ROYAL COLLEGE OF PHYSICIANS OF IRELAND

National Immunisation Advisory Committee

UPDATED RECOMMENDATIONS FOR COVID-19 VACCINATION IN PREGNANCY

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About NIAC

NIAC membership includes representatives from the RCPI, its Faculties and Institutes, the RCSI, the ICGP, the National Immunisation Office, the Nursing and Midwifery Board of Ireland, the Infectious Diseases Society of Ireland, the Travel Medicine Society, the National Virus Reference Laboratory, and lay members. Meetings are attended by representatives from the Department of Health and the HSE. Representatives of the Heal Products Regulatory Agency attend to provide regulatory advice in relation to vaccines.

NIAC meets to consider new evidence about vaccines and provide advice to the Chief Medical Officer and the Department of Health. The Department and the Minister for Health make policy decisions on vaccines which are implemented by the HSE.

Executive summary

Scientific evidence about COVID-19 vaccines is continuously evolving and being refined. Recommendations may be updated when more information becomes available.

- On 26 April 2021, NIAC recommended that pregnant women should be offered mRNA COVID-19 vaccination between 14-36 weeks' gestation following an individual benefit/risk discussion with their obstetric care giver.
- If pregnant women become infected with SARS-COV2 they are at increased risk of hospitalisation, at increased risk of premature delivery if symptomatic in the third trimester and at significantly higher risk of ICU admission.
- In recent times, while pregnant women accounted for 1.3% of cases notified in women, pregnant and postpartum women are over-represented among ICU admissions, accounting for almost 10% of COVID-19 related ICU admissions.
- There is now a growing body of evidence on the safety and effectiveness of COVID-19 vaccination – in both animal and human studies – clearly indicating that that the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy.
- Vaccination is the best way to protect both mother and baby from serious harm and should be available at all stages of pregnancy.
- Pregnant women and their partners should observe all public health and social measures.

Recommendations

1. Pregnant women and adolescents from 12 years of age should be offered mRNA COVID-19 vaccination at any stage of pregnancy following an individual benefit/risk discussion with their obstetric care giver.

2. There should be enhanced efforts to increase vaccine uptake in pregnant women, their partners and eligible household contacts.

1. Background

On 26 April 2021, NIAC recommended that pregnant women should be offered mRNA COVID-19 vaccination between 14-36 weeks' gestation following an individual benefit/risk discussion with their obstetric care giver.

This document updates existing recommendations in light of review of the recent evidence for such gestational limits.

2. Experience of SARS-CoV-2 infection and COVID-19 vaccine in pregnancy 2020 – 2021

Pregnant women are not more likely to contract SARS-CoV-2 than non-pregnant women and the proportion with positive tests has mirrored that in the community throughout the pandemic. Of 317,354 cases notified to the Health Protection Surveillance Centre (HPSC), 2,162 (0.68%) were pregnant or six or more weeks post-partum. This represents 1.3% of cases notified in women (n=162,928).

However, if they do become infected, pregnant women are at increased risk of hospitalisation, at increased risk of premature delivery if symptomatic in the third trimester, and at significantly higher risk of ICU admission, than non-pregnant women of similar age.

Figures from the HPSC show that an increasing proportion of ICU admissions over recent waves of infection is in pregnant and recently delivered women. All were unvaccinated. Many had no underlying condition other than pregnancy.

From 26 June 2021 to 10 August 2021, there were 399 COVID-19 cases in pregnant/ postpartum women; 20 (5%) were hospitalised and five admitted to ICU. This is in contrast to waves 1 and 2 when hospitalisations (0.6-1%) and ICU admissions (0.5%) were lower in pregnant women. Pregnant/recently postpartum women now represent 9.4% of ICU admissions.

Similar data are reported from the UK. A study conducted by the UK Obstetric Surveillance System found that 24% of pregnant women admitted in the first wave had moderate or severe disease, compared to 36% of those infected with the Alpha variant and 45% with the Delta variant. Pregnant women admitted during the Delta period had further increased risk of pneumonia (36.8% vs. 27.5%). ICU stays have been prolonged up to 7 weeks and ECMO required by some. In addition, babies delivered whose mothers are ventilated have suffered adverse effects including those associated with prematurity, exposure to sedative medications, and they may have neurodevelopment sequelae.

