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EDITORIAL

Updated Joint Position Statement on Vaccines From the Society for Birth Defects Research and Prevention and the Organization of Teratology Information Specialists

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1 | Introduction

In April of 2020, the Society for Birth Defects Research and Prevention (BDRP) and the Organization of Teratology Information Specialists (OTIS) published a joint position statement acknowledging the critical role that vaccines play in improving health, including the health of pregnant persons and their children (Rasmussen, Kancherla, and Conover 2020). Since the publication of that statement, new information has emerged that has prompted an update to our 2020 position statement, including additional data that further substantiate the value provided by vaccines, and the availability of two new vaccines to protect pregnant persons and their infants from infectious disease. Challenges to vaccination have increased, with the COVID-19 pandemic leading to a rapid escalation of vaccine misinformation spread online. These challenges have led to declining vaccination rates, which threaten decades of improvements in health (Marks and Califf 2024). Therefore, we have updated our statement to provide our organizations' continued support for vaccination as an essential strategy to protect the health of pregnant persons and their children.

Since our previous position statement, evidence has continued to accumulate regarding the value of vaccinations in reducing morbidity and mortality. A global modeling study estimated that vaccination averted 154 million deaths between 1974 and 2024, including 146 million deaths among children under 5 years of age, with 101 million of those being infants less than 1 year of age. The authors noted that measles vaccination was responsible for the greatest number of lives saved during this time period (93.7 million), accounting for 60.8% of the total (Shattock et al. 2024). Specific to COVID-19, which was excluded from the previous modeling study, an analysis demonstrated that COVID-19 vaccination prevented 14.4 million deaths in the first year that vaccines were available (Watson et al. 2022).

Additional data in support of human papillomavirus (HPV) vaccination have also been published. The clinical trials supporting approval of the quadrivalent HPV vaccine demonstrated its efficacy in the prevention of high-grade cervical lesions, which are precursors to cervical cancer (Future II Study Group 2007). More recent data have gone further to document the vaccine's ability to prevent cervical cancer. In a study in Sweden of nearly 1.7 million participants, vaccination of girls before the age of 17 years with the quadrivalent HPV vaccine was associated with a nearly 90% reduction in cervical cancer incidence compared to those who had not been vaccinated (Lei et al. 2020).

Of particular interest to our societies, global progress toward elimination of rubella and congenital rubella syndrome, a constellation of birth defects caused by rubella infection during pregnancy, continues. During 2012–2022, the percentage of the world's infants vaccinated against rubella increased from 40% to 68%, and the global incidence of rubella declined by 81% between 2013 and 2021 (Ou et al. 2024). As noted by the European Centre for Disease Prevention and Control, "...vaccines stand as one of the most remarkable achievements in public health of the 20th century" (European Centre for Disease Prevention and Control 2024).

2 | New Recommendations for Vaccines During Pregnancy

Since publication of our previous position statement, two new vaccines have become available that, when administered during pregnancy, provide protection to the infant. The first one is the COVID-19 vaccine. Early in the COVID-19 pandemic, data demonstrated that pregnant persons with COVID-19 were at higher risk of being admitted to an intensive care unit (ICU), requiring mechanical ventilation, receiving extracorporeal membrane oxygenation, and of dying, compared with nonpregnant women of childbearing age (Allotey et al. 2020; Zambrano et al. 2020). Having COVID-19 during pregnancy increased the chance of pregnancy complications, including preterm delivery, stillbirth, preeclampsia, and the need for emergency cesarean delivery (DeSisto et al. 2021; Jering et al. 2021; Karasek et al. 2021). Vertical transmission of SARS-CoV-2 is possible, but has been infrequently reported (Jeganathan and Paul 2022). COVID-19 infection in young infants also poses a risk, with research demonstrating that aside from adults ≥ 75 years of age, infants < 6 months of age have the highest rate of COVID-19-associated hospitalization (Havers et al. 2024). Among children hospitalized for COVID-19, 20.3% required ICU admission, with most children admitted to the ICU not having comorbidities (Zerbo et al. 2024).

