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## Immunological and clinical efficacy of COVID-19 vaccines in immunocompromised populations: a systematic review

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30 **Abstract**

31 Background: Available data show that COVID-19 vaccines may be less effective in  
32 immunocompromised populations, who are at increased risk of severe COVID-19.

33 Objectives: We conducted a systematic review of literature to assess immunogenicity,  
34 efficacy, and effectiveness of COVID-19 vaccines in immunocompromised populations.

35 Methods: Data sources: We searched Medline and Embase databases. Study eligibility  
36 criteria, participants, interventions: We included studies of COVID-19 vaccines after  
37 complete vaccination in immunocompromised patients until 31 August, 2021. Studies with <  
38 10 patients, safety data only and case series of breakthrough infections were excluded.

39 Assessment of risk of bias: Risk of bias was assessed via the tool developed by the National  
40 Institutes of Health on interventional and observational studies. Methods of data synthesis:  
41 Immunogenicity was assessed through non-response rate defined as no anti-SARS-CoV-2  
42 spike protein antibodies, efficacy and effectiveness by the relative reduction in risk of SARS-  
43 CoV-2 infection or COVID-19. We collected factors associated with the risk of non-response.  
44 We presented collected data by immunosuppression type.

45 Results: We screened 5,917 results, included 162 studies. There were 157 on  
46 immunogenicity in 25,209 participants, including 7,835 cancer or haematological malignancy  
47 patients (31.1%), 6,302 patients on dialysis (25.0%), 5,974 solid organ transplant recipients  
48 (23.7%), and 4,680 immune-mediated disease patients (18.6%). Proportion of non-  
49 responders seemed higher among solid organ transplant recipients (range 18-100%),  
50 patients with haematological malignancy (range 14-61%), and lower in patients with cancer  
51 (range 2-36%) and patients on dialysis (range 2-30%). Risk factors for non-response included  
52 older age, use of corticosteroids, immunosuppressive or anti-CD20 agent. Ten studies

53 evaluated immunogenicity of an additional dose. Five studies evaluated vaccine efficacy or  
54 effectiveness: three on SARS-CoV-2 infection (range 71-81%), one on COVID-19-related  
55 hospitalization (62.9%), one had a too small sample size.

56 Conclusion: This systematic review highlights the risk of low immunogenicity of COVID-19  
57 vaccines in immunocompromised populations, especially solid organ transplant recipients  
58 and patients with haematological malignancy. Despite lack of vaccine effectiveness data,  
59 enhanced vaccine regimens may be necessary.

60 **Introduction**

61 A set of COVID-19 vaccines has been rapidly developed with high vaccine efficacy in phase 3  
62 studies. However, these large-scale pre-marketing studies provide little information on  
63 vaccine efficacy in immunocompromised populations, while current evidence shows an  
64 increased risk of severe COVID-19 in patients with cancer [1], solid organ transplant [2,3],  
65 end-stage renal disease [4,5], and rheumatic immune-mediated diseases on  
66 immunosuppressive treatment [6].

67 Available data with other vaccines indicate a lower vaccine immunogenicity and efficacy in  
68 immunocompromised patients, such as patients undergoing hemodialysis, solid organ  
69 transplant recipients [7,8], patients with cancer or haematological malignancy [9,10] and  
70 those with autoimmune inflammatory diseases [11], hence raising the concern of potentially  
71 decreased immunogenicity and effectiveness of COVID-19 vaccines.

72 Several studies have been published in the past few months on the immunogenicity of  
73 COVID-19 vaccines in different populations of immunocompromised subjects, leading some  
74 countries such as France, and more recently the United States, to recommend an additional  
75 dose of vaccine [12,13]. We aimed to summarize available evidence on vaccine  
76 immunogenicity and factors associated with non-response to vaccine, efficacy and  
77 effectiveness in these populations through a systematic review of literature.

78 **Methods**

79 *Objectives and outcomes of interest*

80 We conducted a systematic review of literature until 31 August, 2021. The main objective  
81 was to assess evidence on COVID-19 vaccine immunogenicity, efficacy and effectiveness in  
82 immunocompromised populations. The secondary objectives were to determine factors  
83 associated with lack of post-vaccine immunity or low post-vaccine antibody titres, elements  
84 of cellular response following vaccination and benefits of additional doses.

85 Outcomes of interest were vaccine efficacy assessed by the relative reduction in risk of  
86 COVID-19 in randomized placebo-controlled trials, vaccine effectiveness, assessed by the  
87 relative reduction in risk of SARS-CoV-2 infection in observational studies on RT-PCR-  
88 confirmed SARS-CoV-2 infections or in relative reduction in risk of SARS-CoV-2 related  
89 hospitalizations or death, and immunogenicity assessed by the rate of non-responders  
90 defined as no anti-SARS-CoV-2 spike protein antibodies (IgG, total antibodies if IgG  
91 unavailable) as per cut-off defined in each study. If only neutralisation assay data were  
92 available, we defined non-response as absence of neutralising antibodies as per cut-off  
93 defined in the study. Factors associated with lack of post-vaccine immunity or lower post-  
94 vaccine antibody titres, compared to the rest of the population of interest or to a control  
95 group (if any), were defined according to associations found in each study.

96 *Inclusion and exclusion criteria*

97 We included reports of COVID-19 vaccine immunogenicity, efficacy and effectiveness in any  
98 of the following populations: cancer, haematological malignancy, solid organ  
99 transplantation, allogenic stem cell transplantation, autoimmune systemic disease,  
100 autoimmune organ specific disease, inflammatory bowel disease, sarcoidosis,

101 autoinflammatory disease, multiple sclerosis, neuromyelitis optica spectrum disease, chronic  
102 kidney disease, HIV infection, congenital immunodeficiency, patients undergoing  
103 immunosuppressive medications, systemic corticosteroids, monoclonal antibodies. We  
104 grouped studies by type of immunosuppressed population.

105 We included studies of various designs and article types (including preprints given the  
106 rapidly evolving evidence in that field): interventional trials, observational studies, and  
107 original articles, comments, letters, case series. No language restrictions were imposed.

108 Exclusion criteria were reports of an incomplete vaccination schedule (i.e. only one dose for  
109 all available vaccines excepted Ad26.COVID-19 S Janssen vaccine), review or recommendation  
110 articles lacking original data, studies reporting only safety data, case reports, case series  
111 reporting fewer than 10 patients, and case series of breakthrough infections.

#### 112 *Search and data extraction strategies*

113 We searched the databases Medline through PubMed and Embase from inception until 31  
114 August, 2021. We used a series of key words and their corresponding Mesh terms for the  
115 Pubmed search and the same key words as Emtree terms for the Embase search. Full search  
116 strategies are available as supplementary appendix. One investigator (SG) screened titles  
117 and abstracts for eligibility. Two investigators (SG, LBLN) independently read the selected  
118 articles to assess eligibility and met to determine final eligibility. A third investigator (OL)  
119 split the case in case of persistent discrepancy. We screened grey literature (frequent  
120 consultation of core clinical journals' websites, abstracts of the congresses of international  
121 infectious diseases societies, advisory committee on immunization practices' presentations  
122 regarding COVID-19 vaccines in immunocompromised populations) and references lists of  
123 included reports for further studies. One investigator (SG) collected following data from all



124 selected reports: study type, study population, control group (if any), vaccine used,  
125 estimated vaccine efficacy or effectiveness, time from completion of vaccination to  
126 measurement of immunogenicity, methods for measurement of immunogenicity, cellular  
127 response indicators (if any), neutralisation indicators (if any), amount and rate of non-  
128 responders (to an additional dose of vaccine if any), factors associated with non-response or  
129 lower antibody titres (in multivariable analysis, if any, otherwise in univariable analysis). If  
130 studies did not report response status after completion of vaccination schedule for their  
131 entire study population, we only considered the subpopulations for whom those data were  
132 available.

