Vaccinating Pregnant and Lactating Patients Against COVID-19

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Summary of Key Information and Recommendations

COVID-19 vaccine development and regulatory approval are rapidly progressing. Thus, information and recommendations will evolve as more data are collected about these vaccines and their use in specific populations. This Practice Advisory is intended to be an overview of currently available COVID-19 vaccines and guidance for their use in pregnant and lactating patients.

- On December 11, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNtech mRNA vaccine (BNT162b2) for use in individuals age 16 years and older as a 2-dose regimen given 3 weeks apart. This vaccine has shown to be 95% effective at preventing COVID-19 illness after the second dose.
- On December 12, 2020, after an explicit, evidence-based review of all available data, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥16 years for the prevention of COVID-19 illness.
- ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups.
- COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP.
- 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 approved under EUA for the prevention of COVID-19 by pregnant patients. Important considerations include:
  - the level of activity of the virus in the community
  - the potential efficacy of the vaccine
  - the risk and potential severity of maternal disease, including the effects of disease on the fetus and newborn
  - the safety of the vaccine for the pregnant patient and the fetus.
- While a conversation with a clinician may be helpful, it should not be required prior to vaccination, as this may cause unnecessary barriers to access.
- Vaccines currently available under EUA have not been tested in pregnant women. Therefore, there are no safety data specific to use in pregnancy. See details about the Food and Drug Administration's (FDA) EUA process below.
- Pregnancy testing should not be a requirement prior to receiving Pfizer-BioNTech vaccine.
- Pregnant patients who decline vaccination should be supported in their decision. Regardless of their decision to receive or not receive the vaccine, these conversations provide an opportunity to remind patients about the importance of other prevention measures such as hand washing, physical distancing, and wearing a mask.
- Expected side effects should be explained as part of counseling patients, including that they are a normal part of the body's reaction to the vaccine and developing antibodies to protect against COVID-19 illness.
- The mRNA vaccines are not live virus vaccines, nor do they use an adjuvant to enhance vaccine efficacy. These vaccines do not enter the nucleus and do not alter human DNA in vaccine recipients. As a result, mRNA vaccines cannot cause any genetic changes.

COVID-19 Infection Risk in Pregnancy

Available data suggest that symptomatic pregnant patients with COVID-19 are at increased risk of more severe illness compared with nonpregnant peers (Ellington MMWR 2020, Collin 2020, Delahoy MMWR 2020, Panagiotakopoulos MMWR 2020, Zambrano MMWR 2020). Although the absolute risk for severe COVID-19 is low, these data indicate an increased risk of ICU admission, need for mechanical ventilation and ventilatory support (ECMO), and death reported in pregnant women with symptomatic COVID-19 infection, when compared with symptomatic non-pregnant women (Zambrano MMWR 2020). Pregnant patients with comorbidities such as obesity and diabetes may be at an even higher risk of severe illness consistent with the general population with similar comorbidities (Ellington MMWR 2020, Panagiotakopoulos MMWR 2020, Knight 2020, Zambrano MMWR 2020). Given the growing evidence, CDC has included pregnancy as a factor that leads to increased risk for severe COVID-19 illness (CDC). Similar to the general population, Black and Hispanic individuals who are pregnant appear to have disproportionately higher prevalence of COVID-19 infection and death (Ellington MMWR 2020, Moore MMWR 2020, Zambrano MMWR 2020). Further, risk (Zambrano MMWR 2020) of ICU admission was higher for pregnant Asian and Native Hawaiian/Pacific Islander individuals. These disparities are due to a range of social and structural factors including disparities in socioeconomic status, access to care, rates of chronic conditions, occupational exposure, systemic racism, and historic and continued inequities in the health care system.

COVID-19 Vaccines in Development

It is important to note that COVID-19 vaccine development and regulatory approval is a rapidly changing process, and information and recommendations will evolve as more data are collected about these vaccines and their use in specific populations.

