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Planning for the future of maternal immunization: Building on lessons learned from the COVID-19 pandemic

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Abstract

As the worldwide COVID-19 pandemic unfolded, the clinical and public health community raced to understand SARS-CoV-2 infection and develop life-saving vaccines. Pregnant persons were disproportionately impacted, experiencing more severe illness and adverse pregnancy outcomes. And yet, when COVID-19 vaccines became available in late 2020, safety and efficacy data were not available to inform their use during pregnancy because pregnant persons were excluded from pre-authorization clinical trials. Concerns about vaccine safety during pregnancy and

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misinformation linking vaccination and infertility circulated widely, creating a lack of vaccine confidence. Many pregnant people initially chose not to get vaccinated, and while vaccination rates rose after safety and effectiveness data became available, COVID-19 vaccine acceptance was suboptimal and varied across racial and ethnic distribution of the pregnant population. The COVID-19 pandemic experience provided valuable insights that can inform current and future approaches to maternal vaccination against.

Keywords

Vaccine; COVID-19; Maternal immunization

1. Introduction

Pregnant people represent approximately 5 % of reproductive age women and about 1 % of the total population in the U.S. at any given time [1]; yet emerging infectious disease threats during pregnancy are often underrepresented in research, data, and preparedness plans. Many infections pose unique risks to pregnant people, the developing fetus and the neonate [2]. When a new infectious disease such as COVID-19 emerges, the risks are unknown, leading to substantial fear and concern for families hoping for a healthy pregnancy and newborn. Adding to these uncertainties, new prevention and treatment options are generally unavailable for pregnant people because of the lack of early research in this population.

Over the past decade, much has been learned about protecting pregnant people and infants from infectious diseases through vaccination. The introduction of new RNA vaccines for COVID-19 demonstrated how public opinion, data, science, policy, and messaging influence maternal vaccination. The response to COVID-19 provides a case example of the processes, evolution and approach to developing new maternal COVID-19 immunization policies and implementing new maternal vaccines. We outline the approach to COVID-19 maternal immunization and provide best practices to inform current and future maternal immunization strategies.

2. Risk of COVID-19 during pregnancy, the postpartum period and among infants

Early in the pandemic, the effects of SARS-CoV-2 infection on pregnant people, pregnancy outcomes, and infants were unknown. Pregnancy status, a new data element, was requested from jurisdictions as part the U.S. COVID-19 national case report beginning in March 2020 to capture information on this segment of the population [3,4]. Despite incomplete reporting of this data element (only 25 % completion based on unpublished CDC data), by November 2020, surveillance data provided some of the first evidence that SARS-CoV-2 infection resulted in a higher risk of severe disease (i.e., intensive care unit admission, mechanical ventilation, and extracorporeal membrane oxygenation) and death for pregnant people compared to non-pregnant women of reproductive age [4]. (Fig. 1) Subsequently, pre-eclampsia and cesarean delivery were also found to be associated with severe COVID-19 [5–8]. As new COVID-19 variants emerged, adverse pregnancy outcomes continued to be

observed, including higher rates of maternal death, with the highest number of COVID-19 related pregnancy deaths occurring during the period of delta predominance [7,9] COVID-related adverse pregnancy outcomes were also identified during the period of omicron predominance [10].

While case surveillance data identified the risks of SARS-CoV-2 infection during pregnancy, pregnancy and infant outcomes were unknown because longitudinal pregnancy outcomes are not captured as part of national infectious disease surveillance and pregnancy outcomes require time to manifest. CDC's Surveillance for Emerging Threats to Mothers and Babies Network (SET-NET), CDC's surveillance network designed to collect longitudinal data on maternal, pregnancy, neonatal, and infant risks of infectious diseases, was rapidly deployed to incorporate SARS-CoV-2 infection in April 2020 [11] (Fig. 1). SET-NET helped establish the increased frequency of preterm birth with COVID-19 and the increased risks of COVID-19 in pregnant people with comorbidities [12,13]. Subsequent studies identified an increased risk of stillbirth (fetal death at gestational age ≥ 20 weeks) with severe COVID-19 most notable during the period when the Delta variant was predominant [14]. Studies of the placenta from pregnancies affected by SARS-COV-2 suggest a biologic basis for stillbirth based on pathologic findings [15–18].

The increased risks of adverse outcomes associated with SARS-CoV-2 infection extend beyond pregnancy into the postpartum period. A study from New York demonstrated maternal complications, specifically worsening respiratory status among pregnant people with COVID-19 after birth, and a higher rate of fever, hypoxia, and readmission for mothers with COVID-19 compared to mothers without. For individuals who required readmission in the postpartum period for SARS-CoV-2 infection, the average length of stay was approximately 3–4 days [19].

