Interim Guidance

"The use of COVID-19 vaccines in pregnant and lactating patients"

Updated on January 31st 2021

Developed by the Italian Obstetric Surveillance System (ItOSS)

Istituto Superiore di Sanità

COVID-19 Vaccination during Pregnancy and Lactation

There is currently a widespread debate in the scientific community regarding the role of COVID-19 vaccines in pregnant and lactating women, given the absence of safety and efficacy data specific to mRNA vaccine use in these populations, with uncertainty surrounding the potential risks to the mother and the foetus. Vaccination plans offered by most countries are subject to a risk/benefit assessment, which is usually conducted at individual level through appropriate counselling with dedicated healthcare professional.

The following document was developed by the Italian Obstetric Surveillance System (ItOSS) of the Istituto Superiore di Sanità (National Institute of Health) to support and guide both healthcare providers as well as pregnant and lactating women during the clinical decision making process in the midst of the pandemic. The contents of this document have been shared and approved by the following national associations and professional boards of obstetrician-gynaecologists, paediatricians, midwives and anesthesiologists: SIGO (Società Italiana di Ginecologia ed Ostetricia), AOGOI (Associazione degli Ostetrici e Ginecologi Ospedalieri Italiani), AGUI (Associazione Ginecologi Universitari Italiani), AGITE (Associazione Ginecologi Territoriali), FNOPO (Federazione Nazionale Collegi Ostetriche), SIN (Società Italiana di Neonatologia), SIMP (Società Italiana di Medicina Perinatale), SIP (Società Italiana di Pediatria), ACP (Associazione Culturale Pediatri), SIAARTI (Società Italiana di Anestesia, Analgesia, Rianimazione e Terapia Intensiva).

Major current recommendations, issued at national and international level, regarding COVID-19 vaccination in pregnant and lactating women will be summarised and discussed in the present Interim Guidance document.

World Health Organization

WHO's Strategic Advisory Group of Experts on Immunization (SAGE) held an extraordinary general meeting on January 5,, 2021, and on January 8, 2021 issued policy recommendations

(1) regarding the rollout of the first COVID-19 vaccine produced by Pfizer-BioNTech and approved for emergency use. While WHO confirmed safety and efficacy of the Pfizer-BioNTech COVID-19 mRNA vaccine, it also highlighted the lack of data targeting specific populations, including pregnant and lactating women. The Pfizer-BioNTech COVID-19 product is an mRNA vaccine. Within hours or days, our bodies are able to eliminate the mRNA particles used in the vaccine, therefore these particles are unlikely to penetrate the cell nucleus. When studied during animal tests, mRNA vaccines did not appear to affect the pregnancy. Nonetheless, according to these first policy recommendations data is insufficient to recommend the vaccination of pregnant women. Pregnant women experiencing a high risk of exposure (e.g. a health worker) or at higher risk of developing severe COVID-19 (e.g. due to comorbidities) may be considered for vaccination, in discussion with their healthcare provider. Pregnant women should receive appropriate information and should be adequately counseled by their healthcare provider, in order to discuss extensively risks and benefits of the vaccination. WHO does not recommend a pregnancy test prior to the COVID-19 vaccine shot.

Although very little data are available to assess COVID-19 vaccine safety when breastfeeding, the known health benefits yielded by the vaccine for both mothers and babies outweigh the potential risks and it is biologically and clinically unlikely that the vaccine may harm the baby. If a breastfeeding woman is part of a group (e.g. health workers) recommended for vaccination, vaccination can be offered. WHO does not recommend discontinuing breastfeeding after vaccination.

On January 2, 2021, the WHO Strategic Advisory Group of Experts (SAGE) on Immunization published Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19 (2). According to this second set of recommendations, SAGE does not raise a specific reason to believe that the risks outweigh the benefits of vaccination for pregnant women. Therefore pregnant women at high risk of exposure to SARS-CoV-2 (e.g. health workers) or who have comorbidities adding to their risk of severe disease, may be vaccinated in discussion with their health care provider.