Advisory Committee on Immunization Practices Recommendations

The Advisory Committee on Immunization Practices (ACIP) develops recommendations on how to use vaccines to control disease in the United States. The Committee's recommendations are sent to CDC's Director for approval. Once the ACIP recommendations have been reviewed and approved by the CDC Director and the U.S. Department of Health and Human Services, they are published in CDC's Morbidity and Mortality Weekly Report (MMWR). The MMWR publication represents the final and official CDC recommendations for immunization of the U.S. population (ACIP).

ACOG has representation on the ACIP, including on the ACIP COVID-19 working groups. On December 2, 2020 the ACIP voted to recommend that health care workers and long-term care facility residents be prioritized for vaccination in the initial deployment of COVID-19 vaccine (Phase 1a) (CDC 2020). As the availability of vaccine becomes more robust, ACIP will expand these recommendations to include additional priority populations (Phase 1b and Phase 1c).

On December 12, 2020, after an explicit, evidence-based review of all available data, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥16 years for the prevention of COVID-19 (CDC 2020). Following this vote, CDC released an MMWR outlining the recommendations. Additional clinical considerations developed by ACIP for the use of the vaccine in specific populations, including pregnant and lactating individuals, will be posted on the CDC's website shortly. Within these clinical considerations, it is expected that regarding pregnancy, CDC will state that a pregnant individual who is part of a group (e.g., healthcare personnel) recommended to receive a COVID-19 vaccine may choose to be vaccinated. A discussion with their healthcare provider can help the patient make an informed decision. Further, regarding lactation, it is expected that CDC will state that lactating individuals who are part of a group (e.g., healthcare personnel) recommended to receive a COVID-19 vaccine may choose to be vaccinated.

U.S. FDA Emergency Use Authorization and Approval

On December 11, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNtech mRNA vaccine (BNT162b2) for use in individuals age 16 years and older as a 2-dose regimen given 3 weeks apart. This vaccine has been shown to be 95% effective at preventing COVID-19 illness after the second dose.

According to the EUA Fact Sheet for Health Care Professionals, available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. The EUA Fact Sheet for Recipients and Caregivers states "If you are pregnant or breastfeeding, discuss your options with your healthcare provider".

The EUA authority allows the FDA to strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats by facilitating the availability and use of medical countermeasures needed during public health emergencies.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives (FDA 2017).

Data on the safety and effectiveness of the vaccine(s) continues to be collected during the EUA period. (FDA, 2017).

Vaccine Information and Recommendations

At the time of this publication, one vaccine developed for the prevention of COVID-19 has received EUA from the FDA. However, COVID-19 vaccines are rapidly emerging and additional EUAs are likely to materialize. ACOG will strive to update this guidance as quickly as possible while maintaining accurate, evidence-based information.

mRNA COVID-19 Vaccines

The development and use of mRNA vaccines is relatively new. These vaccines consist of messenger RNA (mRNA) encapsulated by a lipid nanoparticle (LNP) for delivery into the host cells. These vaccines utilize the body's own cells to generate the coronavirus spike protein (the relevant antigens), which, similar to all other vaccines, stimulates immune cells to create antibodies against COVID-19. The mRNA vaccines are not live virus vaccines, nor do they use an adjuvant to enhance vaccine efficacy. These vaccines do not enter the nucleus and do not alter human DNA in vaccine recipients. As a result, mRNA vaccines cannot cause any genetic changes (CDC, Zhang 2019, Schlake 2012). Based on the mechanism of action of these vaccines and the demonstrated safety and efficacy in Phase II and Phase III clinical trials, it is expected that the safety and efficacy profile of the vaccine for pregnant individuals would be similar to that observed in non-pregnant individuals. That said, there are no safety data specific to mRNA vaccine use in pregnant or lactating individuals and the potential risks to a pregnant individual and the fetus are unknown.