3. Early COVID-19 vaccination program and pregnant people

Given the known maternal and fetal risks of respiratory illnesses during pregnancy, including SARS-CoV-2 infection and influenza, the prevention of infection through vaccination is critically important during pregnancy [20,21]. Similar to other recently developed vaccines, pregnant people were initially excluded from preauthorization clinical trials of COVID-19 vaccines [22,23]. Their exclusion meant pregnant people and their healthcare providers did not have information, other than animal reproductive toxicity data and indirect data from other non-replicating vaccines, about the safety or effectiveness of these vaccines during pregnancy, at the time they were initially authorized for use in the U.S [24,25]. Instead, misinformation linking vaccines to adverse pregnancy outcomes (e.g., miscarriages) and male and female infertility began to circulate widely [26]. In fact, some authors have coined the term the "misinformation infodemic" to characterize the explosion in inaccurate information that occurred during the COVID-19 pandemic [27].

In the absence of data about mRNA COVID-19 vaccines during pregnancy, CDC worked with the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP) and other clinical and public health entities to examine the safety and effectiveness data from other vaccines during pregnancy, discussed the

mechanism of action of these new vaccines, and considered the accumulating data about the known risks of adverse outcomes associated with SARS-CoV-2 infection during pregnancy, for both mother and infant. Other non-replicating vaccines (e.g., influenza, pertussis) have not demonstrated adverse fetal effects when administered during pregnancy and have also demonstrated immune protection for the neonate [20,21,28,29]. Consistent with other infections and the well-established robust immunologic response in pregnancy with passive immunization of the fetus, early data demonstrated SARS-CoV-2 IgG antibodies in cord blood after SARS-CoV-2 infection [30,31]. However, more data were needed to establish whether maternal COVID-19 vaccination provided neonatal protection from severe SARS-CoV-2 infection.

The initial Emergency Use Authorizations (EUA) for the mRNA COVID-19 vaccines advised pregnant people to “talk to their healthcare providers” to decide whether to be vaccinated [24,25]. This placed a burden on healthcare providers to advise their patients individually, without the benefit of data defining the safety or efficacy of these vaccines to inform patient counseling. Thus, it was critical that the Advisory Committee on Immunization Practices (ACIP), in concert with ACOG, AAP and other clinical partners, agree on how to best advise healthcare providers and pregnant people. In December 2020, public health and clinical experts at the CDC, the Food and Drug Administration, ACOG, and the AAP met and discussed the available data, and determined the risk of fetal safety concerns was likely to be very low, based on the tenets of biologic plausibility and prior experience with other non-replicating vaccines. (Fig. 1) They agreed that although vaccine effectiveness data during pregnancy were not available, mRNA COVID-19 vaccines would likely have substantial maternal health benefits against severe infection and could potentially mitigate the risk of adverse pregnancy outcomes. The tenets and conclusions from this meeting were discussed at the public ACIP meeting in December 2020 for additional discussion. (Fig. 1).

As the vaccines were sequentially recommended for different groups due to vaccine supply constraints, pregnant people represented in groups recommended for COVID-19 vaccines, such as healthcare and essential workers, were included [32]. In fact, pregnant people were never explicitly excluded from CDC’s recommendations, based on the existing evidence and expert consensus, despite the absence of direct evidence on safety and effectiveness during pregnancy. CDC stated that pregnant people could be vaccinated in any trimester of pregnancy, acknowledging the lack of vaccine data for this population. Pregnant women were then given the option to have a conversation with a healthcare provider to inform their decision, although it was explicitly stated that a healthcare provider recommendation was not required for vaccination. The language in the initial CDC clinical considerations released in December 2020 stated “If pregnant persons are part of a group that is recommended to receive a COVID-19 vaccine (e.g., health care personnel or essential worker), they may choose to be vaccinated. A conversation between the patient and the patient’s clinical team might assist with decisions regarding the use of vaccines approved under EUA for the prevention of COVID-19” [32] (Fig. 1). These initial considerations balanced individual autonomy, the limited data available on safety and effectiveness of vaccines during pregnancy, the known risks of COVID-19 during pregnancy, and the safety of other non-replicating vaccines during pregnancy. Importantly, pregnant healthcare workers

and essential workers who faced occupational risks of SARS-CoV-2 infection had the opportunity to evaluate their own risk tolerance, beliefs, and values in the face of the initial uncertainty regarding vaccines during pregnancy [32–34]. As safety and effectiveness data became available for pregnant persons, the clinical considerations were revised in August 2021, to emphasize the emerging data, and concluded that there was a now a clear maternal benefit of vaccination during pregnancy [32–34] (Fig. 1).

