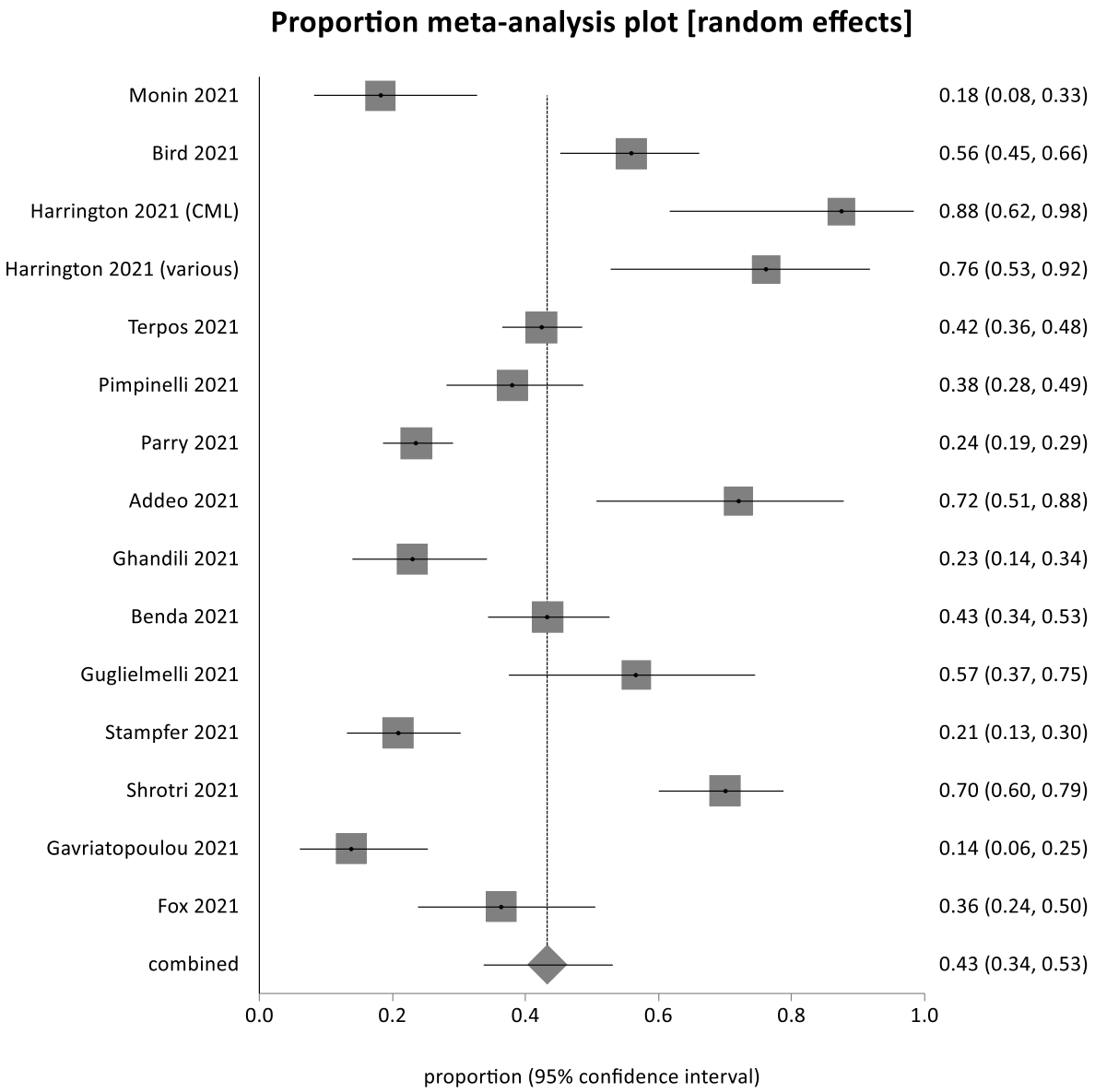
Bias indicators
Begg-Mazumdar: Kendall's -0.279, P = 0.015
Egger: bias = -3.30 (95% CI = -5.36 to -1.24), P = 0.002

Figure S4. Proportion of patients with solid malignancy seroconverting after the first vaccination