133 We collected and synthesized data from studies using an Excel spreadsheet. We used  
134 STATA/IC 15.1 (College Station, Texas, USA) for further data synthesis and creation of graphs.

#### 135 *Risk of bias assessment*

136 We assessed risk of bias through the National Institutes of Health (NIH) quality assessment  
137 tools for controlled interventional studies and observational cohorts [14]. Two investigators  
138 (SG, LBLN) independently assessed risk of bias, discrepancy cases were first discussed  
139 between the investigators, then split by a third investigator (PL) in case of persistent  
140 discordance.

## 141 **Results**

142 We launched searches on 7 June, 2021, again on 21 June, 2021, and set up daily email alerts  
143 on both databases for subsequent days until 31 August, 2021. Searches retrieved 3,544  
144 results on Medline and 2,373 results on Embase, with 525 duplicates. After title and abstract  
145 screening, we retained 271 reports. After full text reading, grey literature and reference lists  
146 inspection, 162 studies were included from 170 reports (some reports detailed different  
147 timepoints of the same study [15–28] (**figure 1**).

148 Most studies were prone to some bias, 21 of them were estimated of good quality  
149 (**Supplementary tables 1-2**). Most frequent sources of bias were lack of definition of  
150 population from which participants were included, of sample size calculation, and of  
151 adjustment on potential confounding factors. The studies on vaccine efficacy or  
152 effectiveness were all considered of good or fair quality in the risk of bias assessment.

153 The vast majority of included studies evaluated vaccines developed by Pfizer (BNT162b2) or  
154 Moderna (mRNA-1273). Thirteen studies included patients who received the vaccine  
155 developed by Janssen (Ad26.COV2.S) [25–27,29–40], nine included patients vaccinated with  
156 the AstraZeneca vaccine (ChAdOx1) [41–49], three included patients receiving the  
157 CoronaVac vaccine (Sinovac Biotech) [50–52], and one randomized controlled trial evaluated  
158 the vaccine developed by Novavax (NVX-CoV2373) vaccine [53]. One study included patients  
159 receiving the BBV152-Covaxin (Bharat Biotech) vaccine [44] and one included patients  
160 receiving the BBIBP-CorV (Sinopharm) vaccine [54].

## 161 **Methods of measurement of post-vaccine immunity**

162 Most studies assessed anti-SARS-CoV-2 immunity through an immunoassay to detect  
163 antibodies targeted at the spike protein, including some targeting specifically the receptor-

164 binding domain (RBD) of the spike protein. Thirty studies reported neutralisation assay  
165 results in addition to anti-SARS-CoV-2 antibody assays [34,37,41,48,51,55–79]. Thirty-one  
166 studies provided data on cellular immunity [17,21,22,34,37,41,45,46,55–67,72,74–77,79–  
167 84].

## 168 **Immunogenicity data**

169 Most studies ( $n=157$ ) reported immunogenicity data amounting to 25,209 participants,  
170 mainly, cancer or haematological malignancy patients (7,835, 31.1%), patients on dialysis  
171 (6,302, 25.0%), solid organ transplant recipients (5,974, 23.7%) and immune-mediated  
172 disease patients (4,680, 18.6%). Eighty-three of those studies included a control population  
173 who also received the vaccine or recovering COVID-19 patients.

### 174 **Cancer and haematological malignancy patients**

175 Forty-three studies reported immunogenicity in patients with haematological malignancy  
176 ( $n=6,259$ , 79.9%) and cancer ( $n=1,480$ , 18.9%) (**supplementary table 3**)  
177 [30,33,35,42,43,49,52,59,60,70,71,76,83–113]. Twenty-three of these studies included a  
178 control population (overall  $n=1,931$ ) [30,33,42,43,60,71,76,85–89,91,92,96,98,104,106–  
179 108,110–112] in which all but fifteen participants developed post-vaccine antibodies  
180 [43,76,88,106,110,112]. Non-response rates among cancer and haematological malignancy  
181 populations ranged from 2% to 61% [30,89,90].

182 Malignancy-specific treatments were repeatedly associated with non-responder status,  
183 whether taken as a whole or specific treatments such as cytotoxic chemotherapy, Bruton  
184 tyrosine kinase inhibitors, anti-CD20 treatment or Daratumumab-based regimens  
185 [30,33,35,42,43,70,71,76,83,85,86,89–92,95,100,102–106,110,112,113] (**supplementary**  
186 **table 3**).

187

### **Patients with haematological malignancy**

188 Non-response rates in patients with haematological malignancy ranged from 14% to 61%  
189 [89,101] (**figure 2A**). Patients with chronic lymphocytic leukemia seemed at high risk of non-  
190 response with rates ranging from 28% to 77% [43,70,83,86,89,93,95,103,107,109]. Patients  
191 with multiple myeloma were at lower risk of non-response: rates ranged from 5% to 34%  
192 [86,88,92–94,103,104,108]. Patients with myeloproliferative neoplasms (chronic myeloid  
193 leukemia and Philadelphia-negative myeloproliferative neoplasms) displayed lower rates of  
194 non-response, ranging from 12% to 20% [86,92,101,113]. In patients with lymphoma, non-  
195 response rates ranged from 30 to 58%, with the highest rate reported by Ghione *et al.* in  
196 patients largely recently treated (52/86) with B-cell depleting treatment  
197 [33,83,86,93,94,100,107]. Patients with hematopoietic stem cell transplantation (HSCT)  
198 displayed non-response rates ranging from 14% to 31% in allogenic HSCT [35,84,102], and  
199 showed maintained response rates in Tzarfati *et al.* (autologous HSCT) and antibody titres in  
200 Maneikis *et al.* (allogenic and autologous HSCT), while they were at increased risk of non-  
201 response in Thakkar *et al.* (mostly autologous HSCT) [30,85,86]. Only Dhakal *et al.* provided a  
202 non-response rate for patients with autologous HSCT which was estimated at 40% (18/45)  
203 [35].

204 Five studies provided results on cellular immunity, two using an enzyme-linked immunospot  
205 (ELISpot) assay [76,84], one with a Fluorospot assay [60] and one with an Interferon-gamma  
206 release assay (IGRA) assay [83]. Non-response rates were usually higher in cellular than in  
207 antibody response [60,83,84] except in one study [76].

208

### **Patients with cancer**

209 Non-response rates in patients with cancer ranged from 2% to 36% [30,52,83,90] (**figure 2B**).  
210 Two large studies found some of the higher rates: Shroff *et al.* (non-response rate 20%,  
211 10/51) provided binary data on seroconversion only with a neutralisation assay, and Karacin  
212 *et al.* (non-response rate 36%, 17/47) included only patients undergoing active specific anti-  
213 cancer therapy which possibly contributed to an increased risk of non-response [52,59].

214 As Shroff *et al.*, Monin *et al.* tested for neutralising antibodies: they found neutralising  
215 antibodies against the wild type and the B.1.1.7 (alpha) variant spike protein in all  
216 participants who produced detectable post-vaccine anti-S IgG [59,60].