3.1. Vaccine safety in pregnant people and infants

During the initial roll-out of the new mRNA COVID-19 vaccines under the EUA, comprehensive COVID-19 vaccine safety monitoring was conducted, leveraging existing systems and launching new ones [35]. CDC monitored reports from the Vaccine Adverse Event Reporting System (VAERS), an adverse event reporting system co-managed by CDC and FDA. VAERS can detect potential safety concerns following vaccination, including among those vaccinated during pregnancy, by capturing retrospective individual case reports. VAERS does not capture the overall number of pregnant people vaccinated and therefore is subject to reporting bias. In December 2020, CDC rapidly established and launched V-safe^{SM}, a smartphone-based active surveillance system in which vaccinated individuals could choose to participate. V-safe ascertained pregnancy status, and people who indicated they were pregnant at the time of or within 30 days of vaccination were offered enrollment in CDC's COVID-19 Vaccine Pregnancy Registry (Fig. 1) [35]. Data obtained through this registry provided the initial reassuring evidence of the safety of COVID-19 vaccines for pregnant people and their infants [23,36,37] (Fig. 1). Vaccinated pregnant participants monitored through CDC's COVID-19 vaccine pregnancy registry did not have increased rates of adverse pregnancy outcomes following mRNA vaccines when compared with baseline rates established prior to the pandemic ([23,36,37]). The safety of COVID-19 vaccines during pregnancy was also studied prospectively in the Vaccine Safety Datalink (VSD), which also provided reassurance of the safety of COVID-19 vaccines during pregnancy [35,38–40].

All data on the safety of COVID-19 vaccines during pregnancy were reviewed by the CDC's ACIP Vaccine Safety Technical (VaST) work group, a group specifically convened to evaluate emerging vaccine safety data [41]. VaST was a critical partnership to review data after the release of these new vaccines and included members who were obstetricians and gynecologists, with extensive expertise in vaccinology and maternal immunology, other ACOG representatives including those with expertise in infections and high-risk pregnancies, pediatricians, and infectious disease specialists. VaST reviewed the maternal immunization safety data from VAERS, v-safe, VSD, and the CDC COVID-19 Vaccine Pregnancy Registry on a regular basis [41]. Subsequently, multiple studies and reviews have confirmed the safety of COVID-19 vaccination [42], including a large living systematic review published in June 2023 [43].

3.2. Vaccine effectiveness during pregnancy

The study of vaccine effectiveness during pregnancy was another important component of the COVID-19 maternal vaccination program. A large retrospective cohort study of over 15,000 participants in Israel demonstrated that the Pfizer-BioNTech mRNA vaccine

administered to pregnant individuals reduced the risk of SARS-CoV-2 infection compared to the unvaccinated group [44]. An observational cohort study of 10,861 pregnant individuals vaccinated with BNT162b2 mRNA vaccine demonstrated that the vaccine is highly protective and effective in pregnant individuals [45]. In a large vaccine effectiveness study conducted in the U.S., maternal mRNA COVID-19 vaccination was associated with protection against COVID-19-associated emergency department and urgent care visits and hospitalizations, with high effectiveness during Delta variant predominance, though somewhat lower protection during Omicron variant predominance. The study also demonstrated waning effectiveness against COVID-19 illness over time with slower waning of effectiveness against serious outcomes, consistent with patterns seen among the general population [46]. These findings demonstrate that COVID-19 vaccines are effective during pregnancy and support recommendations for pregnant people to remain up to date on COVID-19 vaccination as recommended by ACIP. Additional studies have now demonstrated that COVID-19 vaccine can reduce the risk of adverse pregnancy outcomes, including stillbirth [42].

As with any vaccine administered during pregnancy, a key question is whether the vaccine protects young infants from the infection or severe disease or hospitalization through passage of maternal antibodies through the placenta. Data on COVID-19 in infants demonstrated that young infants were at risk for severe disease and hospitalization [47]. Early evidence demonstrated that vaccination against COVID-19 before and throughout pregnancy was associated with detectable maternal anti-spike IgG levels at delivery. A primary vaccination course, prior history of SARS-CoV-2 infection, and a third-trimester booster dose were associated with the highest maternal and umbilical cord antibody levels [31]. Another study demonstrated that vaccinated mothers transfer higher amounts of antibodies to the fetus, compared to antibodies produced with infection-induced immunity to SARS-CoV-2 infection [48]. While these were reassuring and consistent with the expected effects of maternal vaccination, the most important consideration was the protection from severe SARS-CoV-2 infection for infants born to vaccinated people. In a large case-control study in the Overcoming COVID network, maternal vaccination protected against COVID-19 hospitalization in infants aged < 6 months, although protection appeared highest in the first 3 months of life [49]. Maternal vaccination continued to protect infants < 6 months from hospitalization during the omicron period [50]. The timing of vaccination for maximal infant benefit must be weighed carefully against the immune protection from infection for the pregnant people and potential for reducing the risk of stillbirth and other adverse pregnancy outcomes associated with maternal infection. Given these considerations, pregnant people are recommended to stay up to date on vaccination and get vaccinated as soon as they are eligible, regardless of timing during their pregnancy, to ensure maternal, pregnancy and infant benefits are all part of the decision for vaccination.