United States of America

The **Food and Drug Administration** (FDA) has released an Emergency Use Authorization (EUA) for the use of Pfizer BioNtech mRNA (BNT162b2) vaccine in individuals 16 years of age and older, with a dosing regimen of two doses 3 weeks apart. The FDA issued a EUA also for Moderna mRNA-1273 vaccine to be used in individuals aged 18 years and older, with a dosing regimen of two doses 1 month apart (3,4). Both vaccines prevent COVID-19 with 95% efficacy, following administration of both doses. The FDA underlines limited data about the safety of COVID-19 vaccines for people who are pregnant or breastfeeding, without stating a clear contraindication to its use in these populations. According to the FDA "Although data is lacking to assess the

effects of the COVID-19 vaccines during pregnancy and lactation, vaccination should not be contraindicated. Women should discuss the potential benefits and harms deriving from the vaccine with their healthcare provider".

The **Center for Disease Control and Prevention** (CDC) similarly states, "Only limited data are available on the safety of COVID-19 vaccines, including mRNA vaccines, administered during pregnancy and lactation. People who are pregnant and part of a group recommended to receive COVID-19 vaccine, such as healthcare personnel, may choose to be vaccinated. A conversation between pregnant patients and their clinicians may help them decide whether to get vaccinated (5)".

The **American College of Obstetricians and Gynecologists** (ACOG) recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based the priority groups identified by the Advisory Committee on Immunization Practices (ACIP). The Advisory Committee on Immunization Practices (ACIP) develops recommendations on how to use vaccines to control disease in the United States (6). Although ACOG recognizes that none of the COVID-19 vaccines approved under EUA have been tested in pregnant individuals there is a lack of data supporting contraindication of the vaccine during pregnancy as well. Data from Developmental and Reproductive Toxicity (DART) studies for the Pfizer-BioNtech COVID-19 vaccine and the Moderna's mRNA-1273 do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or post-natal development. ACOG therefore recommends that pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups make their own decision regarding COVID-19 vaccination possibly following a discussion with their clinical care team. Individuals considering a COVID-19 vaccine should have access to available information about the safety and efficacy of the vaccine, including information about data that are not available. A conversation between the patient and their clinical team may assist with decisions regarding the use of vaccines for the prevention of COVID-19 by pregnant patients. Important considerations include the level of activity of the pandemic in the community, the potential efficacy of the vaccine, the potential risk and severity of maternal disease, including the effects of disease on the foetus and newborn, and the safety of the vaccine for the pregnant patient and the foetus.

Canada

The Canadian patient information leaflet for the Pfizer-BioNtech mRNA (BNT162b2) vaccine states that safety and efficacy in pregnant women have not yet been established (7). The **Society of Obstetricians and Gynaecologists of Canada** (SOGC) acknowledges the absence of available data regarding safety and efficacy of the Pfizer-BioNtech mRNA (BNT162b2) vaccine during pregnancy and lactation. SOGC released the following statement on the 18th of December

2020, reaffirmed on January 4 and January 28, 2021: "The risk of infection and/or morbidity from COVID-19 outweighs the theorized and undescribed risk of being vaccinated during pregnancy or while breastfeeding. Women who are pregnant or breastfeeding should be offered vaccination at any time if they are eligible and no contraindications exist."(9)

United Kingdom

On the 30th of December 2020 the **Medicines & Healthcare Products Regulatory Agency** and the **Royal College of Obstetricians & Gynaecologists** (RCOG) have revised their previous position that advised against BNT162b2 vaccine administration during pregnancy and breastfeeding until further evidence regarding safety and efficacy would emerge (10,11). The latest guidance issued by the **Joint Committee on Vaccination and Immunisation** (JCVI) (12) specifies that there is no known risk associated with giving non-live vaccines during pregnancy. These vaccines cannot replicate, so they cannot cause infection in either the woman or the unborn child. According to the JCVI recommendations the available data does not indicate any safety concern or harm to pregnancy, yet there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy. JCVI advises that, for women who are offered vaccination with the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines, vaccination in pregnancy should be considered where the risk of exposure to Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV2) infection is high and cannot be avoided, or where the woman has underlying conditions that put her at very high risk of serious COVID-19complications. In these circumstances, clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnant women. JCVI does not advise routine pregnancy testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after vaccination.