217 Both studies, along with Ehmsen *et al.*, reported data on cellular immunity [59,60,83]. In  
218 patients without post-vaccine neutralising antibodies, Shroff *et al.* found a non-response  
219 rate of 60% (6/10) with an ELISpot assay [59]. Non-response rates in Monin *et al.* were 13%  
220 (2/16) in patients with solid cancer and 25% (1/4) of patients with haematological  
221 malignancy with a fluorospot assay [60]. As in patients with haematological malignancy,  
222 Ehmsen *et al.* found a higher non-response rate in cellular (tested via an IGRA assay) than in  
223 antibody response: 54% (109/201) vs 2% (4/201) respectively [83].

#### 224 **Patients on dialysis**

225 Thirty-three studies reported immunogenicity in 6,302 patients on dialysis (**supplementary**  
226 **table 4**) [15–17,21,31,38,44,62–64,74,78,80,114–134]. Non-responder rates ranged from 2%  
227 to 30% (**figure 3**) [125,126]. Four studies were rated “good” in the risk of bias assessment:  
228 they all found low non-response rates ranging from 2% to 5% [21,125,130,133]. Simon *et al.*  
229 found a high non-response rate at 27% (22/80), at least partially explained by the choice of a  
230 higher cut-off (29 U/mL) than the one provided by the manufacturer of the serological assay  
231 [118,135]. Fifteen studies included a control group (n=779 overall), in which all but nine

232 participants developed post-vaccine antibodies  
233 [17,21,63,74,78,80,116,118,120,121,124,126,128,131,134]. Speer *et al.* performed  
234 neutralisation assays which showed the same rate of non-response as the anti-S antibody  
235 assay: 3/17 (18%) [128]. In a further study, Speer *et al.* measured neutralising antibodies in  
236 participants with seroconversion: all showed neutralising antibodies against the B.1.1.7  
237 strain (alpha variant), while only 15/24 had neutralising antibodies against the B.1.351 strain  
238 (beta variant) [78]. Seven studies reported elements of cellular response, using either a flow  
239 cytometry technique [21,62,63,80], an ELISpot assay [64] or an IGRA assay [17,21,74]. Non-  
240 response rates were lower in T-cell response than antibody response in both Bertrand *et al.*  
241 and Sattler *et al.* [62,63]. Four studies found opposite results with higher non-response rates  
242 in cellular than in antibody response [17,21,64,74].  
243 Treatment with immunosuppressive therapies was associated with non-responder status or  
244 lower antibody titres in several studies (**supplementary table 4**) [62,64,129], as well as older  
245 age [17,31,117,118,121,122,124,133] or a lower lymphocyte count [64,124].

#### 246 **Solid organ transplant recipients**

247 Forty-seven studies described immunogenicity across various solid organ transplant  
248 populations (n=5,974), mostly in kidney transplant recipients (n=3,534, 59.2%)  
249 (**supplementary table 5**) [18,20–26,29,34,40,56–  
250 58,62,63,65,66,69,72,73,75,77,79,81,120,126,136–160]. Twenty-four of those studies  
251 included a control group representing overall 1,399 participants  
252 [21,34,57,63,66,69,72,73,75,79,120,126,142–146,148,149,151,152,154–156], among whom  
253 only 12 did not mount a post-vaccine antibody immunity [21,69,145,155]. Non-responder  
254 rates ranged from 18% to 100% [40,149,152] (**figure 4**): 35%-98% in kidney transplant

255 recipients, 19-63% in liver transplant recipients, 25-88% in heart transplant recipients and  
256 59-100% in lung transplant recipients (for studies with subgroup size  $n \geq 10$ ) (**figure 5**).

257 Eleven studies reported results of neutralisation assays [34,63,66,69,72,77,79,126,145].  
258 Non-response rates were close to those in anti-S assays in most studies [63,72,77,126], while  
259 several studies performed the assay only in anti-spike antibody positive participants who  
260 mostly tested positive in neutralisation assays [69,79,145].

261 Fourteen studies included data on T-cell immunity, assessed through an ELISpot assay [56–  
262 58,62,65,75,81], flow cytometry [21,34,63,72,79], or an IGRA assay [21,66]. Most studies  
263 found lower non-response rates in cellular than in antibody response [56–  
264 58,62,63,72,79,81], while two studies found higher non-response rates in cellular than in  
265 antibody response [21,65].

266 Solid organ transplant-specific treatments (calcineurin inhibitors, antimetabolites,  
267 corticosteroids) were often associated with a higher non-response rate or lower antibody  
268 titres [20,21,24,40,56,62,65,69,72,75,81,136,138–142,144,145,148,154–157,159,160]  
269 (**supplementary table 5**). Older age and lower estimated glomerular filtration rate were  
270 repeatedly associated with a non-responder status [21,24,79,120,138,142,144,155]. We  
271 found conflicting results regarding the impact of time since transplantation on vaccine  
272 response: seven studies found higher non-response rates or lower antibody titres in patients  
273 with recent transplantation, Rozen-Zvi *et al.* found a longer time from transplantation was  
274 associated with lower antibody titres [21,62,79,138,139,141,143,155,160].

## 275 **Inflammatory immune-mediated diseases**

276 Thirty-one studies reported immunogenicity in 4,680 patients with inflammatory immune-  
277 mediated diseases (**supplementary table 6**) [27,28,32,36,37,39,45–47,50,51,54,55,82,161–

278 178]. Main represented groups included rheumatoid arthritis (n=665), inflammatory bowel  
279 diseases (n=476) and multiple sclerosis (n=231). Twenty of those studies had a control group  
280 [32,37,45–47,50,51,55,161–164,166,167,169,171,172,174,177,178] (n = 1,609), among  
281 which 16 participants failed to mount a post-vaccine antibody response  
282 [47,50,51,55,163,164].

283 Non-response rates ranged from 0% to 63% (**figure 6**) [36,39,55,168,171,172,177]. Among  
284 the studies with the highest non-response rates, Mrak *et al.* included only patients on  
285 rituximab, Connolly *et al.* included 48 participants with ANCA-associated vasculitis, of whom  
286 44 received rituximab, and Achiron *et al.* and Guerrieri *et al.* found high rates (respectively  
287 47% and 50%) in patients with multiple sclerosis (MS) [164,168]. Six studies tested  
288 participants' sera with neutralisation assays [32,37,51,163,172,174], one tested  
289 neutralisation on a SARS-CoV-2 spike protein bearing the N501Y mutation (present in the  
290 alpha variant) [32]. Two studies provided non-response rates which were either the same as  
291 with anti-S IgG assay (0%, 0/26 [172]) or higher (44%, 375/859 vs 30%, 245/859 with the  
292 anti-S assay [51]).

293 Six studies included elements of cellular response, using a flow cytometry technique [46,55],  
294 an ELISpot assay [37,45,178] or an IGRA assay [82]. Haberman *et al.* found activated CD8+ T-  
295 cells in all 24 participants who were not receiving methotrexate but in none of the 18  
296 patients who were receiving methotrexate [55]. Prendecki *et al.* and Mrak *et al.* found lower  
297 non-response rates in cellular than in antibody response, while Benucci *et al.* found  
298 detectable T-cell response in four patients with no antibodies or low titres [45,82,178].

299 Specific treatments of the inflammatory disease negatively impacted post-vaccine response:  
300 B-cell depleting agents [28,50,161–165,169,175], methotrexate and other disease-modifying



301 anti-rheumatic drugs (DMARDs) or corticosteroids [28,50,51,55,161–163,176]. When  
302 analysed, impact of TNF inhibitors varied across studies: while some found an association  
303 with a lower risk of non-response or no impact on response or antibody titres  
304 [28,46,161,163], two studies found they were associated with absence of seroconversion or  
305 low antibody titres [51,171].