The Centers for Disease Control and Prevention (CDC) recommends COVID-19 vaccination for everyone over the age of 6 months, noting that vaccination is especially important for groups with risk factors for severe COVID-19, which includes pregnant persons (Centers for Disease Control and Prevention 2024c). Numerous studies evaluating the safety of COVID-19 vaccines in pregnancy have found no increased risk of spontaneous abortion, congenital anomalies, preterm birth, small for gestational age, stillbirth, admission to a neonatal intensive care unit (NICU), or neonatal death when a COVID-19 vaccine is given at any time in pregnancy (Badell et al. 2022; Denoble et al. 2024; Jorgensen et al. 2023; Kharbanda et al. 2024; Lipkind et al. 2022; Zauche et al. 2021).

In addition to reassuring safety data, when a COVID-19 vaccine is administered during pregnancy, protection is conferred to both the pregnant person who is vaccinated and the infant. Infants born to persons who are vaccinated during pregnancy have been shown to have some protection against COVID-19 for the first few months of life, with research demonstrating a significantly reduced risk for COVID-19-related hospitalization among infants aged < 6 months when a COVID-19 vaccine is received in pregnancy (Halasa et al. 2022). These findings are particularly important because infants are not eligible for COVID-19 vaccination until they are at least 6 months old and must rely on transplacental antibody transfer for protection early in life.

The second vaccine, which has recently become available and provides protection to the infant, is the respiratory syncytial virus (RSV) vaccine. RSV is a common respiratory virus with seasonal transmission (e.g., transmission in the fall and winter in most of the United States). RSV is the leading cause of infant hospitalization in the United States, with 2%–3% of infants less than 6 months of age requiring hospitalization for RSV infection annually (Debessai et al. 2024; Hall et al. 2009; Langley and Anderson 2011; Suh et al. 2022). While there are factors that place infants at increased risk for severe disease including young age, preterm birth, congenital heart defects, chronic lung disease of prematurity, immunodeficiency, and neurologic and neuromuscular conditions (Committee on Infectious Diseases et al. 2024), most infants and young children hospitalized for RSV infection have no underlying conditions (Hall et al. 2013).

In 2023, the US Food and Drug Administration (FDA) approved two new options for prevention of RSV in infants. The first is a maternal vaccine (RSVPreF or Abrysvo) to be given from September through January in most of the United States to pregnant persons between 32 weeks and 0 days through 36 weeks and 6 days gestation, which has been shown to reduce the risk of RSV-associated lower respiratory tract infection in infants during the first 6 months of life (Fleming-Dutra et al. 2023). The second option to protect infants from RSV is a monoclonal antibody (nirsevimab or Beyfortus) that is recommended for infants younger than 8 months of age born during or entering their first RSV season, and for infants and children aged 8–19 months who are high risk for developing RSV-associated lower respiratory tract infection and entering their second season (Jones et al. 2023). Most infants should either receive the maternal vaccine given during pregnancy or the monoclonal antibody, but not both: there is no preferential recommendation of one option over the other since both have shown to be highly effective in reducing RSV-associated lower respiratory tract illness in infants (Debessai et al. 2024). Both options should be discussed with patients during pregnancy so families can make an informed decision on how to best protect their infant from severe RSV infection.

In the Phase 3 randomized clinical trial for the RSVPreF vaccine, pregnant persons received the vaccine or placebo between 24 and 36 weeks of gestation. Preterm birth occurred in 5.7% (95% CI, 4.9–6.5) of infants born to persons who received the vaccine during pregnancy, compared to 4.7% (95% CI, 4.1–5.5) of those born to persons who received the placebo during pregnancy, a difference that was not statistically significant (Kampmann et al. 2023). Most of the preterm births were late preterm (at 34 to < 37 weeks gestation), occurred more than 30 days after vaccination, and were from a single country (Food and Drug Administration 2023; Rasmussen and Jamieson 2024). However, given the concern about a possible association with preterm birth raised by a clinical trial of a different RSV vaccine that was not approved for use in pregnancy (Dieussaert et al. 2024), FDA approval of RSVpreF was limited to use between 32 weeks and 0 days through 36 weeks and 6 days of gestation to remove the potential risk for extremely preterm or very preterm births (Rasmussen and Jamieson 2024). Newer data has provided additional reassurance on the topic of preterm birth; in a cohort study of nearly 3000 pregnant persons at two New York City hospitals, the RSVpreF vaccine was not associated with an increased risk of preterm birth (adjusted odds ratio 0.87, 95% CI, 0.62–12.20) (Son et al. 2024). CDC will monitor for vaccine-associated adverse events through its vaccine safety monitoring systems, and the manufacturer has been required by the FDA to conduct post-marketing studies including a pregnancy registry (CorEvitas 2024; Fleming-Dutra et al. 2023).