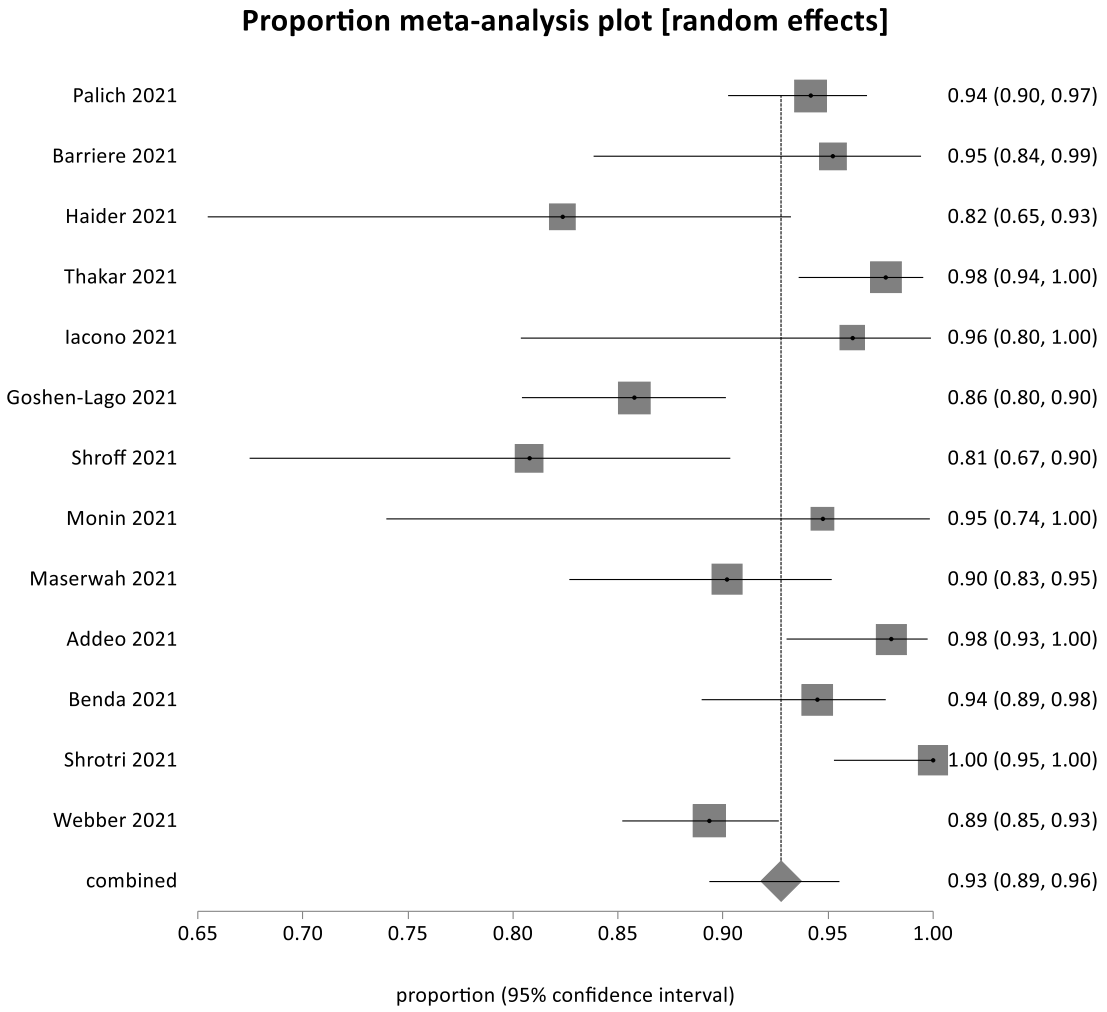
Non-combinability of studies
Cochran Q = 569.3 (df = 9) P < 0.0001
I^2 = 98.4% (95% CI = 98.1% to 98.6%)

Figure S5. Proportion of patients with hematological malignancy seroconverting after the first vaccination