### 306 **Other immunosuppressed populations**

307 Five studies conducted in people living with HIV found low non-response rates ranging from  
308 0 to 4% [48,68,179] (among those, two studies were estimated of good quality in the risk of  
309 bias assessment [48,68]) or comparable antibody titres compared to an HIV-negative  
310 population [41,67].

311 Two studies by Hagin *et al.* and Abo-Helo *et al.* reported results of immunogenicity of the  
312 BNT162b2 vaccine in patients inborn errors of immunity (mostly common variable  
313 immunodeficiency): non-response rates were respectively 23% (6/26) and 27% (4/15)  
314 [61,180].

315 Lustig *et al.* reported immunogenicity data in 2,607 healthcare workers who received  
316 BNT162b2, among whom 74 with an autoimmune disease and 12 with another  
317 immunosuppression were evaluated following the second dose [181]. Immunosuppression,  
318 but not autoimmune diseases, was associated with lower antibody titres. Kageyama *et al.*  
319 found a non-response rate of 4% (1/23) in healthcare workers who received corticosteroids  
320 [182].

### 321 **Effect of an additional dose of vaccine**

322 Ten studies reported the effect of an additional dose following a complete vaccination  
323 [16,19,22,23,25,26,75,77,129,153,157]. Seven were conducted in solid organ transplant  
324 recipients [22,23,25,26,75,77,153,157] (**supplementary table 5**): non-response rates  
325 following the additional dose in the initially non-responders ranged from 51 to 68% [75,153].  
326 Hall *et al.* conducted a randomized placebo-controlled trial (the only study rated “good” in  
327 the risk of bias assessment among those studying an additional dose), testing a third dose of  
328 the Moderna vaccine in 117 solid organ transplant recipients, and showed a lower non-  
329 response rate in the vaccine arm (45%, 27/60) than in the placebo arm (82%, 47/57) [77].  
330 Alejo *et al.* continued the study by Werbel *et al.* and offered a fourth dose of vaccine to 18  
331 patients of whom 50% (3/6) of the non-responders after the third dose showed positive  
332 antibody testing after the fourth dose [25,26]. Three studies were conducted in patients  
333 with end-stage renal disease [16,19,129]: non-response rates following the additional dose  
334 among the initially non-responders ranged from 50 to 60% (**supplementary table 4**).

### 335 **Effect of vaccine type**

336 Immunogenicity varied across vaccine type: the Pfizer [21,38,39,103,130,159] and Janssen  
337 vaccines [38,39] were repeatedly associated with non-response status or lower antibody  
338 titres compared to the Moderna vaccine. Two studies found higher odds of non-response  
339 when vaccinated with the Janssen vaccine compared to the two mRNA vaccines [27,40].

### 340 **Vaccine efficacy and effectiveness data**

341 Five studies reported data in immunosuppressed populations [53,183–186]. A randomized  
342 controlled trial of the Novavax vaccine against the B.1.351 (beta) variant reported outcomes  
343 in a subgroup of 148 HIV-positive participants who were seronegative for SARS-CoV-2 at  
344 baseline. Efficacy could not be estimated in the group of people living with HIV: only 6

345 events occurred in this subgroup (4 in the 76 participants in the vaccine group and 2 in the  
346 72 participants in the placebo group) [53]. Nonetheless, vaccine efficacy estimates were  
347 lower when including participants living with HIV (efficacy: 49.4%, CI 95%: [6.1-72.8]) than  
348 when analysis was restricted to HIV-negative participants (efficacy: 60.1%, CI 95%: [19.9-  
349 80.1]). Other phase 3 randomized controlled trials did not include immunosuppressed  
350 patients or did not provide subgroup analysis results [187–190]. Three observational  
351 retrospective studies estimated effectiveness on RT-PCR-proven SARS-CoV-2 infection in  
352 immunocompromised patients: a study in patients with inflammatory bowel diseases  
353 reported an 80.4% vaccine effectiveness of mRNA vaccines [184], an Israeli cohort included  
354 patients with immunosuppression (no further details) with a reported effectiveness of 71%  
355 (CI 95%: 37%-87%), notably lower than across the entire study population (90%, CI 95%: 79-  
356 95%) [183], and a study in solid organ transplant recipients found an incidence rate ratio of  
357 0.19 (CI 95%: 0.049-0.503) [186]. One study evaluated effectiveness on COVID-19-related  
358 hospitalizations in a test-negative design and found an effectiveness of 62.9% (CI 95%: 20.8-  
359 82.6%) in an immunocompromised population (no further details), lower than across the  
360 non-immunocompromised population (91.3%, CI 95%: 85.6-94.8%) [185].

361

362 **Discussion**

363 This review is the first to report available data on COVID 19 vaccination in different  
364 populations of immunocompromised patients. It highlights lower immunogenicity of COVID-  
365 19 vaccines in these patients than estimated in most previous clinical studies conducted in  
366 healthy volunteers [191–193]. Non-response rate varies widely and is higher in solid organ  
367 transplant recipients (especially lung and renal transplant recipients), patients with  
368 haematological malignancy (most of all patients with chronic lymphocytic leukemia), and  
369 lower in patients with cancer, patients on dialysis, and with varying levels across different  
370 immune-mediated diseases (seemingly higher in patients with MS), possibly due to  
371 differences in therapeutics. These variations are consistent with findings in other vaccines  
372 (influenza, pneumococcal and hepatitis B vaccines) among solid organ transplant recipients  
373 [194,195], patients with haematological malignancies [196,197], while patients on dialysis  
374 often display satisfying immunogenicity [198] or higher than solid organ transplant  
375 recipients [199]. Only a few studies provided information on cellular immunity and  
376 neutralisation assays. While some seemed to indicate a better cellular response than  
377 humoral antibody response [45,56–58,62,63,72,76,79,81], others found opposite results  
378 [17,21,60,64,65,74,76,83,84]. Lack of standardization of assays to detect T-cell immunity and  
379 various performances across different techniques (flow cytometry or ELISpot/fluorospot)  
380 may partly explain these discrepancies [200]. Further data on T-cell-mediated immunity are  
381 needed to determine to which extent post-vaccine immunity is compromised.

382 The majority of included studies involved mRNA-based vaccines. This is the consequence of  
383 the early availability of those vaccines, with data suggesting high immunogenicity in healthy  
384 volunteers and elderly, of particular interest in immunocompromised patients who are at

385 high risk of severe COVID-19 [191]. As mRNA vaccines are used for the first time, those are  
386 the first data we have on mRNA vaccines in immunocompromised populations. We only  
387 included studies on full vaccination schedules, thus data on ChAdOx1 nCoV-19 are still  
388 scarce, given the extended interval between the two doses implemented in some national  
389 vaccination campaigns [201]. Immunogenicity data suggesting higher immunogenicity of  
390 mRNA-based vaccines (especially the Moderna vaccine) compared to adenovirus-based  
391 vaccines warrant further investigation [27,30,38–40,170].

392 Risk factors for non-response status often included older age, which is consistent with data  
393 provided by phase 1 and 2 studies of COVID-19 vaccines [191,192], as well as in other  
394 vaccines such as influenza, pneumococcal and hepatitis B vaccines [202–205].

395 Immunosuppressive therapy, biological agents, especially B-cell depleting agents, often  
396 negatively impact immune responses to COVID-19 vaccines. These reports are consistent  
397 with immune response to other vaccines in populations receiving such treatments:  
398 mycophenolate [194], anti-CD20 agents (in a rheumatological indication [206,207],  
399 haematological malignancy [208,209] or multiple sclerosis [210]), methotrexate [211], while  
400 TNF inhibitors variously affect immunogenicity [211,212].