Side Effects

Expected side effects should be explained as part of counseling patients, including that they are a normal part of the body's reaction to the vaccine and developing antibodies to protect against COVID-19 illness. Most study participants experienced mild side effects similar to influenza-like illness symptoms following vaccination such as injection site reactions (84.1%), fatigue (62.9%), chills (31.9%), muscle pain (38.3%), joint pain (23.6%), and headaches (55.1%). In the study subgroup of persons age 18-55 years fever greater than 38°C occurred in 3.7% after the first dose and 15.8% after the second dose (FDA 2020). Most of these symptoms resolved by day 3 after vaccination. Patients should be counseled about more severe side effects and when to seek medical care. For more information and details on side effects, see Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Pfizer-BioNTech COVID-19 Vaccine from the CDC.

Pregnancy Considerations

Despite ACOG's persistent advocacy for the inclusion of pregnant individuals in COVID-19 vaccine trials, none of the COVID-19 vaccines approved under EUA have been tested in pregnant individuals. However, studies in pregnant women are planned. Data from Developmental and Reproductive Toxicity (DART) studies for the Pfizer-BioNtech COVID-19 vaccine are anticipated in mid-December, according to the manufacturer. From what has been communicated so far regarding these forthcoming data, there have not been any major safety signals identified. These animal model studies provide the first safety data to help inform the future of clinical trials in pregnancy.

Among participants of Phase II/III clinical studies in non-pregnant adults, a few inadvertent pregnancies that have occurred are being followed to collect safety outcomes.

ACOG Recommendations

Pregnant Individuals

ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups. While safety data on the use of COVID-19 vaccines in pregnancy are not currently available, there are also no data to indicate that the vaccines should be contraindicated, and no safety signals generated from DART studies for the Pfizer-BioNtech vaccine. Therefore, in the interest of allowing pregnant individuals who would otherwise be considered a priority population for a vaccine approved for use under EUA, make their own decisions regarding their health, ACOG recommends that pregnant individuals should be free to make their own decision in conjunction 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 approved under EUA 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 fetus and newborn, and the safety of the vaccine for the pregnant patient and the fetus. While a conversation with a clinician may be helpful, it should not be required prior to vaccination as this may cause unnecessary barriers to access.

Clinicians should review the available data on risks and benefits of vaccination with pregnant patients, including the risks of not getting vaccinated in the context of the individual patient's current health status, and risk of exposure, including the possibility for exposure at work or home and the possibility for exposing high-risk household members. Conversations about risk should take in to account the individual patient's values and perceived risk of various outcomes and should respect and support autonomous decision-making (ACOG 2013).

Pregnant women who experience fever following vaccination should be counseled to take acetaminophen, as fever has been associated with adverse pregnancy outcomes. Acetaminophen has been proven to be safe for use in pregnancy and does not appear to impact antibody response to COVID-19 vaccines.

Pregnant patients who decline vaccination should be supported in their decision. Regardless of their decision to receive or not receive the vaccine, these conversations provide an opportunity to remind patients about the importance of other prevention measures such as hand washing, physical distancing, and wearing a mask.

Lactating Individuals

ACOG recommends COVID-19 vaccines be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP. While lactating individuals were not included in most clinical trials, COVID-19 vaccines should not be withheld from lactating individuals who otherwise meet criteria for vaccination. Theoretical concerns regarding the safety of vaccinating lactating individuals do not outweigh the potential benefits of receiving the vaccine. There is no need to avoid initiation or discontinue breastfeeding in patients who receive a COVID-19 vaccine.

Individuals Contemplating Pregnancy

Vaccination is strongly encouraged for non-pregnant individuals within the ACIP prioritization group(s). Further, ACOG recommends vaccination of individuals who are actively trying to become pregnant or are contemplating pregnancy and meet the criteria for vaccination based on ACIP prioritization recommendations. Additionally, it is not necessary to delay pregnancy after completing both doses of the COVID-19 vaccine.

If an individual becomes pregnant after the first dose of the COVID-19 vaccine series, the second dose should be administered as indicated. If an individual receives a COVID-19 vaccine and becomes pregnant within 30 days of receipt of the vaccine, participation in CDC's V-SAFE program should be encouraged (see below for more information on CDC's V-SAFE program).

Importantly, routine pregnancy testing is not recommended prior to receiving a COVID-19 vaccine.