3.3. COVID-19 vaccine uptake and the importance of partnerships

Because healthcare workers were prioritized for early COVID-19 vaccination as part of the initial vaccine roll-out in December 2020, they were among the first to evaluate their individual risk of occupational exposure to SARS-CoV-2 infection and to weigh the benefits of vaccination in the context of the unknown risks of vaccination during pregnancy

[23,36,37]. Many healthcare providers observed firsthand the devastating consequences of the infection, and healthcare workers who were pregnant were among the first who chose to get vaccinated in the first months of the vaccine program. Based on survey data, most healthcare workers desired vaccination; however, persons who were pregnant, lactating or attempting pregnancy reported more negative feelings towards vaccination [51]. Pregnant healthcare workers who were early adopters of the vaccine and who enrolled in v-safe and CDC's COVID-19 vaccine pregnancy registry provided the initial information on reactogenicity and safety of the COVID-19 vaccines during pregnancy [23,36,37]. This information proved crucial in establishing the early safety data on COVID-19 vaccines during pregnancy, a key factor that enhanced the uptake of maternal COVID-19 vaccine in the U.S. [23,36,37]. As of May 1, 2021, approximately 26 % of pregnant people in Vaccine Safety Datalink (VSD) had completed the primary series of a COVID-19 vaccine. By December 25, 2021, vaccination coverage among pregnant persons had increased to 68 %; however, this included women who were vaccinated prior to pregnancy. (Fig. 2) Vaccination with updated COVID-19 vaccines is currently low among pregnant people with approximately 16 % being up to date with recommended COVID-19 vaccines. (Fig. 3).

There are a multitude of reasons for vaccine hesitancy during pregnancy among pregnant individuals as well as initially among providers. One common misconception that has been deeply-rooted in U.S. culture is the false notion that vaccines cause autism, a mistaken belief that has circulated for decades. While there is clear and compelling evidence that vaccines do not cause autism, this notion still induces unfounded fear among pregnancy persons [52]. With regard to COVID-19 vaccine specifically, a systematic review of COVID-19 vaccine uptake among pregnant women identified some of the two key reasons for declining vaccination-mistrust in the government, and fear about the safety and side effects of COVID-19 vaccines [22]. A more recent analysis identified several themes of misinformation related to COVID-19 vaccine and pregnancy, including a risk of miscarriage, a risk of the mRNA affecting the placenta and risks of both male and female infertility, including the false notion that a vaccinated person can transfer the risk of infertility to an unvaccinated person [26]. And finally, some authors have identified therapeutic nihilism as a cause of physician hesitancy for COVID-19 vaccines during pregnancy. Therapeutic nihilism has been defined as "skepticism regarding the worth of therapeutic agents especially in a particular disease" and this notion become the prevailing approach to new vaccines and therapeutic agents after the effects of thalidomide and diethylstilbestrol use became well-known [53]. In the absence of clinical trials data related to COVID-19 vaccine during pregnancy, concerns about potential unknown effects may have allowed the perspective of therapeutic nihilism to predominate decisions about vaccination during pregnancy [53].

Vaccine uptake varied by race and ethnicity throughout the pandemic with the lowest vaccine uptake among Black individuals who were pregnant [54] (Fig. 2). Although some of the gaps in COVID-19 vaccination coverage have been reduced over time, black pregnant people, who were at a greater risk of severe outcomes from COVID-19, continue to have the lowest vaccination coverage. (Fig. 2) This disparity in vaccine uptake is likely multi-factorial, resulting from a combination of reduced vaccine access, distrust of the accelerated vaccine development pathway, distrust of the government, and other reasons for low vaccine confidence [55]. Multiple steps were taken to increase coverage and reduce

disparities among adults in racial and ethnic communities, most notably by working with partners at the national, state, local and community levels through the Partnering for Vaccine Equity Program. Activities focused on assessing community needs, building clinical and community partnerships and identifying and training trusted messengers to educate and build vaccine confidence among community members [56].

Examples of successful approaches to address vaccine hesitancy among pregnant people employed during COVID-19 included motivational interviewing; strong and consistent individual healthcare provider recommendations; clinician and public-targeted podcasts and media campaigns; the use of community, physician, and social media influencers; personal testimonials, including individual motivations as well as tragedies or regrets, related to COVID-19 vaccination; and social media campaigns to dispel misinformation [57]. One podcast hosted by ACOG, entitled “Labor of Love”, directly addressed some of the common concerns expressed by pregnant people and provided the real-world data and examples to support the vaccine recommendations produced by ACOG, CDC, and other medical organizations [58]. Internet panels conducted regularly examined barriers to vaccination over time and determined modifiable factors resulting from vaccine hesitancy. These surveys were valuable in uncovering and addressing common misperceptions [59]. Two public health messaging campaigns, “Pregnant and Protected” and “From Me, To You”, collect personal testimonials and spotlight factual information to encourage pregnant people to make informed decisions about vaccination. These campaigns, which launched in August 2023 and in January 2023, help to address vaccine hesitancy among pregnant persons across multiple vaccine platforms [60].