401 This systematic review of literature highlights currently missing data. We identified only 5  
402 articles on vaccine efficacy or effectiveness in immunosuppressed populations. Estimates of  
403 effectiveness appear lower than in the general population [183,213,214], which is consistent  
404 with the findings of this review regarding a diminished immunogenicity and reports of more  
405 breakthrough infections observed in these populations [215–217]. Data on variants of  
406 concern include the dedicated randomized controlled trial [53] and the study by Chodick *et*  
407 *al.* which took place during periods of high local prevalence of the alpha variant [183].

408 However, data on the delta variant are still missing, and studies in the general population  
409 suggest a reduced effectiveness against SARS-CoV-2 infection (but not against severe forms)  
410 with this variant [218,219]. No study has yet reported effectiveness nor efficacy of an  
411 additional dose of vaccine in immunocompromised populations. Further studies with longer  
412 follow-up will help determine long-term immunogenicity. Literature data are still scarce if  
413 existent in many immunocompromised populations, including patients with inborn errors of  
414 immunity, allogenic stem cell transplantation, and people living with HIV. A search of the  
415 ClinicalTrials.gov database on 31 August, 2021, revealed two ongoing randomized controlled  
416 trials in immunocompromised populations: one comparing the Moderna and Pfizer vaccines  
417 in solid organ transplant recipients and people living with HIV, and one in patients with  
418 chronic kidney disease and dialysis comparing the Moderna and Pfizer vaccines as third dose  
419 after two doses of mRNA vaccines. Other phase II or phase III studies evaluating currently  
420 not approved COVID-19 vaccines include people living with HIV.

421 This review has certain limitations. The included studies assessed post-vaccine antibody  
422 response through various anti-Spike protein assays, performed at different timepoints.  
423 Heterogeneity in populations and methods used to assess immunogenicity and frequent lack  
424 of details on included populations make it difficult to perform meta-analysis with currently  
425 available data, which is why we chose not to do so. Most included studies were  
426 observational with a small sample size, thus permitting little adjustment on confounding. We  
427 could not perform additional analyses of factors associated with non-response as individual  
428 data were mostly unavailable, thus we reported those as mentioned by the authors. Large  
429 studies with standardized assays allowing comparisons are needed [220]. Nonetheless, this  
430 review provides a comprehensive understanding of the current evidence to help decision-  
431 making regarding vaccination strategies in immunocompromised patients.

432 Targeted strategies might prove interesting in those populations, such as additional doses  
433 (currently recommended in France [12]), as suggested by some data presented in this review  
434 [16,24,26,129]. Other approaches such as heterologous vaccination [221,222], increased  
435 doses (as in hepatitis B vaccine [223,224]) might enhance immunogenicity, while  
436 prophylactic administration of monoclonal antibodies [225] or “cocooning” vaccination of  
437 relatives and healthcare workers offer potential alternatives [226].

438 Overall, this systematic review highlights a diminished immunogenicity of COVID-19  
439 vaccines, including mRNA-based vaccines, in immunocompromised populations, with varying  
440 levels across different types of immunodepression. Alternative strategies are necessary to  
441 provide sufficient protection to these patients.

442 **Registration and protocol**

443 No protocol was prepared for this review. The review was not registered.

444 **Declaration of competing interests**

445 Dr Loubet reports personal fees from Pfizer, non-financial support from Sanofi Pasteur, non-  
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451 Pasteur, support for attending meetings and/or travel from Pfizer, Janssen, Sanofi Pasteur  
452 and participation on a data safety monitoring board or advisory board for Sanofi Pasteur and  
453 MSD, all unrelated to the submitted work.

454 **Data availability**

455 Extracted data are made available almost entirely in the review (including supplementary  
456 tables). Remaining data regarding the serological assays are made available on request.

457 **Authors' contribution**

458 SG, LBLN, PL and OL designed the review. SG screened titles and abstract for eligibility. SG  
459 and LBLN independently assessed articles for inclusion. OL split the case in case of  
460 discrepancy. SG and LBLN independently assessed risk of bias of included studies. PL split the  
461 case in case of discrepancy. SG extracted data from the included studies. SG and LBLN jointly  
462 verified figures extracted from the studies. SG, LBLN, PL and OL drafted the first versions of



463 the manuscript. ET, XdL and LW critically reviewed the manuscript. All authors received and  
464 approved the current version of the manuscript.

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## Legends for figures

### Figure 1: Flow chart of study selection

### Figure 2: Rates of non-response in patients with haematological malignancy (A) and cancer (B).

Grey dashes represent the 95% confidence intervals. The studies are ordered by population size. Only studies with subgroup size  $n \geq 10$  are represented.

**Figure 3: Rates of non-response in patients on dialysis.** We reported the latest endpoint within 30 days following vaccine completion if several endpoints were available. We reported the outcome following second dose in the studies reporting post-vaccine immunity following an additional dose. The studies are ordered by population size. Grey dashes represent the 95% confidence intervals. Only studies with subgroup size  $n \geq 10$  are represented.

Speer\*: Speer C, Göth D, Benning L, Buylaert M, Schaier M, Grenz J, et al. Early Humoral Responses of Hemodialysis Patients after COVID-19 Vaccination with BNT162b2. *Clin J Am Soc Nephrol CJASN* 2021. <https://doi.org/10.2215/CJN.03700321>.

**Figure 4: Rates of non-response in solid organ transplant recipients.** We reported the latest endpoint within 30 days following vaccine completion if several endpoints were available. We reported the outcome following second dose in the studies reporting post-vaccine immunity following an additional dose. Grey dashes represent the 95% confidence intervals. The studies are ordered by population size.

Hall\*: Hall VG, Ferreira VH, Ierullo M, Ku T, Marinelli T, Majchrzak-Kita B, et al. Humoral and cellular immune response and safety of two-dose SARS-CoV-2 mRNA-1273 vaccine in solid organ transplant recipients. *Am J Transplant Off J Am Soc Transplant Am Soc Transpl Surg* 2021. <https://doi.org/10.1111/ajt.16766>.

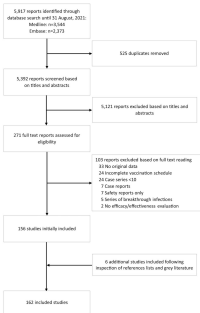
Boyarsky\*: Boyarsky BJ, Chiang TP-Y, Ou MT, Werbel WA, Massie AB, Segev DL, et al. Antibody Response to the Janssen COVID-19 Vaccine in Solid Organ Transplant Recipients. *Transplantation* 2021. <https://doi.org/10.1097/TP.0000000000003850>.