Health Equity Considerations and Racial and Ethnic Minority Groups

Racial and ethnic minority groups have been disproportionately affected by the COVID-19 pandemic. Individuals in racial and ethnic minority groups are more likely to have severe illness and even die from COVID-19 likely due to a range of social and structural factors including disparities in socioeconomic status, access to care, rates of chronic conditions, and occupational exposure, systemic racism, and historic and continued inequities in the health care system. Access to and confidence in COVID-19 vaccines is of critical importance for all communities, but willingness to consider vaccination varies by patient characteristics, in part due to historic injustices and systemic racism that has eroded trust in some communities of color. According to a recent Kaiser Family Foundation survey, only 50% of Black Americans compared with 65% of White Americans, would definitely or probably get vaccinated against COVID-19 even if the vaccine was free and determined safe by scientists, many citing distrust as a concern (Hamel 2020). When discussing COVID-19 vaccines with an individual who expresses concerns, it is critical to:

- Be aware of historical and current injustices perpetuated on communities of color
- Actively listen to and validate expressed fears and concerns
- Continue to support patients who decide not to be vaccinated, share resources, and encourage the continued use of prevention measures

If the patient is amenable to further discussion:

- Inform about the testing process, existing safety data and continued monitoring of safety and efficacy data on COVID-19 vaccines; there have not been shortcuts with the testing of this vaccine
- Discuss the increased incidence of infection and severe illness from COVID-19 in racial and ethnic minority groups
- Explain that individuals representing racial and ethnic minority groups were included in clinical trials (9.8% of Pfizer-BioNtech overall Phase II/III participants were Black and 26.2% were Hispanic/Latinx)

Additional Resources for Communicating with Communities of Color

- Centers for Disease Control and Prevention. Health Equity Considerations and Racial and Ethnic Minority Groups. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html. Retrieved December 13, 2020
- Chandler R, Guillaume D, Parker AG, Mack A, Hamilton J, Dorsey J, et al. The impact of COVID-19 among Black women: evaluating perspectives and sources of information [published online November 5, 2020]. Ethn Health. DOI: 10.1080/13557858.2020.1841120. Available at: https://www.tandfonline.com/doi/full/10.1080/13557858.2020.1841120. Retrieved December 11, 2020.
- Silverman E. STAT-Harris poll: the share of Americans interested in getting Covid-19 vaccine as soon as possible is dropping. STAT. October 19, 2020. Available at: https://www.statnews.com/pharmalot/2020/10/19/covid19-coronavirus-pandemic-vaccine-racial-disparities/. Retrieved December 11, 2020.
- Joint statement on ensuring racial equity in the development and distribution of a COVID-19 vaccine. Health Leads blog. October 26, 2020. Available at: https://healthleadsusa.org/communications-center/blog/joint-statement-on-covid19-vaccine-equity/ . Retrieved December 11, 2020.
- American College of Obstetricians and Gynecology. Addressing health equity during the COVID-19 pandemic. Position Statement. Washington, DC: ACOG; 2020. Available at: https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2020/addressing-health-equity-during-the-covid-19-pandemic. Retrieved December 11, 2020.

Vaccine Confidence

Vaccine hesitancy, particularly around COVID-19 vaccines, exists among all populations. When communicating with patients it is extremely important to underscore the general safety of vaccines and emphasize the fact that no steps were skipped in the development and evaluation of COVID-19 vaccines. This can be done by briefly highlighting the safety requirements of vaccines, and ongoing safety monitoring even after vaccines are made available. The following are some messages to consider using when discussing COVID-19 vaccines with patients:

Vaccines are one of the greatest public health achievements of the 20th century. Before the widespread use of vaccines, people routinely died from infectious diseases, several of which have since been eradicated thanks to robust immunization programs.