Several authors have suggested additional strategies to improve vaccine uptake for vaccines recommended in pregnancy, such as encouraging providers emphasize the importance of vaccination to protect the fetus or newborn during vaccine counselling [52], and directly targeting the root causes of physician vaccine hesitancy [53]. To address the root causes of physician hesitancy, Chervenak and colleagues make a strong ethical case that because COVID-19 vaccination for pregnant women should be considered as standard of care, providers should be required to document their vaccine recommendation in the patient’s medical chart and revisit the issue of vaccination at subsequent visits for patients who decline [53]. Finally, to address the rapid the spread and strong foothold of vaccine misinformation, Berkowitz and Vann recommended improving information regulation on social media through community standards, surveillance algorithms, and adding warning labels to potentially misleading posts. In addition, they suggest that organizations implement health misinformation policies, standardize community strategies, provide resources to debunk misinformation, and educate individuals on the early identification of misinformation [26].

Throughout the pandemic, CDC worked closely with clinical partners to discuss the emerging evidence regarding the risks and benefits of vaccination of pregnant people. Beginning in March 2020, CDC engaged weekly with ACOG, specifically with the established Immunization, Infectious Disease, and Public Health Preparedness workgroup consisting of national experts in maternal infections, vaccinology, maternal immune response, and emergency response. This collaboration was of the utmost importance

when safety data were scarce and surveillance data were pointing to a substantial risk of COVID-19 for pregnant people and an increased risk of adverse pregnancy outcomes. The workgroup became even more important as data emerged from the CDC COVID Vaccine Pregnancy Registry and other vaccine safety platforms. These partnerships provided ongoing opportunities to evaluate the new evidence in real time and align recommendations across the public health and clinical community, to ensure consistent messages for the pregnant population and their healthcare providers [41]. In addition, ACOG regularly convened their CDC-funded Maternal Immunization Task Force with members from American College of Nurse Midwives (ACNM), Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN), American Association of Family Physicians (AAFP), Nurse Practitioners for Women's Health (NPWH), and the Society for Maternal-Fetal Medicine (SMFM) to ensure organizations could share information and align messaging. A key success of this Task Force is that pregnant people received the same messages about the benefits of COVID-19 vaccines from any provider they visited. ACOG also led a national effort to request that other organizations align their recommendations with those of CDC and ACOG. In February 2021, 20 professional medical organizations signed a letter indicating their support for pregnant persons having access to COVID-19 vaccines (Box 1, Fig. 1). In July 2021, ACOG and the SMFM released a joint statement affirmatively recommending COVID-19 vaccination for all pregnant and postpartum individuals [61]. (Fig. 1) This statement was promptly followed by a similar statement from CDC. (Fig. 1) These recommendations were widely disseminated across multiple communication platforms, received extensive national media coverage and were a clear and compelling example of the impact of clear, coordinated consistent messaging. Strong partnerships across clinical organizations, public health entities, federal, state and local partners and with the media that are built prior to public health emergencies are key to the rapid dissemination of reliable, trustworthy health information [27].

Broader efforts in partnership at the national, state, local, and community levels were critical to implement COVID-19 vaccination programs and those are highlighted elsewhere in this supplement [62]. All levels of partnership were vital; however, the success of COVID-19 vaccination to decrease disparities among adults overall would not have been possible without extensive clinical partnerships, direct community engagement, and ongoing partnerships with community-based organizations. Many of these partners are trusted messengers in their communities and amplified and tailored messages around the safety and importance of maternal COVID-19 vaccination, while recognizing that disparities by race and ethnicity for this population remain [58]. Given the rapid rise in misinformation, during future public health emergencies, exploration of partnerships with social media companies may improve the accuracy of health information available to the public and may curtail some of the challenges that occur when inaccurate information is widely available [27].

3.4. Best practices to inform the future of maternal immunization

Pregnant people and their families face a disproportionate burden of uncertainty and fear during new infectious disease outbreaks because of the unique nature of pregnancy. While COVID-19 affected the entire population, the inherent complexities of pregnancy, combined with the known maternal risks of respiratory diseases such as influenza, combined

with the lack of information about the safety and efficacy of vaccines presented major challenges. In the absence of data, misinformation circulated, and distrust grew, preventing widespread vaccine acceptance among pregnant people. Unvaccinated pregnant people died and stillbirths occurred [9,14,15,58]. The preponderance of misinformation around pregnancy was related to unfounded concerns about fetal risks following vaccination and concerns about the effects of vaccines on future fertility [26]. As a result of the COVID-19 maternal immunization experience several groups have put forth calls to action to galvanize a more concerted effort around maternal immunization programs, including the FIGO Committee on Infections During Pregnancy [63]. Based on our experience during the COVID-19 pandemic, we believe it is critically important to ensure the early and ongoing success of maternal immunization by: 1) maintaining robust disease surveillance systems to determine the specific risks to pregnant people, their pregnancies and their infants; 2) promoting the inclusion of pregnant people in research and surveillance protocols; 3) rapidly collecting and examining vaccine safety and effectiveness data, and reviewing with relevant experts and clinical partners who are primarily responsible for the care of pregnant people; 4) developing consistent messaging across partners and updating the messages as data evolve; and 5) fortifying sustainable relationships with community-level partners to inform CDC and help disseminate information in culturally-competent ways. We have provided specific a detailed list of best practices for maternal immunization derived from the experience with the COVID-19 (Box 2) [26].