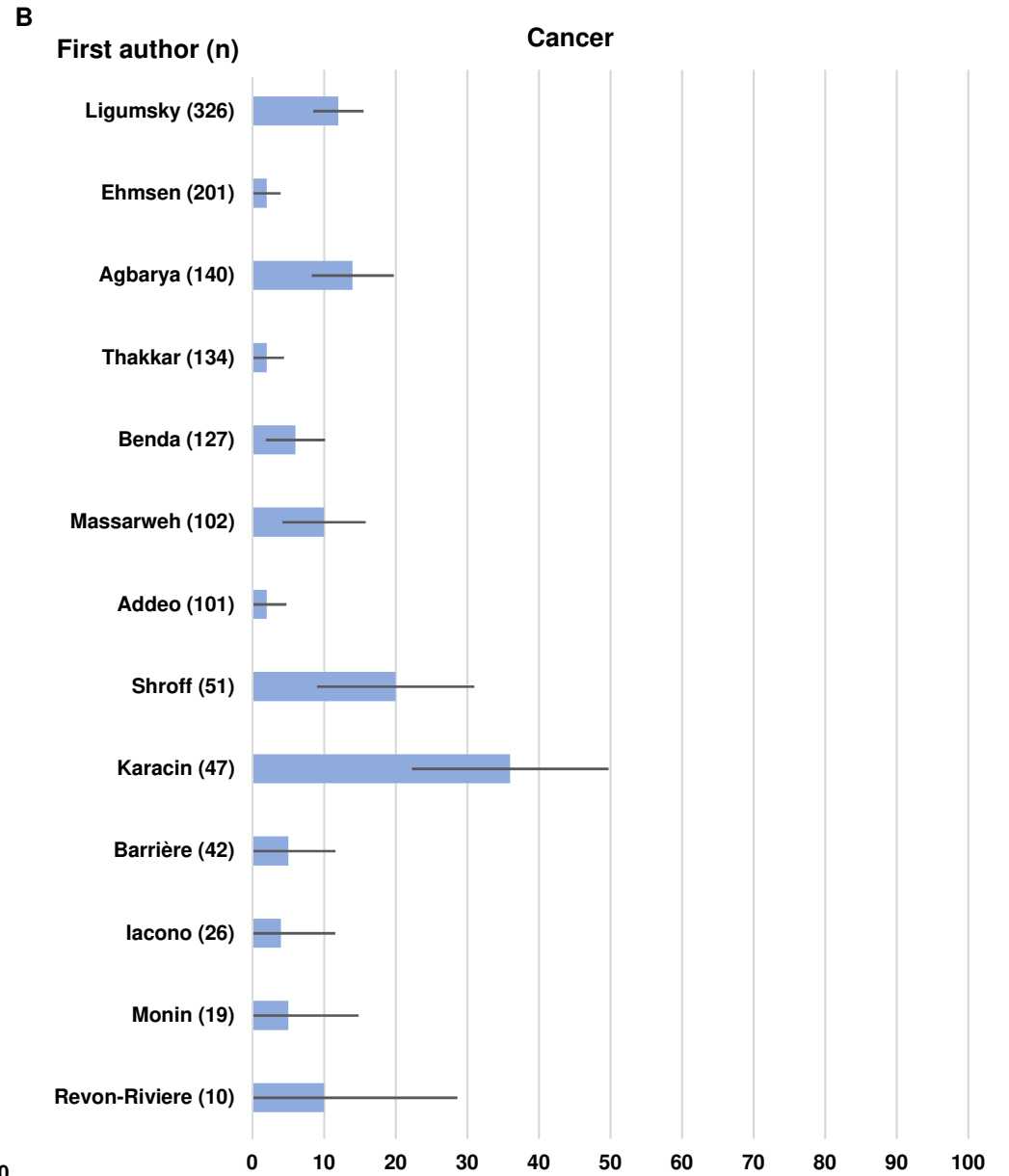
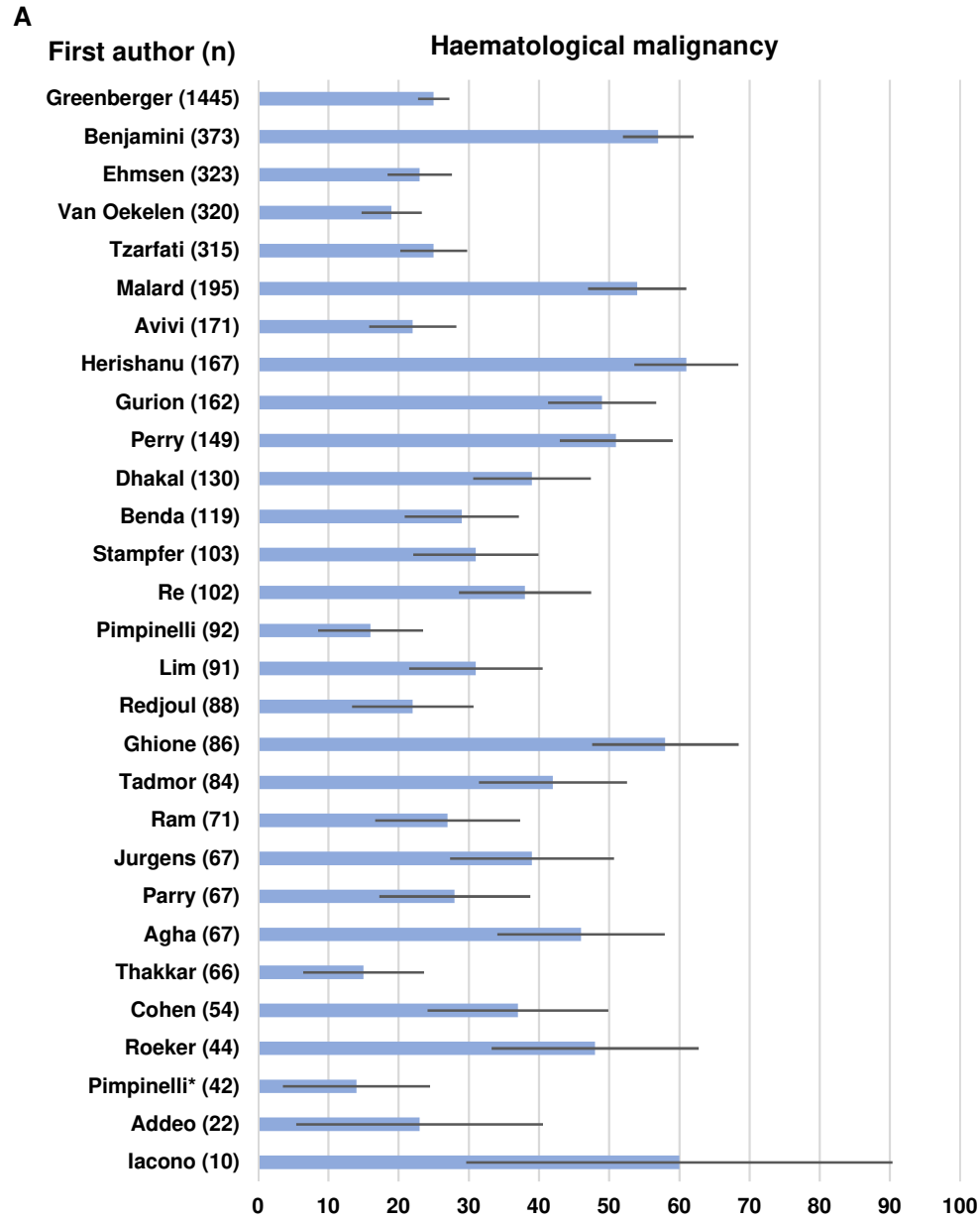
### Figure 5: Rates of non-response in solid organ transplant recipients: kidney (A), liver (B), heart (C) and lung (D).

We reported the latest endpoint within 30 days following vaccine completion if several endpoints were available. We reported the outcome following second dose in the studies reporting post-vaccine immunity following an additional dose. Grey dashes represent the 95% confidence intervals. The studies are ordered by population size. Only studies with subgroup size  $n \geq 10$  are represented.