JCVI also indicates that there is no known risk associated with giving non-live vaccines whilst breastfeeding. Therefore, breastfeeding women may be offered vaccination with the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines. The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women (12).

The **Commission on Human Medicines** (CHM), considering the release of new data regarding the Pfizer/BioNTech vaccine, has suggested adding the following revision to the guidance regarding vaccination of pregnant and breastfeeding women: administration of the COVID-19 mRNA Vaccine in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus. Patients should be appropriately counseled by their healthcare providers on the benefits and risks of the vaccinations and a case by case decision is warranted. Breastfeeding women can receive the vaccination against COVID-19 (10).

European Union

On December 21, 2020, the Committee for Medicinal Products for Human Use (CHMP) of the **European Medicines Agency** (EMA) concluded by consensus that sufficiently robust data on the safety and efficacy of the COVID-19 mRNA Pfizer/BioNtech vaccine (Comirnaty) are now available to authorise the use of the product to to prevent coronavirus disease 2019 (COVID-19) in people from 16 years of age (13). On the 6th of January EMA authorised the use of COVID-19 Vaccine Moderna to prevent Coronavirus disease (COVID-19) in people from 18 years of age (14). On January 28, 2021, EMA authorised the use of COVID-19 vaccine AstraZeneca to prevent Coronavirus disease (COVID-19) in people from 18 years of age.

Both Pfizer/BioNtech and Moderna vaccines contain an mRNA molecule, encapsulated in lipid nanoparticles that allow its entry in human cells and the release of the necessary information to replicate the spike protein. The vaccine mRNA does not enter the cell nucleus and does not alter human DNA and is rapidly degraded following inoculation. Once the vaccine is administered, human cells are able to read the vaccine mRNA and temporarily produce the spike protein. The immune system of a vaccine recipient gains the ability to identify and label the spike protein as a foreign antigen and mounts an immune response. If SARS-CoV-2 is encountered following vaccination, the immune system is able to recognise and contrast the antigen having acquired immunological memory through the vaccination process. The vaccine can be offered to individuals with previous SARS-CoV-2 infection and to immunocompromised patients.

Although data regarding the use of vaccines in pregnancy and lactation are lacking, EMA reports that no harmful effects with respect to pregnancy and lactation were observed during animal studies. The decision to receive the vaccine during pregnancy and lactation should be based upon a discussion with the healthcare provider and on a case-by-case basis, taking into consideration benefits and possible risks.

AstraZeneca COVID-19 vaccine is composed of chimpanzee adenovirus encoding the SARS-CoV-2 Spike glycoprotein (ChAdOx1-S). The adenovirus itself cannot reproduce and does not cause disease. Once it has been given, the vaccine delivers the SARS-CoV-2 gene into cells in the body of the recipient. The cells use the gene to produce the spike protein. The person's immune system treats this spike protein as foreign and produces antibodies and T cells against this protein. According to EMA "Preliminary animal studies do not show any harmful effects in pregnancy, however data on the use of COVID-19 Vaccine AstraZeneca during pregnancy are very limited. Although there are no studies on breast-feeding, no risk from breast-feeding is expected. The decision on whether to use the vaccine in pregnant women should be made in close consultation with a healthcare professional after considering the benefits and risks".

Italian Interim Guidance on Pfizer/BioNtech (Comirnaty) and Moderna mRNA vaccines during pregnancy and lactation

