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## COVID-19 vaccination in pregnancy—number needed to vaccinate to avoid harm

Pregnant women are vulnerable to COVID-19, with increased risk of more severe illness and pregnancy complications, particularly if infected during the third trimester.<sup>1</sup> Based on prior experience with vaccines in pregnancy, and with no hypothesised mechanisms for fetal harm, similar efficacy and side-effects to the non-pregnant population were anticipated with vaccination against SARS-CoV-2 in pregnancy. Current, albeit limited, data support this; no major safety signals were observed in animal reproductive toxicology studies or with post-marketing surveillance. However, until recently, there was little consensus regarding routine vaccination in pregnancy, and vaccine hesitancy in pregnant women remains high.<sup>2</sup>

Informed health-care decision making requires balancing of benefits and risks. This is challenging when considering COVID-19 vaccination and pregnancy because of variations in individual risk of SARS-CoV-2 infection geographically<sup>3</sup> and temporally, as well as the relative paucity of trial data in this population. However, the average benefits of vaccination can be weighed against the average risks. As a general principle, vaccination of pregnant women should be recommended only if the number needed to vaccinate (NNV) to prevent maternal and fetal harm from COVID-19 is lower than the NNV to cause harm.

Absolute estimates of the NNV, based on point estimates of the benefits versus risks of COVID-19 vaccination in pregnancy, are provided in the appendix, along with methodological information. Considering benefit, the NNV to prevent SARS-CoV-2 infection in pregnancy ranges from 11 to prevent any infection to 206 to prevent one

symptomatic infection. The NNV to prevent severe maternal COVID-19 was 412–2058, and to avoid mechanical ventilation was 1371–6857. The NNV for fetal benefit, by avoiding pregnancy complications, is as low as 200 for preterm or caesarean birth (176 and 182, respectively) and 463 for neonatal problems, and as high as many thousands to avoid a small-for-gestational age baby or stillbirth.

Considering harm, COVID-19 vaccination commonly causes local side-effects, but serious adverse events are rare and no more common than in vaccination outside pregnancy (appendix). The NNV with mRNA vaccines to cause one case of myocarditis (itself usually mild and self-limiting) is just over 37 000, and with viral vector vaccines to cause one excess case of thrombosis thrombocytopenia syndrome almost 50 000. Importantly, there is no increased risk of pregnancy complications.

Real-life estimates of NNV for pregnant women are likely to be lower (ie, better) than those estimated here based on rising cumulative rates of SARS-CoV-2 infection over time, particularly among unvaccinated individuals, and prevalence of SARS-CoV-2 variants of concern. Also, pregnant women may have or live with other young children who are unlikely to receive COVID-19 vaccination but are likely to be socialising with others at activities and daycare.

The balance of risk favours COVID-19 vaccination in pregnancy, particularly to avoid severe maternal infection or preterm or caesarean birth. These data should be used to address and avoid vaccine hesitancy driven by knowledge gaps.

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## COVID-19 vaccine intentions in Australia

Prior to the availability of a COVID-19 vaccine and when case numbers were low, our longitudinal survey with Australian adults showed that 85.8% (3741 of 4362) were willing to be vaccinated in April, 2020, and 89.8% (1144 of 1274) in July, 2020.<sup>1,2</sup> Younger adults perceived themselves to be at less risk of infection and were less willing to receive a vaccine.

Since then, Australia's vaccine rollout has gained rapid momentum in some states, due in part to an outbreak of the highly contagious delta (B.1.617.2) variant. In July–August, 2021, we did a nationally representative survey of 2050 adults aged 18–49 years (appendix p 1) to



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understand barriers to vaccine uptake in a group underrepresented in current research and with lower vaccine uptake. Participants indicated their intentions on a six-point scale.<sup>3</sup> We found that 871 (42.5%) intended to get a COVID-19 vaccine as soon as possible, 467 (22.8%) would get it when they had time, 177 (8.6%) would delay being vaccinated, 223 (10.9%) planned to avoid getting it for as long as possible, 121 (5.9%) said that they would never get a COVID-19 vaccine, and 191 (9.3%) were unsure.

In adjusted analyses, higher perceived threat of COVID-19 (adjusted odds ratio 0.92 [95% CI 0.88–0.97]), increased concern about getting COVID-19 (0.24 [0.16–0.37] for very concerned vs not at all concerned), greater confidence in the government (0.54 [0.49–0.60]), and higher trust in institutions (0.58 [0.52–0.63]) were associated with increased intention to vaccinate (appendix pp 1–2). Participants with the lowest level of education had lower intentions to vaccinate (1.33 [1.03–1.72] for high-school or less vs university educated).

The top three reasons for lower intention to vaccinate were not knowing enough about how safe a COVID-19 vaccine would be (60.6%; 458 of 756), concern about blood-clotting risk (27.5%; 151 of 1500), and worry about long-term side-effects (26.3%; 185 of 704), supporting previous findings.<sup>4</sup>

At the time of the survey, two vaccines were approved in Australia: Pfizer-BioNTech (Comirnaty) and Oxford-AstraZeneca (Vaxzevria). Among our sample, 63.3% (1297 of 2050) preferred the Pfizer-BioNTech vaccine, whereas 4% (81) preferred the Oxford-AstraZeneca vaccine. Pfizer-BioNTech was consistently perceived as being more effective than Oxford-AstraZeneca (appendix p 2).

Separate to issues affecting vaccination intention, our findings also reflect access barriers. When

asked what makes it hard to get a COVID-19 vaccine, 908 (44.3%) of 2050 reported lack of vaccine supply and 668 (32.6%) said that the waiting time is too long. Further barriers included the vaccination site being too far away (8.9%, 182), inconvenient opening times (7.8%, 160), being unable to leave work (6.3%, 129), or caring duties (4.8%, 98). 462 (22.5%) stated that they would feel “not at all” comfortable going to a mass vaccination clinic to receive a vaccine. 420 (20.5%) did not know how to book an appointment and 318 (17%) had been unable to book an appointment.

These findings highlight key areas that need immediate attention to ensure the long-term success of vaccine programmes globally. Public health messaging needs to continue targeting groups with lower education and trust to address motivational barriers to vaccination and explicitly acknowledge and alleviate the vaccine safety concerns of this younger cohort. This survey identified small but critical practical barriers to vaccine uptake which must be urgently managed by authorities for populations to reach vaccination targets.

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Many countries have approved the use of Pfizer-BioNTech's mRNA BNT162b2 vaccine for children aged 12–17 years,<sup>1</sup> and there are safety and efficacy trials underway in children younger than 12 years.<sup>2</sup> Published research examining parents' hesitancy to vaccinate their children against COVID-19 has been based on data from samples selected using non-probability-based selection methods, which are not likely to be representative.<sup>3</sup>

We report data from the August 2021 Australian National University (ANU) COVID-19 impact monitoring survey,<sup>4</sup> a nationally representative, predominantly online survey examining parental vaccine hesitancy. The survey was done 1 month before the Australian Government advised that children aged 15–17 years were allowed to be vaccinated. Of the 3125 adults surveyed, 763 were living in households with at least one child younger than 18 years. For each child, parents were asked: “If a safe and effective vaccine to prevent COVID-19 were available to <NAME>, would you make the decision for them to...?”. Responses for 1368 children were provided, with 581 (42.5%) indicating that they would definitely, 497 (36.3%) would probably, 156 (11.4%) would probably not, and 134 (9.8%) would definitely not get their child vaccinated. Parents with