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Joint IFFS/ ESHRE statement on COVID-19 vaccination for pregnant women and those considering pregnancy

Over the course of one year, SARS-CoV-2 (COVID-19) infection increased to over 103 million cases with over 2.2 million deaths reported worldwide by February 1, 2021 (1). While increasing numbers of new cases are still being reported in many countries and total mortality continues to rise, the successful development and year-end deployment of several vaccines targeting COVID-19 offer new hope that the pandemic can finally be contained. We are now entering a new phase of the pandemic with ongoing surges in many regions with variable and inconsistent implementation of mitigation strategies (social distancing, protective personal equipment, and frequent handwashing) while massive vaccination programs are now being undertaken.

The pandemic has imposed unique challenges for risk and mitigation counseling for women who are planning pregnancy or recently have conceived. Since the factors driving the spread and ultimate containment of COVID-19 are impacting countries differentially, it is not possible to make universal recommendations at this time. Although there is a burgeoning of relevant scientific publications, there is a paucity of rigorous, high-quality data with which to make specific recommendations regarding the management of COVID-19 in pregnancy (1). Women who contract COVID-19 during pregnancy are at increased risk for severe disease, death, and adverse pregnancy outcomes such as pre-term delivery and cesarean delivery (1-3). Several registries for pregnant women who have tested positive for COVID-19 are underway but no data have yet been released.

Several professional reproductive medicine organizations issued recommendations recently citing the recent availability of new vaccines and the possible use by pregnant women or those attempting a pregnancy. This joint statement summarizes relevant information about COVID-19 vaccination during or when attempting a pregnancy and mitigation strategies with the intent of helping health care providers and their patients make appropriate decisions.

Although recently released vaccines appear to be highly effective in preventing COVID-19 infection and severe disease and their manufacturers are planning clinical trials to include pregnant women, no data regarding the effects (safety or efficacy) of the vaccines in pregnancy have yet emerged (4-6). A small population of women who conceived in the initial clinical trials is being closely followed, and a limited amount of development and toxicity animal data offer some reassurance regarding the safety of the vaccine in pregnancy. Most of the COVID-19 vaccines initially released utilized mRNA or DNA that do not confer risk of COVID-19 infection (see Table 1 and 2). Over

100 vaccines are at various stages of development, and results have been published regarding ten of them. They employ a variety of different technologies, including the use of adenovirus vectors, messenger RNA encapsulated in lipid nanoparticles, and inactivated SARS-CoV-2 virus (7). None has been produced with live-attenuated viruses (such as rubella, rubeola, varicella and mumps vaccines) which are contraindicated in pregnancy, but the safety profile for pregnant women of SARS-CoV-2 vaccines under development is unknown for any of them. It is anticipated that more vaccines will be imminently approved. The attached tables list current recommendations for women planning to conceive and those who are pregnant or breast-feeding (See Tables 1 and 2). They will be periodically updated. While there are no known risks -other than side effects- for administering the COVID-19 vaccine in pregnancy or in breastfeeding women, the actual safety profile awaits completion of clinical trials that are imminently underway.

All countries have groups of patients reluctant to utilize vaccines. The urgency and manner in which the COVID-19 vaccines were developed have created unique concerns for this constituency. Their concerns should be acknowledged but the available evidence suggests that the potential benefits of vaccination strongly exceed the hypothetical risks.

The clinical scenarios differ among women who are considering pregnancy versus those that have already conceived.

Women who plan to conceive but are not yet pregnant have the following options:

- Defer pregnancy until steps to effectively mitigate the risk of the pandemic have been undertaken (i.e. substantially reduced virus transmission or availability of vaccines and ready access to prenatal care). In areas with ineffective control of the pandemic and limited current resources for vaccination, this may represent a preferable option.
- Proceed with efforts at conception, continue with mitigation measures and seek a COVID-19 vaccination as soon as possible. Concerns regarding the ability of the local public health infrastructure to continue providing access to optimal antenatal and delivery care when critical care resources are diverted to managing patients with acute, severe coronavirus infections should also be considered when making recommendations.

