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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.

PO'B is co-chair of the Royal College of Obstetricians and Gynaecologists Vaccine Committee. EM has received grants from Gedeon Richter, Chugai Pharma, and Kebomed, and was an adviser to Pfizer in 2018. AK is a member of the COVAX working group and principal investigator of the PregCov trial and the Pfizer COVID vaccine trial. PH is the chief investigator of the PregCov trial. All authors are leading and collaborating on COVID-19 vaccine studies.

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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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See Online for appendix

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