The Italian Medicines Agency (Agenzia Italiana del Farmaco- AIFA) authorized marketing and reimbursement by the NHS of the Pfizer/BioNtech mRNA vaccine (Comirnaty) on December 22nd 2020 (15). The vaccine is approved for individuals aged 16 years and older, presents no absolute contraindications and requires no special precautions for specific subpopulations such as the elderly, immunocompromised people or subjects with coagulation disorders and at risk of bleeding. There are also no contraindications for pregnant or breast-feeding women". AIFA has published a series of answers to frequently asked questions on the website, which include a specific question regarding the possibility of receiving the vaccine during pregnancy and lactation. According to AIFA "There is limited experience with use of the vaccine in pregnant women. Animal studies do not indicate harmful effects with respect to pregnancy. Although there are no studies on breast-feeding, no risk for breast-feeding is expected based on biological plausibility. In general, the decision on whether to use the vaccine in pregnant or breast-feeding women should be made in close consultation with a healthcare professional after considering the benefits and risks."(16) AIFA authorised marketing of the Moderna vaccine for prevention of COVID-19 in subjects aged 18 or over on January 7, 2021 (17). The efficacy and safety profile of the Moderna mRNA vaccine is substantially equivalent to Comirnaty. Moderna vaccine is characterised by a particularly favourable risk/benefit ratio of the vaccine in the population at greater risk. The vaccination schedule of Moderna varies compared to Comirnaty: it provides for two administrations 28 days apart, instead of 21 days and immunity is considered fully acquired starting 2 weeks after the second administration, instead of one.

Italy has therefore decided to offer the vaccine to pregnant and lactating women in consultation with their healthcare providers and after close consideration of the risks/benefits. The decision to offer the vaccine to pregnant and breastfeeding patients is targeted mainly towards women that present a high risk of exposure to SARS-CoV2 infection or underlying conditions that put them at increased risk of materna/fetal/perinatal complications following infection. In these circumstances, clinicians should discuss the risks and benefits of vaccination with the woman for an informed decision regarding her health and the vaccine.

We will examine the principal aspects related to vaccine administration to offer a comprehensive set of information directed to all healthcare providers involved with pregnant and lactating women (general practitioners, public health specialists, gynaecologists, midwives, neonatologists and paediatricians) to support effective and clear counseling with their patients considering COVID-19 vaccinations.

-Efficacy and potential safety of vaccines

Phase II and III studies involved around 44.000 randomized individuals and demonstrated safety and efficacy of Comirnaty vaccine in adults aged 16 years or over (13). The trials showed a 94.6% reduction in the number of symptomatic COVID-19 cases 7 days after receiving the

second dose. Data regarding vaccine safety derives from an interim analysis involving 37.586 adults (9.500 of these individuals were followed up at least 2 months after vaccination). Safety monitoring of the vaccine will continue for two years following vaccine administration. No clinically significant differences in the number of adverse reactions were observed in the vaccine group compared to the controls, except for lymph node swelling (0.3% in the vaccine group vs 0.1% in the placebo group). The most frequently observed adverse reactions included: redness at the injection site (66-83%), fatigue (51-59%) and headache (39-52%). Fever (11-16%) was more common after the administration of the second dose of the vaccine.

Phase II and III studies involving around 30.000 randomized individuals demonstrated safety and efficacy of Moderna vaccine in adults aged 18 years or over (14). The trials showed a 94.1% reduction in the number of symptomatic COVID-19 cases in individuals receiving 2 doses of the vaccine 28 days apart. The most frequently observed adverse reactions included: redness at the injection site, fatigue, chills and fever, headache, lymph node swelling, muscle and joint pain, nausea and vomiting.

-Safety of the vaccines during pregnancy

Pregnant patients were not included in phase II and III studies assessing the efficacy and safety of the vaccines against COVID-19, therefore there is no available data regarding this population. The only available data derives from animal studies that did not display any harmful effects of the vaccine during pregnancy. During the Comirnaty and Moderna trials respectively 23 women (12 in the vaccine group and 11 in the placebo group) and 13 women (6 in the vaccine group and 7 in the placebo group) became pregnant and have been followed up during pregnancy, with no adverse reaction noted up to the current time (13,14). In general, vaccine administration during pregnancy is immunogenic, safe and effective. Prior experience with other vaccines supports the hypothesis that the efficacy of COVID-19 vaccination in pregnant and non-pregnant patients might be similar. We have no evidence regarding the optimal gestational age for COVID-19 vaccine administration. Since fever can be experienced following inoculation of the vaccine, it may be reasonable to delay the vaccination during the first trimester, to avoid possible development of neural tube defects or of any other malformation (18). The vaccine is deemed safe during breastfeeding. This assumption is based on the concept that while COVID-19 vaccine yields a negligible risk to the breastfed baby, the discontinuation of breastfeeding come with a well-established loss of key benefits to the child (19-21).