While the initial ACIP recommendations for COVID-19 vaccines did not exclude pregnant people and initial guidance clearly stated that pregnant healthcare workers could be vaccinated, providers were unsure if a consultation was needed prior to vaccination, or if the vaccine was recommended for pregnant individuals because of the lack of safety and efficacy data. Over time, as the safety data in pregnant people became available, and the benefits of COVID-19 vaccination among pregnant people was defined, communications about the available data and the benefits and safety of the COVID-19 vaccines during pregnancy was strengthened. Given that recommendations require a strong evidence base, and safety and efficacy data during pregnancy were lacking, misinformation rapidly spread. Initial studies regarding safety and efficacy of vaccines need to include pregnant people to ensure health care providers and public health practitioners have the necessary data to inform maternal vaccination recommendations. Planning for new immunizations and future pandemic, including the collection of pregnancy data, will ensure this population has appropriate access to and uptake of vaccines that could save lives and prevent adverse pregnancy outcomes.

While COVID-19 vaccine and other vaccine uptake during pregnancy during the pandemic was and remains suboptimal [55,57,64], a recent metanalysis identified a strong association between acceptance of other vaccines, including influenza and/or Tdap, with COVID-19 vaccine acceptance [65]. In addition, the availability of COVID-19 vaccines in the prenatal setting is highly associated with administration [57]. The interplay between acceptance of different vaccines during pregnancy is a key consideration as the number of vaccines recommended during pregnancy continues to grow. Low vaccination coverage among pregnant people remains a major public health concern, not only for COVID-19, but for influenza and Tdap [55,64].

Partnership between public health and clinical organizations dedicated to the care of pregnant people and infants is essential during public health emergencies. Clear, consistent messaging regarding the available scientific evidence and informed, expert opinion can minimize the impact of misinformation. Vaccine discussions benefit from a balanced approach, one that emphasizes both the disease risks and the benefits of vaccination to the pregnant person, the pregnancy, and the fetus and infant. In the early stages of a new vaccine roll-out, the expert opinions of OBGYNs, pediatricians, infectious disease experts, and vaccinologists may play a large role in decision-making, before a large evidence base is available. Ensuring unfettered access to vaccination for pregnant people, without the requirement of a physician note, is important, even in the absence of perfect data. Based on the experience with COVID-19 vaccine, capturing data from early adopters of vaccination during pregnancy can inform evolving recommendations and improve vaccine acceptance. Transparent and timely communication to the public and to health care providers, including forecasting the expected evolution in recommendations as more data accumulate, can generate more public trust from the onset and throughout a pandemic. Expert scientists, public health and clinical partners working together on maternal workgroups can examine the emerging data rapidly. Consistent processes of including obstetricians and gynecologists and pediatricians throughout vaccine discussion can inform national maternal vaccination policies and can assist in the assessment of emerging safety data during public health emergencies. Continuous monitoring of the public perception of maternal vaccines through social media and other channels can provide information on facilitators and barriers to maternal vaccine acceptance. Non-traditional community partnerships that engage pregnant people could also be beneficial, particularly if the partnerships are tailored to the needs and infrastructure of the community. Finally, as the number of vaccines offered during pregnancy increases and maternal immunization is increasingly relied upon to protect mothers, pregnancies and infants, we need to examine how this effects vaccine acceptance and implementation. Strategies to successfully communicate recommendations for multiple vaccines during pregnancy are needed. Lessons learned from previous infectious disease outbreaks can inform best practices and standardized protocols for data collection and maternal immunization policies that protect pregnant people and infants from vaccine preventable diseases.

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No data were used for the research described in the article.

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Box 1

List of Organizations that Endorsed COVID-19 Vaccination During Pregnancy

Sponsors:

American College of Obstetricians and Gynecologists (ACOG)

Co-sponsors:

American Academy of Family Physicians (AAFP)

American College of Nurse-Midwives (ACNM)

Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN)

Endorsed by:

American Academy of Pediatrics (AAP)

American Academy of Physician Assistants (AAPA)

American College of Physicians (ACP)

American Medical Association (AMA)

American Pharmacists Association (APhA)

American Public Health Association (APHA)

Association of Immunization Managers (AIM)

Immunization Action Coalition (IAC)

Infectious Diseases Society of America (IDSA)

Infectious Diseases Society for Obstetrics and Gynecology (IDSOG)

National Association of County and City Health Officials (NACCHO)

National Association of Chain Drug Stores (NACDS)

National Foundation for Infectious Diseases (NFID)

National Medical Association (NMA)

National Association of Nurse Practitioners in Women's Health (NPWH)

Society for Maternal-Fetal Medicine (SMFM)

Vaccinate Your Family (VYF)

Box 2

Best Practices for the Future of Maternal Immunization

Maternal Child Health Surveillance and Vaccine Data.