Each choice offers potential benefits and risks. The first option may pose the least risk but may not be the best option for women with a shorter reproductive horizon. The second option may be undertaken if the patient decides that the potential benefits of proceeding with vaccination outweighs the COVID-19 infection risks cited for her current time and place.

Those women who are currently pregnant face the following choices:

- Continue all established mitigation strategies and defer COVID-19 vaccination until after pregnancy.

- Seek a COVID-19 vaccine as soon as possible and continue established mitigation strategies including social distancing, mask-wearing, and hand washing.

The issue of COVID-19 vaccine administration in pregnancy is currently the most contentious topic. Various professional organizations have offered guidance that has ranged from a strong endorsement of pregnant women receiving vaccination to a more cautious stance (8-15). COVID-19 vaccination is currently being offered to pregnant women at high risk for infection (e.g. primarily health care workers) in some countries such as the US, but universal recommendations have not yet emerged. However, in early 2021 a trend is emerging in which more healthcare agencies and professional societies are proposing that pregnant women be offered the vaccine when available. Prioritization strategies have been recommended for women considered to be “extremely vulnerable” by the UK’s Joint Committee on Vaccination and Immunisation (JCVI) (14). Other individuals meriting special consideration include frontline healthcare workers and others with high occupational exposure risk and those with significant co-morbidities such as respiratory, cardiovascular or renal disease; diabetes, obesity, or hypertension (12-15). Recognizing that pregnant women constitute a high-risk category but have not been identified as a high-priority group for vaccines, there have been recent appeals to specifically recruit and include them in subsequent research studies (16).

The decision to receive or decline the vaccine rests on individual risk, availability of the vaccine, and the potential recipients’ concerns regarding unknown risks of the new vaccines. Professional advice is strongly recommended both in pregnant women and those planning to conceive, particularly as knowledge and counseling are continuing to evolve.

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Table 1: Vaccine recommendations for patients planning to conceive

| | General population | Categories at social risk | Comorbidities - categories with clinical history of HIV | Contraindications | Recommended waiting time after vaccine administration (Months) |
|----------------|--------------------|---------------------------|---|-------------------|--|
| WHO1 | - | - | - | | - |
| CDC1 | R | R | R | | no waiting time |
| EMA | - | - | - | | - |
| JCVI | R | R | R | | no waiting time |
| Pfizer | - | - | - | | - |
| Moderna | - | - | - | | - |

R= recommended, NR= not recommended, MBG= may be considered, NA= non applicable, - = no advice given, ¹advice for mRNA vaccines only

Table 2: Vaccine recommendations for pregnant or breastfeeding women

| | General population | Categories at risk of exposure/ infection | Comorbidities - Categories with clinical history of HIV (independent of pregnancy) | Comorbidities (any) and pregnancy | Contraindications | Recommended waiting time for pregnancy after vaccine administration (Months) | Breastfeeding women |
|------------------------|--------------------|---|--|-----------------------------------|--|--|------------------------|
| WHO¹ | NR | MBC | MBC | - | History of severe allergic reaction/hypersensitivity to vaccine components | NA | - |
| CDC¹ | NR | R | R | R | History of severe allergic reaction/hypersensitivity to vaccine components | NA | MBC (no risk expected) |
| EMA | NR | MBC | MBC (immunocompromised) | - | History of severe allergic reaction/hypersensitivity to vaccine components | NA | MBC (no risk expected) |
| JCVI | NR | MBC | MBC | MBC | History of severe allergic reaction/hypersensitivity to vaccine components | NA | MBC |
| Pfizer | R | R | R | - | History of severe allergic reaction/hypersensitivity to vaccine components | NA | R |
| Moderna | NR | MBC | MBC | - | History of severe allergic reaction/hypersensitivity to vaccine components | NA | unknown |
| AstraZeneca | NR | MBC | MBC | - | History of severe allergic reaction/hypersensitivity to vaccine components | NA | unknown |

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