Taking all these factors into consideration we can conclude that while no harmful mechanisms of the mRNA vaccines during pregnancy and lactation have been observed or hypothesized, the true impact of the vaccination in this population remains currently unknown due to lack of evidence.

-Potential maternal/fetal/perinatal risks of COVID-19

The currently available data regarding SARS-CoV-2 infection in pregnancy report a very low absolute risk of serious adverse maternal and perinatal outcomes; the majority of pregnant women affected by SARS-CoV-2 infection manifests mild to moderate symptoms (22.23).

An Italian prospective population-based study launched by ItOSS has described the maternal/fetal and neonatal incidence, risk factors, clinical evolution and outcomes of SARS-CoV-2 infection during the first wave of the pandemic in women with a confirmed SARS-CoV-2 infection accessing health facilities during pregnancy, childbirth and puerperium (24-26). From the 25th of February to the 31st of July 2020 (a timeframe that encompasses the first wave of the pandemic in Italy), the national incidence rate of SARS-CoV-2 was estimated around 3.2 cases per 1000 women that had delivered (5.9 in the North, 1.6 in the Centre and 0.4/1000 in the South of the country). 525 infected women delivered in the specified timeframe. Of these 109 (20.8%) developed COVID-19 pneumonia and 21 (4%) suffered from serious morbidity, directly attributable to the virus in one third of the cases. Intensive care was required for 14 women (2.7%), of which 5 received endotracheal intubation. No maternal deaths were observed. No neonatal deaths were observed, while 4 stillbirths were noted. Of the 538 babies included in the study, 12 (2.2%) developed a serious illness, directly attributable to the virus in 7/12 cases. 10 (1.9%) neonates reported a positive swab for SARS-CoV-2 within 24 hours from birth; one of these babies developed acute respiratory distress and was admitted to intensive care. No significant differences in the number of positive swab tests were observed at discharge between babies that had been separated from their mothers and those that had not and no differences in neonatal outcomes between breastfed and non-breastfed neonates were reported (224,25).

-Individual risk of infection in patients with comorbidities

The documented risk factors for the development of serious forms of COVID-19 include: maternal age ≥ 35, underlying conditions such as asthma, obesity, diabetes or hypertension, black ethnicity or other ethnic minority groups (22,23). The ItOSS study revealed a greater risk of developing COVID-19 related pneumonia among women from Africa, Asia, South-America and Eastern Europe and among women with underlying conditions (obesity/hypertension) (24,25). The presence of these characteristics puts these patients at greater risk of poor maternal/fetal and perinatal outcomes and should be considered when assessing the risks and benefits of COVID-19 vaccination.

In conclusion, the ItOSS data does not suggest a greater risk of SARS-CoV-2 infection during pregnancy compared to the general population. According to the study, pregnant women with SARS-CoV-2 infection tend to have mild forms of the disease with generally good outcomes. Patients with underlying conditions or known risk factors (such as being part of an ethnic minority) may experience severe forms of COVID-19 and worst maternal/fetal/perinatal outcomes.

-Levels of disease activity within the woman's community and workplace

When conducting a risk/benefit analysis, the individual risk of infection should be assessed. This individual risk is based on the level of community spread and on the risk of workplace exposure of the pregnant or breastfeeding individual. For example, if the pregnant or lactating woman works as a healthcare provider or caregiver in conditions of high risk of exposure to the virus, it should be considered when deciding whether to receive the vaccine or not.

