

COVID-19 vaccination in pregnancy

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The speed of the UK's COVID-19 vaccination programme has been breathtaking, with more than 41 million doses administered by mid-April. However, almost inevitably with such a huge and rapidly evolving programme, some aspects have not been handled so well. For years, there have been pleas for pregnant women to be involved in and not excluded from clinical trials.¹ So it is disappointing that pregnant and breastfeeding women were excluded from all COVID-19 vaccine research last year, although such trials are due to start soon. The adverse consequences of this exclusion have been compounded by initial guidance from the Joint Committee on Vaccination and Immunisation (JCVI) in which it identified priority groups for vaccination.² Although pregnant and breastfeeding women could fall in six of the nine groups, JCVI recommended that women should be advised 'not to come forward for vaccination if they may be pregnant or are planning a pregnancy within 3 months of the first dose'; there was also no advice for women who are breast feeding. This is despite early reports showing, and later ones confirming, that pregnant women with COVID-19 have more ITU admissions than age-matched non-pregnant women.³

At the end of 2020, JCVI changed its stance to state that 'there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy' but advised that vaccination should be considered for pregnant women where risk of exposure is high and cannot be avoided or where underlying conditions put them at very high risk of serious complications of COVID-19.⁴ JCVI also advised that those trying to conceive do not need to avoid pregnancy after vaccination and women who are breast feeding may be offered vaccination. A decision aid is available to help clinicians discuss vaccination issues with pregnant women.⁵ In April 2021, the belated JCVI recommendation for pregnant women to be offered routine COVID-19 vaccination at the same time as the rest of the population is to be welcomed.⁶ The timing of the first dose should be decided on an individual basis, women at the highest risk may wish

to have it as early as possible in pregnancy and others may choose to wait until the end of the first trimester if they have concerns about the early gestation period; it should certainly be before the third trimester as this is the time of the greatest COVID-19 risk.

Social media posts have worried women with false claims about the harms of COVID-19 vaccination. Such messages spread rapidly and add to the importance of capturing data from pregnant women to establish reliable information. The recent Cumberlege report on the safety of medicines and medical devices highlighted the need for a 'system-wide healthcare intelligence unit to facilitate early signal detection', with all interactions between a patient and the health service captured in an electronic health record.⁷ The report noted that 'innovation without comprehensive pre-market testing and post-marketing surveillance and long-term monitoring of outcomes is, quite simply, dangerous'. It is particularly disappointing that lessons are not being learnt and that it is not yet possible to reliably collect data relating to COVID-19 vaccination in pregnancy prospectively. Although administration of all COVID-19 vaccines is logged, this process cannot record if the person is pregnant, nor subsequently link to pregnancy outcome. This is a wasted opportunity, which in addition to providing valuable vaccine safety data could also link with COVID-19 test results to give a dashboard of vaccine efficacy in pregnancy. Currently, reporting is fragmented across the yellow card scheme with its inherent biases of harm, the voluntary inadvertent vaccination in pregnancy notification system, and, most recently, the UK Obstetric Surveillance System which together with the UK Teratology Information Service collected data on pregnant women who received a COVID-19 vaccine in February and March 2021. It is to be hoped that the Royal College of Obstetricians and Gynaecologists' COVID-19 vaccination working group, in conjunction with other organisations will deliver a joined-up,

effective, 21st-century Cumberlege-approved solution to help pregnant women make informed choices. This needs to be an urgent priority.

Competing interests None declared. Refer to the online supplementary files to view the ICMJE form(s).

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