UK ICU data has shown a maternal mortality rate of 2.3% in pregnant women requiring ICU care since 1 May 2021. No fully vaccinated pregnant women were hospitalised between 1 February 2021 (when vaccination data collection commenced) and 11 July 2021.

In August 2021, Northern Ireland reported the first death from COVID-19 in a healthy unvaccinated pregnant woman.

National COVID-19 vaccine uptake data of pregnant women and their partners are not available. The Rotunda Hospital regularly surveys inpatients as to their vaccination status. As of 10 August 2021, only 39% of inpatients and 41% of partners were fully vaccinated.

3. COVID-19 vaccine safety and effectiveness

A growing body of evidence on the safety and effectiveness of COVID-19 vaccination – in both animal and human studies – indicates that the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy.

In the US, there were no obvious safety signals among almost 4,000 pregnant women who received mRNA COVID-19 vaccines, or in their babies.

In a retrospective cohort study of over 15,000 pregnant women in Israel, Comirnaty® was associated with a significantly lower risk of SARS-CoV-2 infection compared with no vaccination and adverse events were as expected.

Ongoing preliminary surveillance data from the Better Outcomes Registry & Network (BORN) in Ontario, Canada among almost 40,000 COVID-19 vaccinated individuals do not suggest any pattern of increased risk of adverse pregnancy or birth outcomes.

Data in a recent preprint from the Centers of Control and Prevention (CDC) in the US reported that mRNA COVID-19 vaccination before or during pregnancy is not associated with an increased risk of spontaneous abortion (12.8%) when compared to the expected range of spontaneous abortions in recognised pregnancies (11-16%). These findings add to accumulating evidence that mRNA COVID-19 vaccines during pregnancy are safe. Previous studies estimating cumulative risk of spontaneous abortion in the general population have reported similar estimates.

There is no evidence COVID-19 vaccines affect fertility and COVID-19 vaccines can be given at any interval before or during IVF treatment.

4. International recommendations

A number of countries have no gestational limit for COVID-19 vaccination of pregnant women.

In the US, COVID-19 vaccination is recommended for all people aged 12 years and older, including people who are trying to become pregnant, may become pregnant, are pregnant, or are breastfeeding.

In Canada, the National Advisory Committee on Immunization (NACI) strongly recommends that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorised age group who are pregnant or breastfeeding. Informed consent should include

discussion about emerging evidence on the safety of mRNA COVID-19 vaccines in these populations. In Ontario, all pregnant individuals in the authorised age group are eligible and recommended to be vaccinated as soon as possible, at any stage in pregnancy.

In the UK, the Joint Committee on Vaccination and Immunisation has advised that women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group.

In Australia, pregnant women and adolescents aged 12 years and older are a priority group for vaccination. An mRNA vaccine should be routinely offered to pregnant people at any stage of pregnancy.

In Finland, Greece, Italy, Spain, Argentina, Brazil and Israel, COVID-19 vaccines are recommended for all pregnant women at any stage in pregnancy.

5. Conclusions

There is emerging local evidence to suggest an increase in serious adverse maternal and neonatal outcomes from COVID-19 in recent months. There is now significant experience with the use of mRNA COVID-19 vaccines in pregnancy and no safety concerns have been raised.

Vaccination is the best way to protect both mother and baby from serious harm.

Limited data suggest that vaccine uptake in pregnant women and their partners is sub optimal.

Recommendations

1. Pregnant women and adolescents from 12 years of age should be offered mRNA COVID-19 vaccination at any stage of pregnancy following an individual benefit/risk discussion with their obstetric care giver.

2. There should be enhanced efforts to increase vaccine uptake in pregnant women, their partners and eligible household contacts.

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AMENDMENTS & CLARIFICATIONS

02.09.2021: EXECUTIVE SUMMARY 3rd bullet corrected to read

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