Interim Guidance "The use of COVID-19 vaccines in pregnant and lactating patients"
Italian Obstetric Surveillance System (ItOSS)
Istituto Superiore di Sanità

- Pregnant and breastfeeding patients have not been included in the Pfizer/BioNtech (Comirnaty), Moderna and AstraZeneca vaccine trials, therefore there is currently no evidence regarding the safety and efficacy of these vaccines in this population.
- There is currently no evidence supporting a biological link between mRNA vaccine administration and risk of adverse pregnancy outcomes. No harmful effects with respect to pregnancy and lactation were observed during animal studies.
- Pregnant and breastfeeding women have not been included in the priority groups of the COVID-19 vaccination campaign since the vaccine is currently not routinely recommended for these individuals.
- Data from the ItOSS study (conducted during the first wave of the pandemic in Italy) revealed a low risk of adverse maternal and perinatal outcomes in pregnant and infected women. Higher rates of COVID-19 related complications have been observed in pregnant women with comorbidities (hypertension/obesity) or part of ethnic minority groups.
- COVID-19 vaccine should be considered for pregnant women at high risk of viral exposure (i.e. healthcare providers, caregivers) or with underlying conditions that increase the risk of severe COVID-19 development. The decision whether to receive the vaccine during pregnancy and lactation for women in these categories should be discussed with the healthcare provider and individual choice should be carried out on a case-by-case basis, taking into consideration benefits and possible risks.
- If a woman becomes pregnant after receiving the COVID-19 vaccine, there is no evidence suggesting the need to terminate.
- If a woman becomes pregnant between the first and second dose of the COVID-19 vaccine she can delay the inoculation of the second dose and complete the vaccination

after childbirth. If the woman is part of a high-risk category vaccination should be carried out according to the vaccination schedule.

- Lactating women can receive the vaccination without discontinuation of breastfeeding.

References

1. WHO. Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing. Interim guidance. 8 January 2021 (https://apps.who.int/iris/rest/bitstreams/1326072/retrieve)

2. WHO. Interim Recommendations for the use of the Moderna m-RNA-1273 vaccine against COVID-19. Interim guidance. 25 January 2021. https://apps.who.int/iris/rest/bitstreams/1328356/retrieve

3. FDA News Release. FDA takes key action in fight against COVID-19 by issuing emergency use authorization for first COVID-19 vaccine. December 11, 2020. https://www.fda.gov/emergencypreparedness-and-response/coronavirus-disease-2019-covid-19/pfizer- biontech-covid-19-vaccine

4. Fact Sheet for Health Care providers administering vaccine (vaccination providers). Emergency use authorization (EUA) of Pfizer-Biontech COVID_19 vaccine to prevent coronavirus disease 2019 (COVID19). https://www.fda.gov/media/144413/downloadhttps://www.epicentro.iss.it/coronavirus/sars-cov-2- dashboard)

5. CDC. Vaccine Recommendations and Guidelines of the Advisory Committee on Immunization Practices (ACIP). https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html

6. American College of Obstetricians and Gynecologists (ACOG). Vaccinating pregnant and lactating patients against COVID-19. December 13, 2020. https://www.acog.org/clinical/clinical-guidance/practice- advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19

7. Pfizer-BioNTech COVID-19 Vaccine (CoVID-19 mRNA Vaccine) Product Monograph (Canada)

8. SOGC Statement on COVID-19 Vaccination in Pregnancy 20 December 2020 https://sogc.org/common/Uploaded%20files/Latest%20News/SOCG_Statement_COVID-19_Vaccination_in_Pregnancy.pdf

9. SOCG Statement on COVID-19 Vaccination in Pregnancy January 28th 2021. https://www.sogc.org/common/Uploaded%20files/Latest%20News/SOGC_Statement_COVID-19_Vaccination_in_Pregnancy.pdf

10. Medicines & Health Care Products Regulatory Agency. Regulatory approval of Pfizer/BioNTech vaccine for COVID-19. Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 vaccine. Updated 30 December 2020. https://www.gov.uk/government/publications/regulatory-approval-of-pfizer- biontech-vaccine-for-covid-19

11. Royal College of Obstetricians & Gynaecologists (RCOG). Update advice on COVID-19 vaccination in pregnancy and women who are breastfeeding. News 30 December 2020.