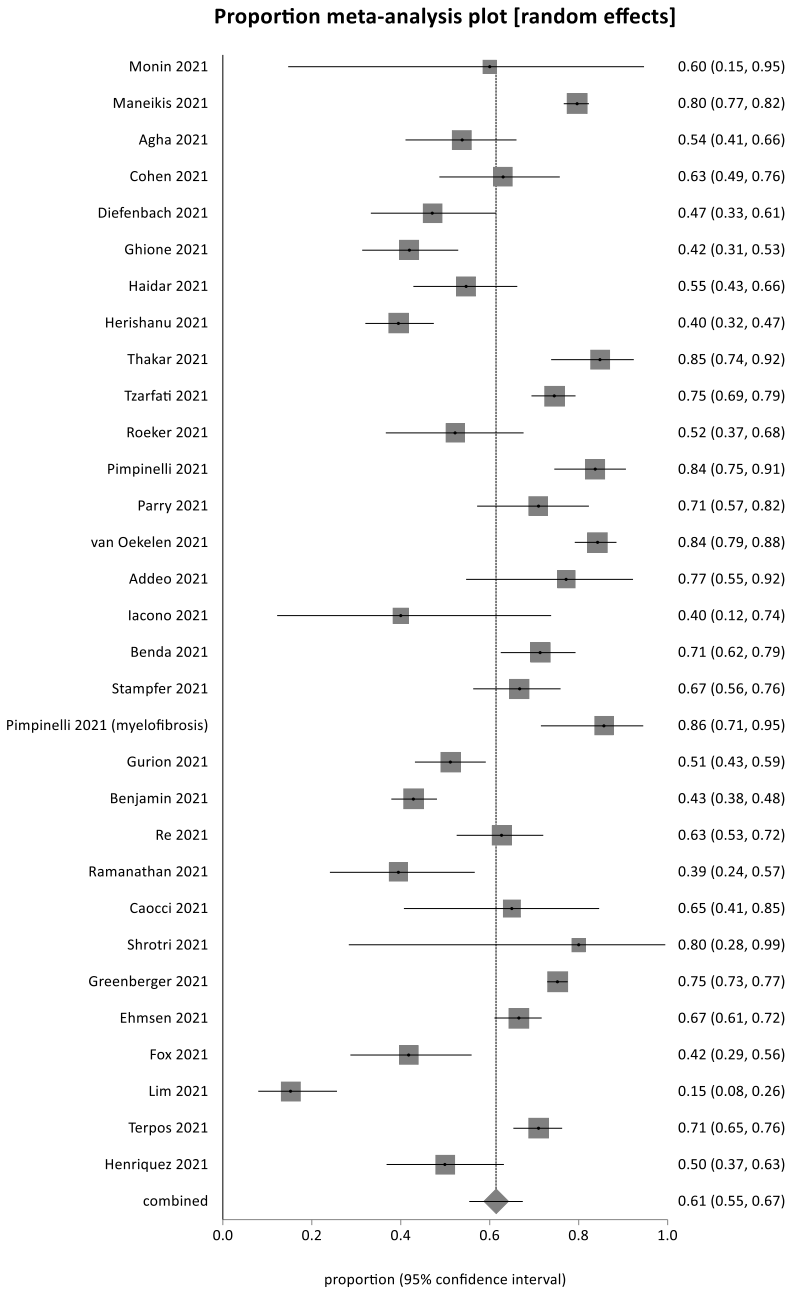
Non-combinability of studies
Cochran Q = 177.3 (df = 14) P < 0.0001
I^2 = 92.1% (95% CI = 89.2% to 93.9%)

Figure S6. Proportion of patients with solid malignancy seroconverting after the second vaccination