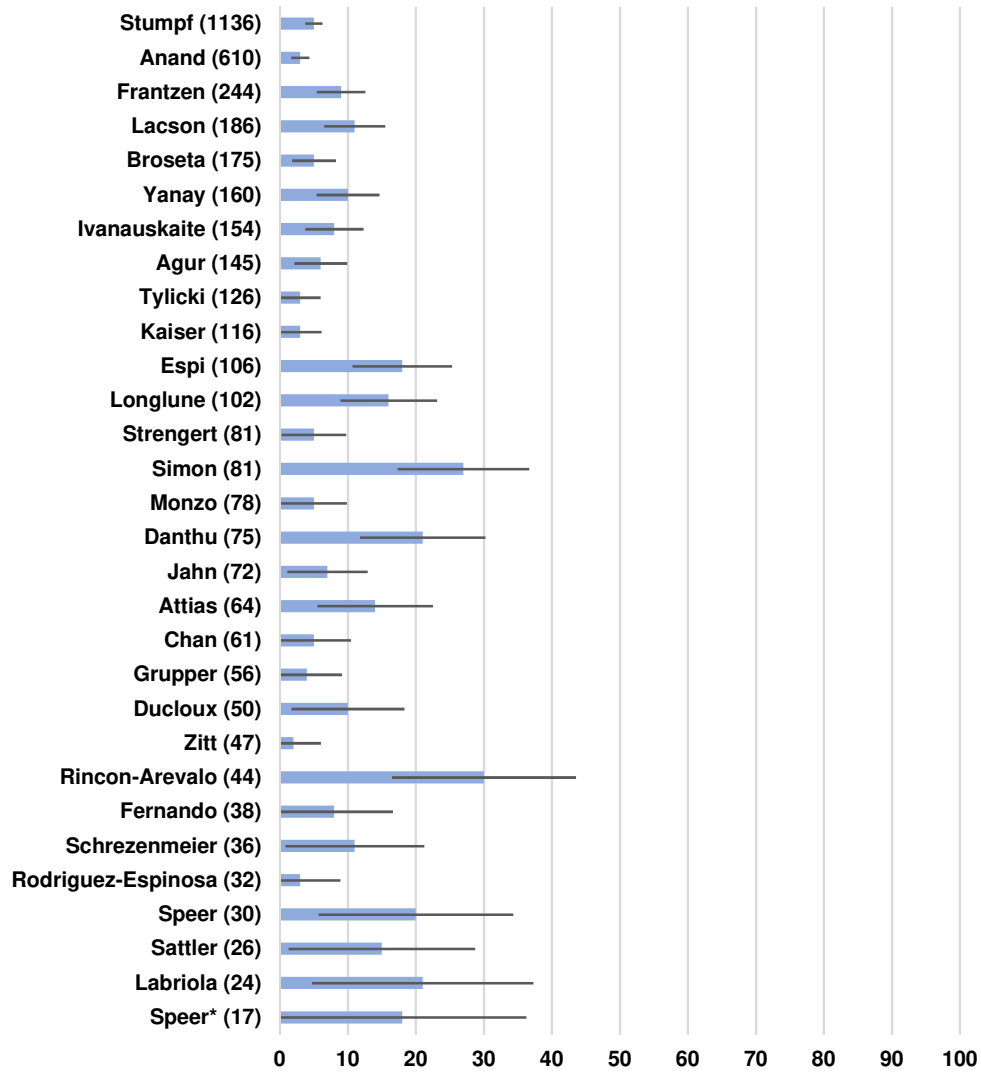
Hall\*: Hall VG, Ferreira VH, Ierullo M, Ku T, Marinelli T, Majchrzak-Kita B, et al. Humoral and cellular immune response and safety of two-dose SARS-CoV-2 mRNA-1273 vaccine in solid organ transplant recipients. *Am J Transplant Off J Am Soc Transplant Am Soc Transpl Surg* 2021. <https://doi.org/10.1111/ajt.16766>.

**Figure 6: Rates of non-response in patients with autoimmune inflammatory diseases.** Grey dashes represent the 95% confidence intervals. The studies are ordered by population size.