- Several vaccines have safely been given to pregnant and lactating individuals for decades.
- The rigor of COVID-19 vaccine clinical trials with regards to monitoring safety and efficacy meet the same high standards and requirements as with a typical vaccine approval process.
- While there has been a worldwide attempt to develop COVID-19 vaccines rapidly, this does not mean that any safety standards have been relaxed. In fact, there are additional safety monitoring systems to track and monitor these vaccines, including real-time assessment.
- Side effects such as influenza-like-illness can be expected with these vaccines, however this is a normal reaction as the body develops antibodies to protect itself against COVID-19. COVID-19 vaccines cannot cause COVID-19 infection. It is important not to be dissuaded by these side effects, because in order to get the maximum protection against COVID-19, patients need two doses of the vaccine.
- Safety monitoring continues well beyond the EUA administration.
  - CDC's V-SAFE: A new active surveillance smartphone-based after-vaccination health checker for people who receive COVID-19 vaccines. V-SAFE will use text messaging and web surveys from CDC to check in with vaccine recipients for health problems following COVID-19 vaccination. Information on pregnancy status at the time of vaccination and at subsequent follow up time points will also be collected. The system will provide telephone follow up to anyone who reports medically significant (important) adverse events or exposure to COVID-19 vaccines during pregnancy or periconception period.
  - Vaccine Adverse Event Reporting System (VAERS): A national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the CDC and the FDA. Healthcare professionals are encouraged to report any clinically significant adverse events following vaccination to VAERS, even if they are not sure if vaccination caused the event. In addition, we are anticipating that the following adverse events will be required to be reported to VAERS for COVID-19 vaccines administered under an Emergency Use Authorization (EUA):
    - Vaccine administration errors (whether associated with an adverse event or not)
    - Serious adverse events (irrespective of attribution to vaccination) (such as death, life-threatening adverse event, inpatient hospitalization)
    - Multisystem inflammatory syndrome (MIS) in children [if vaccine is authorized in children] or adults
    - Cases of COVID-19 that result in hospitalization or death
  - CDC's National Healthcare Safety Network (NHSN): An acute care and long-term care facility monitoring system with reporting to the Vaccine Adverse Event Reporting System or VAERS
  - Vaccines and Medications in Pregnancy Surveillance System (VAMPSS): A national surveillance system designed to monitor the use and safety of vaccines and asthma medications during pregnancy
  - FDA is working with large insurer/payer databases on a system of administrative and claims-based data for surveillance and research
  - Additional safety monitoring information can be found here: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

References

1. Advisory Committee on Immunization Practices. ACIP recommendations. Available at: https://www.cdc.gov/vaccines/acip/recommendations.html. Retrieved December 11, 2020.

2. Centers for Disease Control and Prevention. COVID-19 (coronavirus disease): people with certain medical conditions. Available at: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Retrieved December 11, 2020.

3. Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19): people with certain medical conditions. Available at: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Retrieved December 7, 2020.

4. Centers for Disease Control and Prevention. Local reactions, systemic reactions, adverse events, and serious adverse events: Pfizer-BioNTech COVID-19 Vaccine. Available at: https://www.cdc.gov/vaccines/covid-19/info-by-manufacturer/pfizer/reactogenicity.html. Retrieved December 13, 2020

5. Centers for Disease Control and Prevention. Understanding mRNA COVID-19 Vaccines. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html. Retrieved December 13, 2020

6. Centers for Disease Control and Prevention. Health equity considerations and racial and ethnic minority groups. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html. Retrieved December 13, 2020

7. Collin J, Byström E, Carnahan A, Ahrne M. Public Health Agency of Sweden's Brief Report: pregnant and postpartum women with severe acute respiratory syndrome coronavirus 2 infection in intensive care in Sweden. Acta Obstet Gynecol Scand 2020;99:819-22. Available at: https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/aogs.13901. Retrieved December 11, 2020.

8. Delahoy MJ, Whitaker M, O'Halloran A, Chai SJ, Kirley PD, Alden N, et al. Characteristics and maternal and birth outcomes of hospitalized pregnant women with laboratory-confirmed COVID-19 - COVID-NET, 13 states, March 1-August 22, 2020. COVID-NET Surveillance Team. MMWR Morb Mortal Wkly Rep 2020;69:1347-54. Available at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6938e1.htm. Retrieved December 11, 2020.