https://www.rcog.org.uk/en/news/updated-advice-on-covid-19-vaccination-in-pregnancy-and-women- who-are-breastfeeding/
12. Joint Committee on Vaccination and Immunisation. COVID-19 vaccination: a guide for women of childbearing age, pregnant or breastfeeding. Updated 28 January 2021. https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding
13.European Medicines Agency. Comirnaty. 21 December 2020. -https://www.ema.europa.eu/en/news/ema-recommends-first-covid-19-vaccine-authorisation-eu
https://www.ema.europa.eu/en/medicines/human/summaries-opinion/comirnaty
14.European Medicines Agency. COVID-19 Vaccine Moderna. 06 January 2021 -https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-moderna-authorisation-eu
-https://www.ema.europa.eu/en/medicines/human/summaries-opinion/covid-19-vaccine-moderna
European Medicines Agency. COVID-19 Vaccine AstraZeneca. 29 January 2021. -https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-astrazeneca-authorisation-eu
15. Agenzia Italiana del Farmaco Autorizzato il vaccino BioNTech/Pfizer. 22 Dicembre 2020 https://www.aifa.gov.it/web/guest/-/autorizzato-il-vaccino-biontech-pfizer
16. AIFA Domande e risposte EMA su Comirnaty (21.12.2020) https://www.aifa.gov.it/documents/20142/847374/Comirnaty_ITA.pdf/4bab0937-0bad-0de9-0152- 9cba051ceb7e
17. Agenzia Italiana del Farmaco Autorizzato il vaccino Moderna. 07 Gennaio 2021 https://www.aifa.gov.it/web/guest/-/covid-19-aifa-autorizza-vaccino-moderna
18. Graham JM Jr. Update on the gestational effects of maternal hyperthermia. Birth Defects Res 2020;112:943–52. doi: 10. 1002/bdr2.1696
19. Hare H Womersley K Healthcare workers who breastfeed should be offered the covid-19 vaccine December 21, 2020 https://blogs.bmj.com/bmj/2020/12/21/healthcare-workers-who-breastfeed-should- be-offered-the-covid-19-vaccine/
20. Accademy of Breastfeeding Medicine (ABM). ABM Statement. Consideration for COVID-19 vaccination in lactation. December 14 2020. https://www.bfmed.org/abm-statement-considerations-for- covid-19-vaccination-in lactation#:~:text=According%20to%20the%20CDC%20Advisory,the%20mother%20or%20her%20child.
21. Società Italiana di Neonatologia (SIN) Position paper ad interim su "vaccinazione anti-COVID19 e gravidanza" SIN - dicembre 2020 https://www.sin-neonatologia.it/
22. Allotey J, Stallings E, Bonet M, et al.; PregCOV-19 Living Systematic Review Consortium. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. BMJ 2020;370:m3320
23. Knight M, Bunch K, Vousden N, Morris E, Simpson N, Gale C, O'Brien P, Quigley M, Brocklehurst P, Kurinczuk JJ; UK Obstetric Surveillance System SARS-CoV-2 Infection in Pregnancy Collaborative Group. Characteristics and outcomes of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK: national population based cohort study. BMJ. 2020 Jun 8;369:m2107. doi: 10.1136/bmj.m2107. PMID: 32513659; PMCID: PMC7277610.
24. Maraschini A, Corsi E, Salvatore M.A. and Donati S. Coronavirus and birth in Italy: results of a national population-based cohort study. Ann Ist Super Sanità 2020;56(3):378-388. doi: 10.4415/ANN_20_03_17

25. Epicentro L'infezione da SARS-CoV-2 in gravidanza: studio prospettico dell'Italian Obstetric Surveillance System (ItOSS) https://www.epicentro.iss.it/coronavirus/sars-cov-2-gravidanza-parto- allattamento-studio-prospettico-itoss
26. Corsi E, Maraschini A, Perrone E, et al. The preparedness of the Italian obstetric surveillance system in the response to the emergency of the SARS-CoV-2 pandemic: methodological aspects of a population- based study. Epidemiol Prev 2020; 44 (5-6) Suppl 2:81-87. doi: 10.19191/EP20.5-6.S2.089

Translated by: Francesca Conway MD, MSC candidate London School of Hygiene and Tropical Medicine - Londra