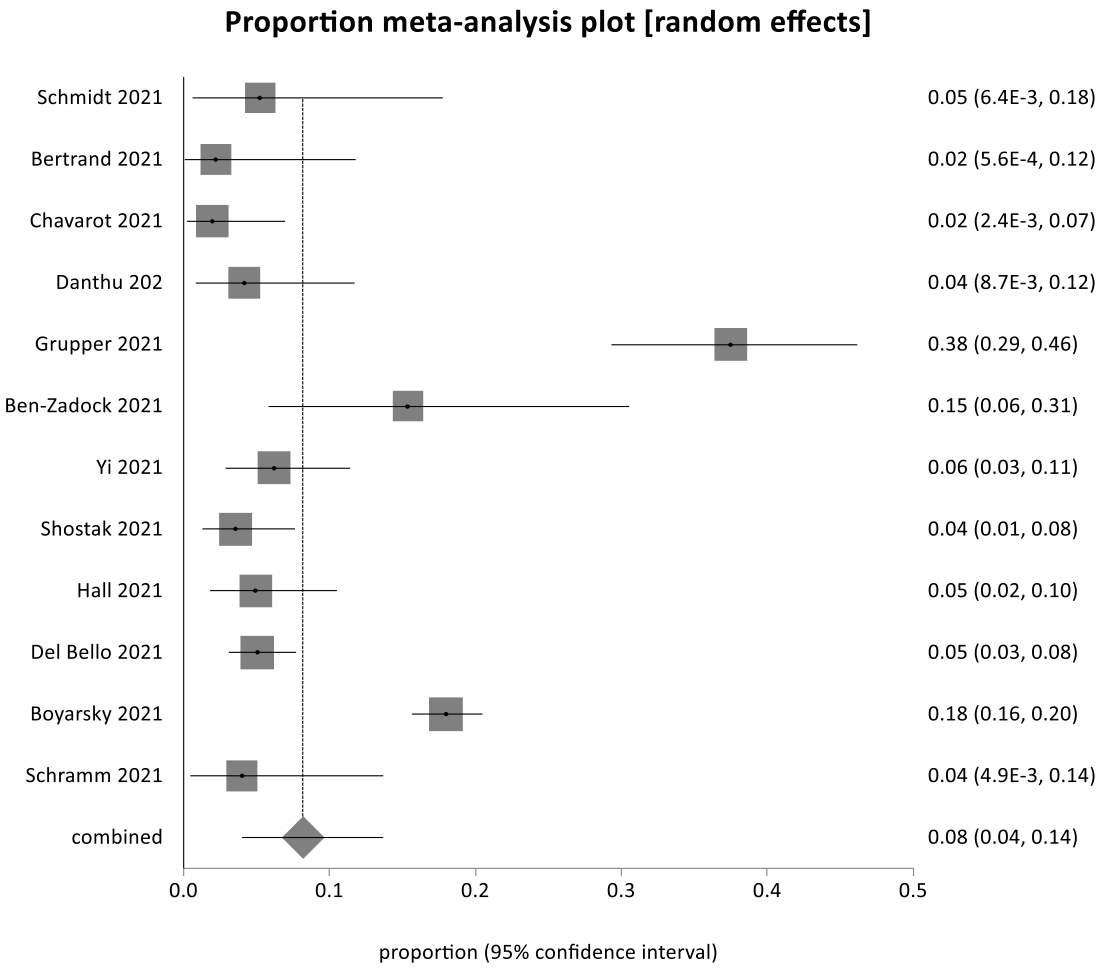
Non-combinability of studies
Cochran Q = 56.4 (df = 12) P < 0.0001
I^2 = 78.7% (95% CI = 61.8% to 86.2%)

Figure S7. Proportion of patients with hematological malignancy seroconverting after the second vaccination



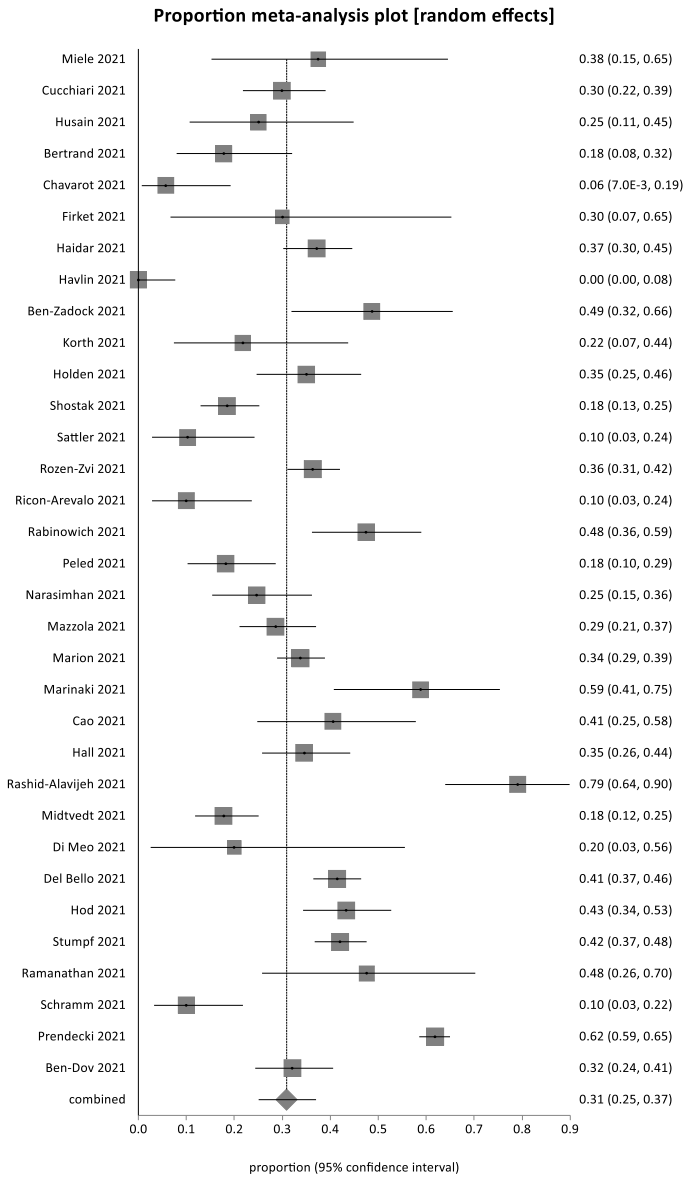
Non-combinability of studies
Cochran Q = 527.8 (df = 30) P < 0.0001
I^2 = 94.3% (95% CI = 93.2% to 95.2%)