9. Ellington S, Strid P, Tong VT, Woodworth K, Galang RR, Zambrano LD, et al. Characteristics of women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status - United States, January 22-June 7, 2020. MMWR Morb Mortal Wkly Rep 2020;69:769-75. Available at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6925a1.htm. Retrieved December 11, 2020.

10. Ethical issues in pandemic influenza planning concerning pregnant women. Committee Opinion No. 563. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:1138-43. Available at: https://journals.lww.com/greenjournal/Fulltext/2013/05000/Committee_Opinion__No__563__Ethical_Issues_in.47.aspx. Retrieved December 11, 2020.

11. Hamel L, Lopes L, Muñana C, Artiga S, Brodie B. The undefeated survey on race and health. San Francisco, CA: Kaiser Family Foundation; 2020. Available at: https://www.kff.org/report-section/kff-the-undefeated-survey-on-race-and-health-main-findings/. Retrieved December 11, 2020.

12. Knight M, Bunch K, Vousden N, Morris E, Simpson N, Gale C, et al. Characteristics and outcomes of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK: national population based cohort study. UK Obstetric Surveillance System SARS-CoV-2 Infection in Pregnancy Collaborative Group. BMJ 2020;369:m2107. Available at: https://www.bmj.com/content/369/bmj.m2107. Retrieved December 11, 2020.

13. Moore JT, Ricaldi JN, Rose CE, Fuld J, Parise M, Kang GJ, et al. Disparities in incidence of COVID-19 among underrepresented racial/ethnic groups in counties identified as hotspots during June 5-18, 2020 - 22 states, February-June 2020. COVID-19 State, Tribal, Local, and Territorial Response Team. MMWR Morb Mortal Wkly Rep 2020;69:1122-6. Available at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6933e1.htm. Retrieved December 11, 2020.

14. Panagiotakopoulos L, Myers TR, Gee J, Lipkind HS, Kharbanda EO, Ryan DS, et al. SARS-CoV-2 infection among hospitalized pregnant women: reasons for admission and pregnancy characteristics - eight U.S. health care centers, March 1-May 30, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1355-9. Available at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6938e2.htm. Retrieved December 11, 2020.

15. Pfizer-BioNTech COVID-19 vaccine (BNT162, PF-07302048). Vaccines and Related Biological Products Advisory Committee briefing document. Available at: https://www.fda.gov/media/144246/download. Retrieved December 11, 2020.

16. Schlake T, Thess A, Fotin-Mleczek M, Kallen KJ. Developing mRNA-vaccine technologies. RNA Biol. 2012;9(11):1319-1330. doi:10.4161/rna.22269. U.S. Food and Drug Administration. December 11, 2020 communication to Pfizer Inc. Available at: https://www.fda.gov/media/144412/download. Retrieved December 13, 2020

17. U.S. Food and Drug Administration. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Pfizer-Biontech COVID-19 vaccine to prevent Coronavirus Disease 2019 (COVID-19). Available at: https://www.fda.gov/media/144413/download. Retrieved December 13, 2020

18. U.S. Food and Drug Administration. Fact Sheet for Recipients and Caregivers. Emergency Use Authorization (EUA) of the Pfizer-Biontech COVID-19 vaccine to prevent Coronavirus Disease 2019 (COVID-19) in individuals 16 years of age and older. Available at: https://www.fda.gov/media/144414/download. Retrieved December 13, 2020

19. U.S. Food and Drug Administration. Emergency Use Authorization of medical products and related authorities. Monitoring and reporting of adverse events. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#monitoring. Retrieved December 13, 2020

20. Zambrano LD, Ellington S, Strid P, Galang RR, Oduyebo T, Tong VT, et al. Update: characteristics of symptomatic women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status - United States, January 22-October 3, 2020. CDC COVID-19 Response Pregnancy and Infant Linked Outcomes Team. MMWR Morb Mortal Wkly Rep 2020;69:1641-7. Available at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6944e3.htm. Retrieved December 11, 2020.

21. Zhang C, Maruggi G, Shan H and Li J (2019) Advances in mRNA Vaccines for Infectious Diseases. Front. Immunol. 10:594. doi: 10.3389/fimmu.2019.00594

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