- Capture pregnancy status as a component of routine public health case surveillance of infectious diseases and add pregnancy status to other disease-specific surveillance systems
- Maintain and expand the Surveillance for Emerging Threats to Mothers and Babies Network and other maternal child health surveillance systems to ensure high priority infectious diseases and maternal, pregnancy and infant outcomes are monitored and the system is ready for future public health emergencies
- Leverage large electronic health data systems and other administrative data to assess the risk of rare outcomes during pregnancy and create linkages between maternal and infant records
- Maintain safety surveillance systems that rapidly collect maternal, pregnancy and infant outcomes, collect or link data to measures related to social determinants of health, and include denominator data to characterize the frequency proportion of the pregnant population and infants experiencing adverse events.
- Provide accurate and timely information on any observed risks associated with new vaccines and disseminate information rapidly to the public and dispel misinformation
- Consider vaccination data implementation and data needs for pregnant individuals and their infants across different vaccine platforms and diseases during pregnancy to ensure information is patient-centered
- Improve pregnancy status reporting at the time of vaccination in all vaccination venues, including pharmacies, to determine the true number of individuals vaccinated during pregnancy and disseminate this information publicly

Clinical Recommendations for Vaccines during Pregnancy.

- Advocate for the inclusion of pregnant persons in early clinical trials of vaccines as well as other preventive and therapeutic agents
- Provide clear rationale for maternal vaccine recommendations and, in the absence of clinical trial data, use the tenets of biologic plausibility, subject expert experience and indirect evidence of other vaccines to determine initial recommendations and ensure systems are in place to capture data of early vaccine uptake and outcomes
- Forecast clearly that recommendations may change as more data accumulate and if recommendations change, share scientific rationale

- Institute an ACIP maternal vaccination workgroup to develop consistent processes for evaluation of maternal vaccine data and recommendations acorss vaccine platforms
- Ensure that fetal safety is considered as one factor in risk–benefit discussions regarding maternal vaccination, but not the only factor in decision-making about maternal vaccination
- Ensure maternal, pregnancy and infant risks and benefits related to the infectious disease are considered in risk–benefit analyses of new vaccines
- Ensure equitable access to vaccines for pregnant people, at convenient times and locations, without requirements for a documented physician or healthcare provider recommendation
- Include pregnant people in the process of developing vaccine recommendations

Partnerships & Communications.

- Actively partner with key community-based and other organizations to examine data and develop and promote consistent recommendations
- Assess and address barriers to vaccine uptake and embrace a multi-pronged media and social media focused approach to address vaccine hesitancy and vaccine misinformation
- Facilitate and expand partnerships with clinical, public health, and community-based organizations. Include leaders and trusted messengers with lived experience from communities who suffer health inequities including vaccination disparities to represent and understand the needs of pregnant persons and families.

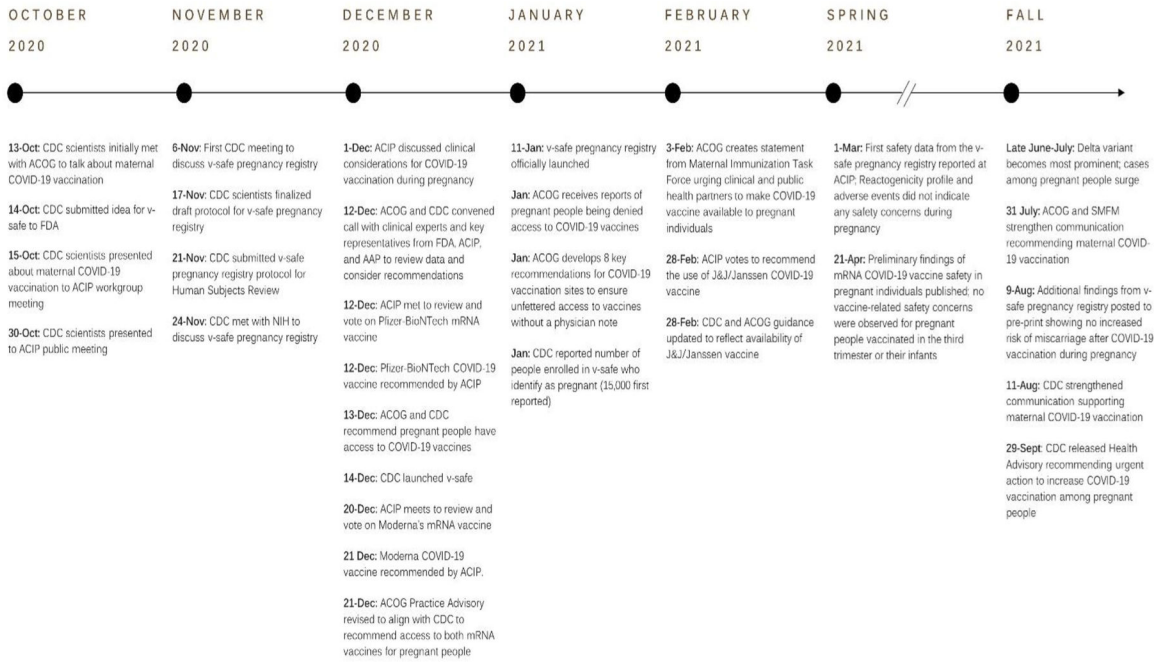

Fig. 1.