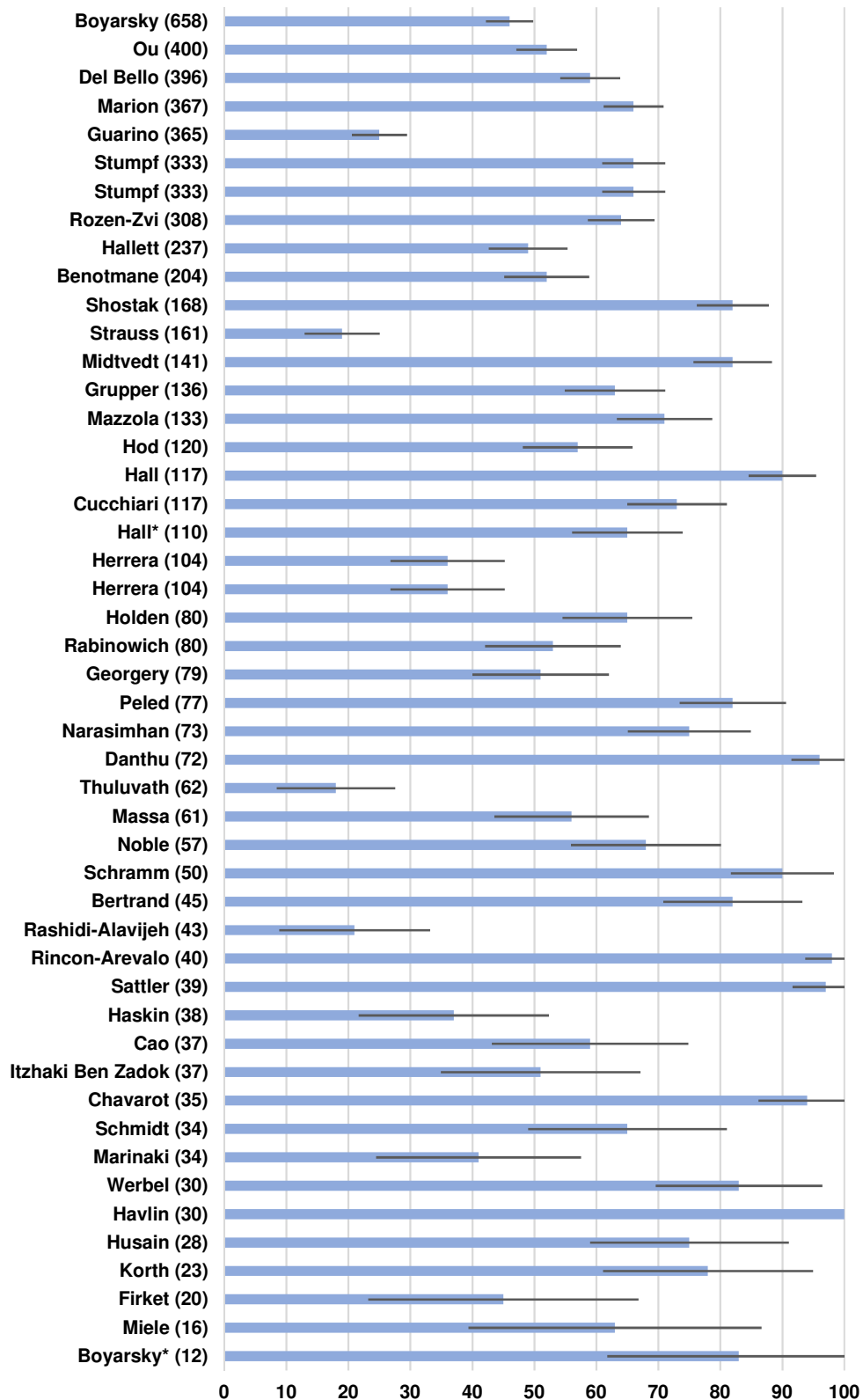


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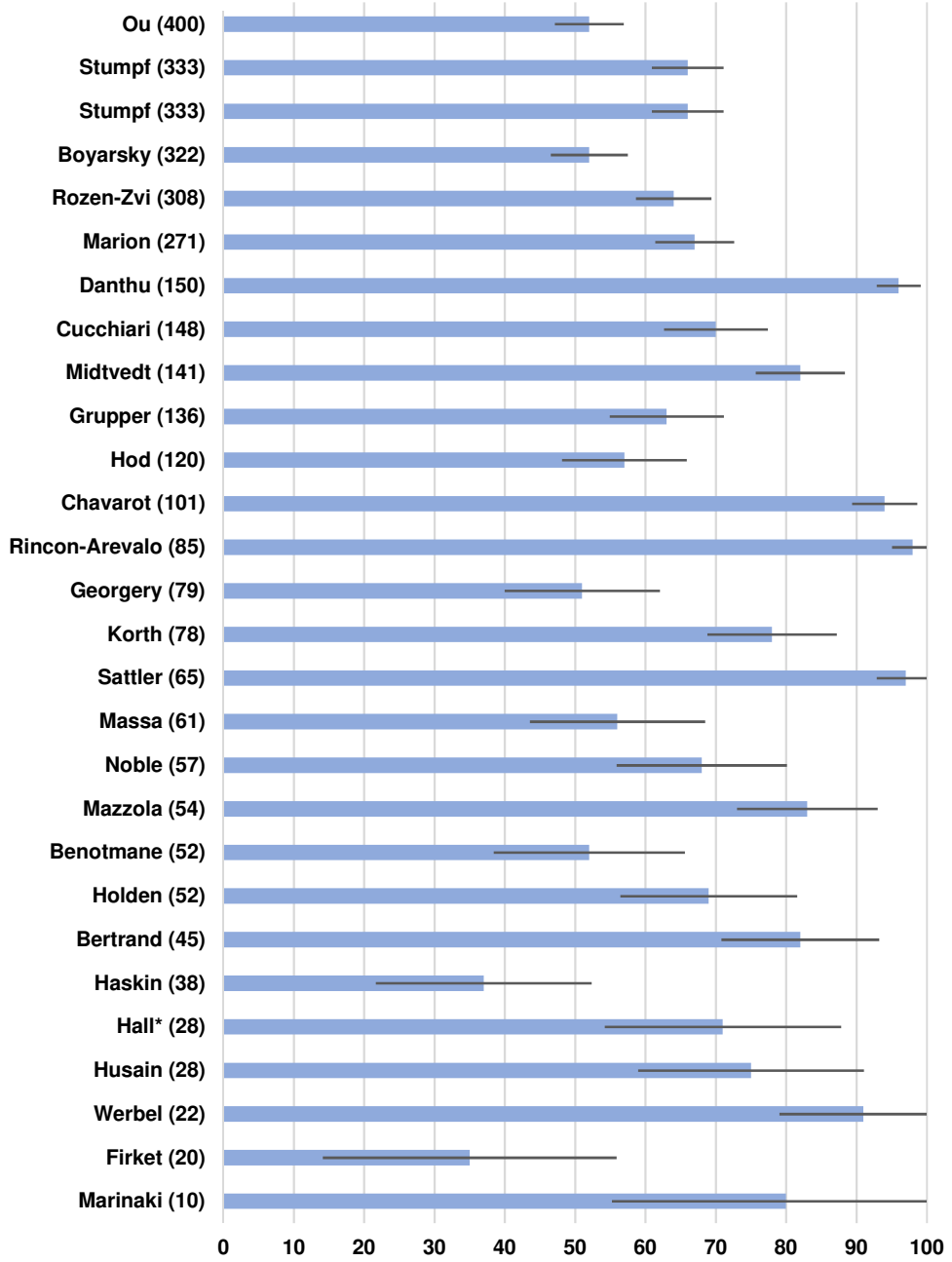


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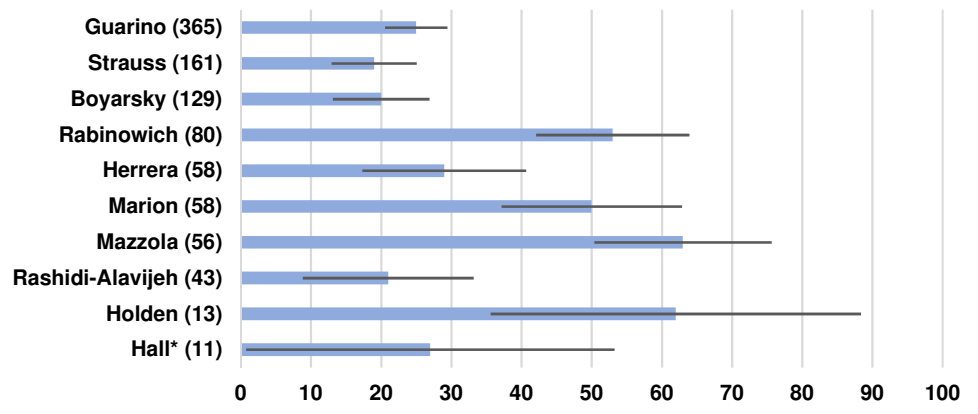
**A First author (n)**

**Kidney transplant recipients**



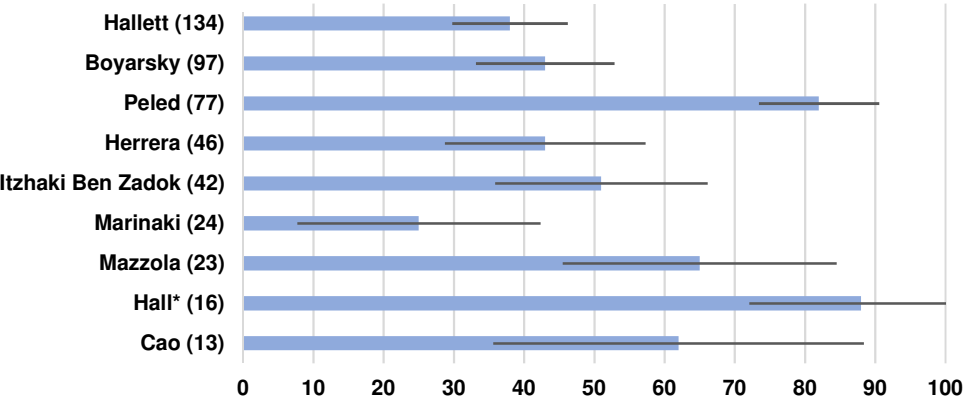
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**Liver transplant recipients**



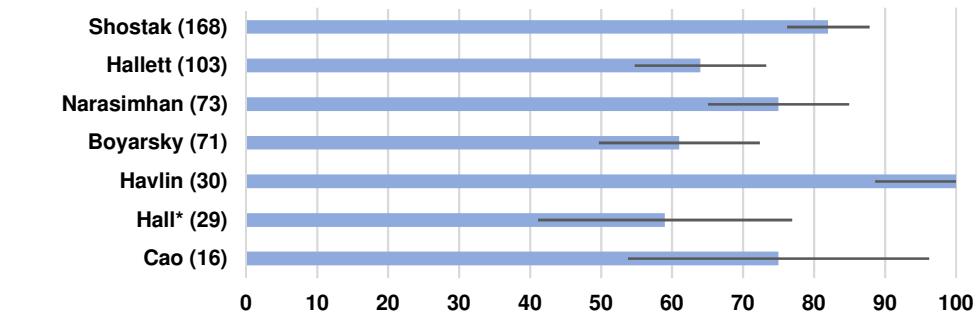
**C First author (n)**

**Heart transplant recipients**



**D First author (n)**

**Lung transplant recipients**



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