Figure S8. Proportion of transplant patients seroconverting after the first vaccination



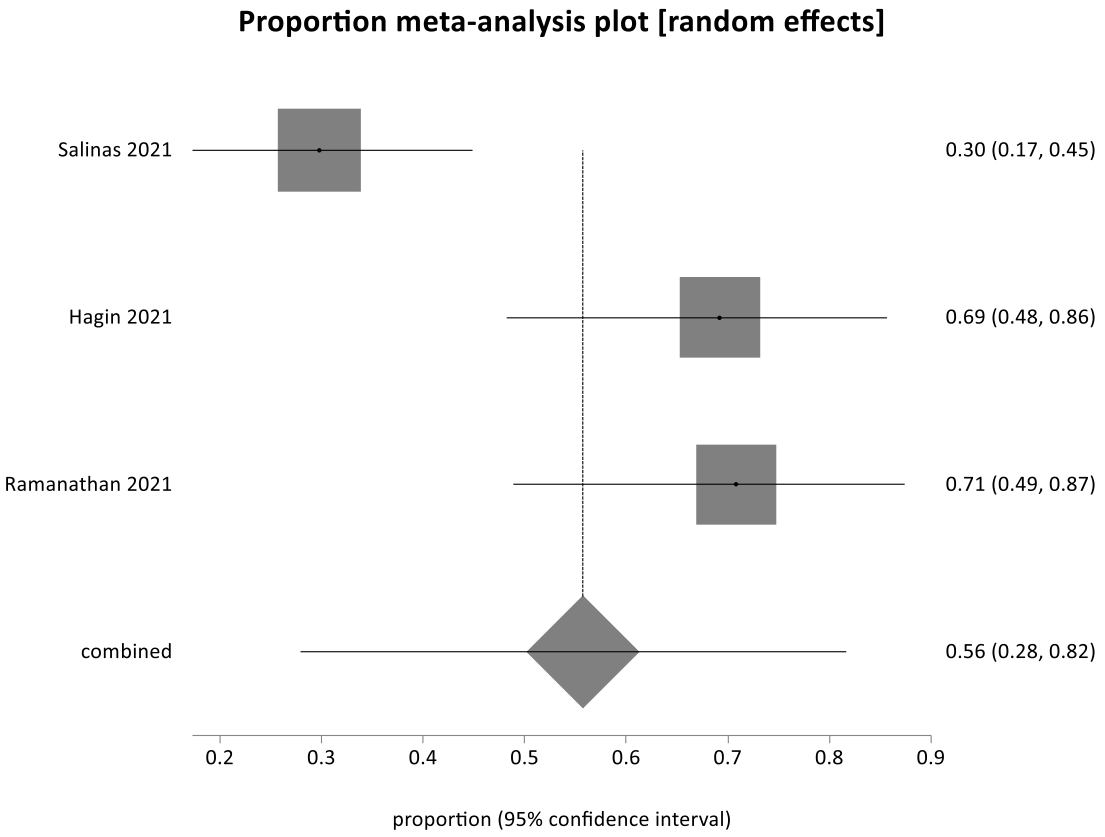
Non-combinability of studies
Cochran Q = 165.0 (df = 11) P < 0.0001
I^2 = 93.3% (95% CI = 90.7% to 94.9%)