Timeline for COVID-19 Maternal Immunization: adapted from ACOG timeline with permission from original author Sarah Carroll.

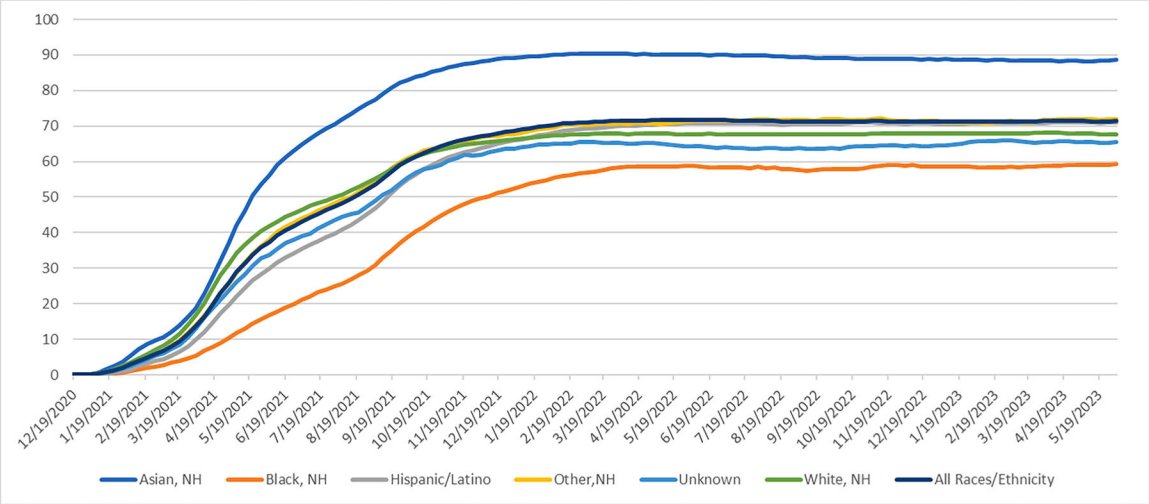

Fig. 2.

Percent of pregnant people ages 18–49 years who completed the primary series* of COVID-19 vaccine before or during pregnancy overall, by race and ethnicity, and week ending date-Vaccine Safety Datalink**, December 14, 2020-May 19, 2023.

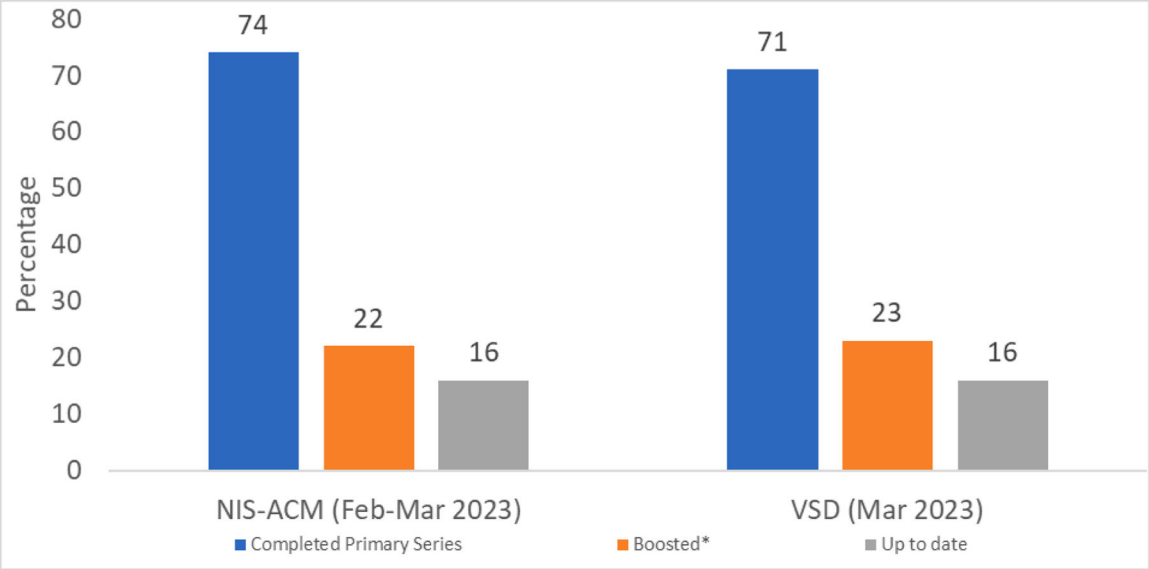

Fig. 3.

Percentage of pregnant people who have received COVID-19 primary vaccine series and bivalent booster based on data from two different sources as of March 2023: National Immunization Survey and Vaccine Safety Datalink.