Figure S9. Proportion of transplant patients seroconverting after the second vaccination



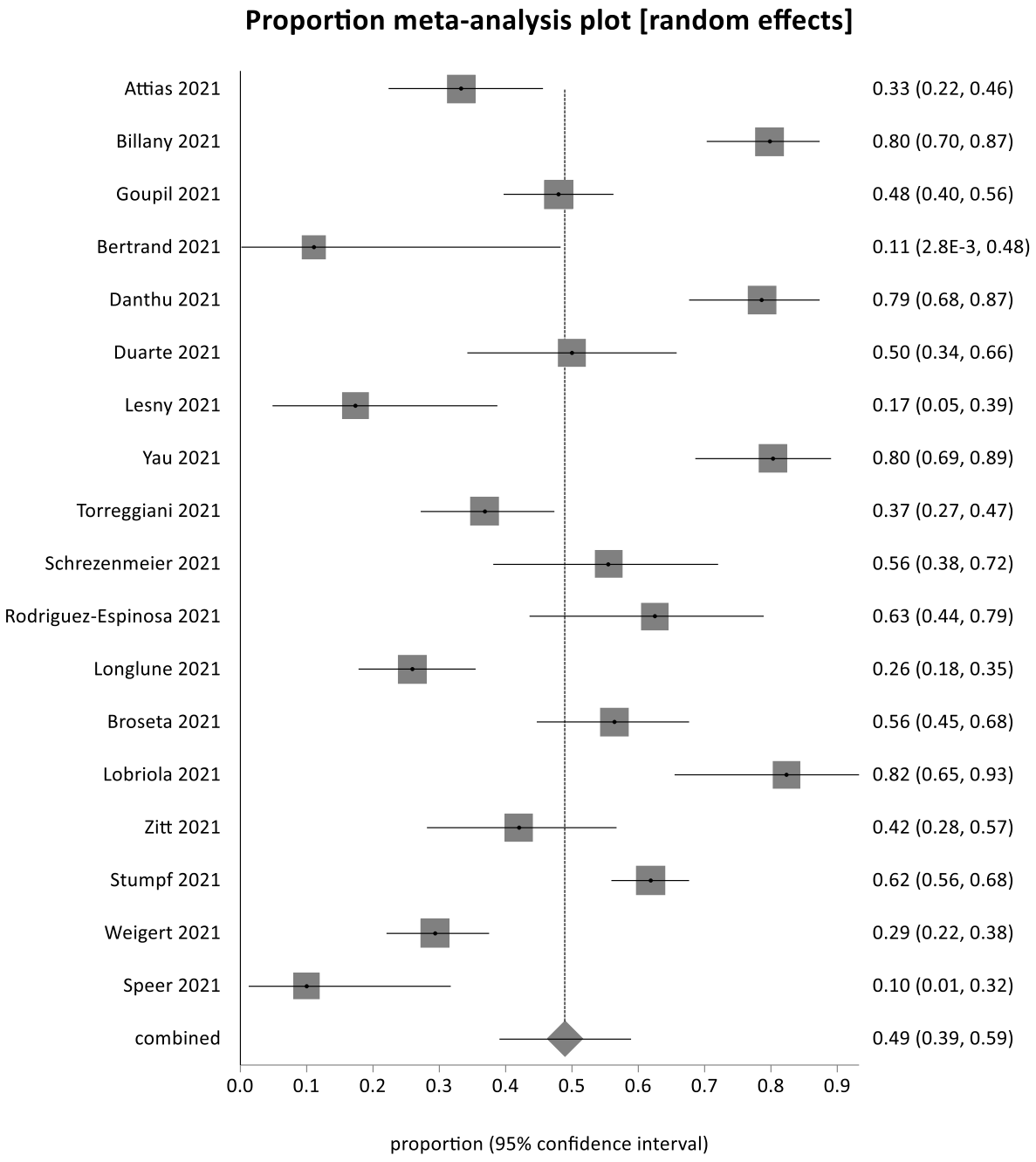
Non-combinability of studies
Cochran Q = 514.7 (df = 32) P < 0.0001
I^2 = 93.8% (95% CI = 92.6% to 94.7%)

Figure S10. Proportion of primary immune deficiency patients seroconverting after the second vaccination



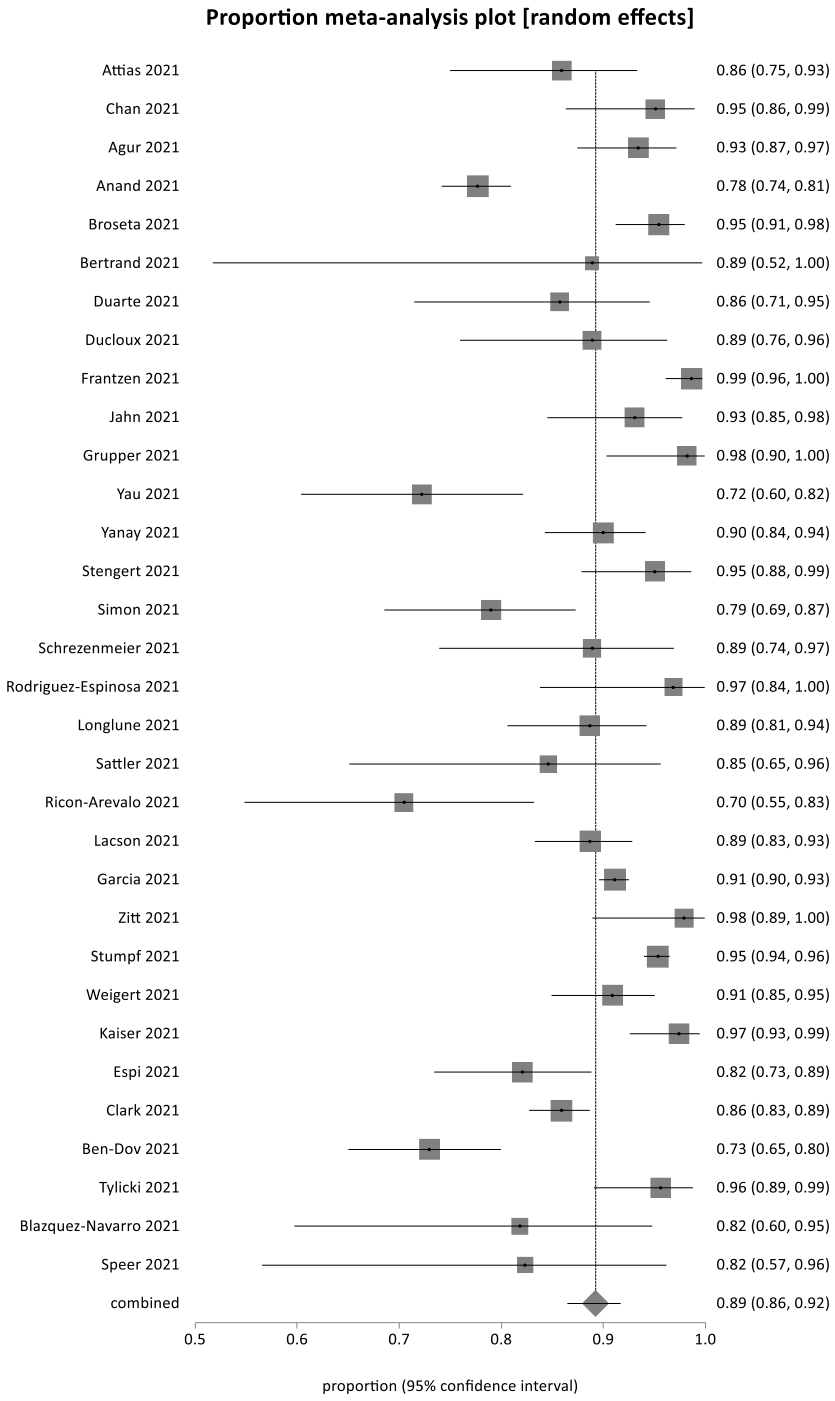
Non-combinability of studies
Cochran Q = 15.8 (df = 2) P = 0.0004
I^2 = 87.4% (95% CI = 47.3% to 94%)

Figure S11. Proportion of dialysis patients seroconverting after the first vaccination



Non-combinability of studies
Cochran Q = 225.6 (df = 17) P < 0.0001
I^2 = 92.5% (95% CI = 90.0% to 94.1%)

Figure S12. Proportion of dialysis patients seroconverting after the second vaccination



Non-combinability of studies
Cochran Q = 284.2 (df = 31) P < 0.0001
I^2 = 89.1% (95% CI = 86.1% to 91.2%)

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