3 | Updated Recommendations for Vaccination During Pregnancy and Challenges to Vaccine Uptake

The maternal RSV vaccine and the COVID-19 vaccine add to the two previously recommended vaccines (inactivated influenza vaccine and the combined tetanus toxoid, reduced diphtheria toxoid, acellular pertussis [Tdap] vaccine) to bring the total number of vaccines routinely recommended during pregnancy to four. Several professional organizations including the American College of Obstetricians and Gynecologists (ACOG), Society for Maternal-Fetal Medicine (SMFM), American College of Nurse-Midwives (ACNM), and American Academy of Pediatrics (AAP) have endorsed CDC recommendations for these vaccines during pregnancy (American Academy of Pediatrics 2024; American College of Nurse-Midwives 2024; American College of Obstetricians and Gynecologists 2024b; Society for Maternal-Fetal Medicine 2024). However, despite their well-documented safety and effectiveness and the endorsement of leading professional organizations, uptake of these vaccines remains low. According to an internet panel survey conducted March 26–April 11, 2024, less than half (47.4%) of pregnant persons reported receiving the influenza vaccine before or during pregnancy (Centers for Disease Control and Prevention 2024b). The percent of pregnant patients receiving vaccination was lower than before the COVID-19 pandemic, when 57.5% of pregnant patients were vaccinated (during the 2019–2020 season). Nearly 60% (59.6%) of pregnant patients received the Tdap vaccine during pregnancy, an increase from 53.8% vaccinated during the 2019–2020 season. Only 30.9% of pregnant women had received an updated 2023–2024 COVID-19 vaccine before or during their pregnancy (Centers for Disease Control and Prevention 2024b).

In the internet panel survey (Centers for Disease Control and Prevention 2024b), no disparities were observed among racial or ethnic groups for influenza vaccination; however, differences in coverage rates by race–ethnicity were seen for receipt of the Tdap and the updated COVID-19 vaccines. Tdap vaccination was the lowest among non-Hispanic Black pregnant persons, with coverage among Hispanics similar to that seen in non-Hispanic Whites. The uptake of the updated COVID-19 vaccine among non-Hispanic White pregnant persons was similar to that among non-Hispanic Blacks; however, both had coverage rates lower than that seen among Hispanic pregnant persons. For all three vaccines, coverage was higher among women who had more than a college degree, compared with women who had a college degree or less. Coverage was highest among persons who reported a provider offer or referral for all three vaccines, and lowest among those who received no recommendation (Centers for Disease Control and Prevention 2024b).

The low uptake of COVID-19 vaccines during pregnancy is also a problem in other countries. In a systematic review and meta-analysis, which included 11 studies with over 700,000 pregnant persons (including data from Japan, Israel, the United Kingdom, Scotland, and the United States), only 27.5% (95% CI, 18.8%–37.0%) of pregnant persons were vaccinated against COVID-19 (Galanis et al. 2022). The most frequent reasons given for declining vaccination during pregnancy included mistrust of the government, diagnosis of COVID-19 during pregnancy, and concerns for safety and side effects of COVID-19 vaccines. Vaccine uptake was higher among those of older maternal age, among White and Asian pregnant persons (compared to Hispanic or Black race–ethnicity), those who trusted the vaccine's effectiveness, and those who feared contracting COVID-19 during pregnancy (Galanis et al. 2022).

Limited data are available on uptake of the maternal RSV vaccine, given that the vaccine was approved by the FDA recently (in August of 2023). In an internet panel survey of 678 women at 32–36 weeks gestation during September 2023–January 2024, 32.6% of pregnant persons reported receiving an RSV vaccine during pregnancy. Among 866 mothers of an infant born during August 2023–March 2024, 44.6% reported that their infant had received nirsevimab. This survey demonstrated that 55.8% of infants were protected from RSV by either maternal RSV vaccine, infant nirsevimab, or both. Provider recommendation was again associated with higher likelihood of a pregnant person receiving vaccination or an infant receiving nirsevimab (Razzaghi et al. 2024).

Guidelines have been developed to increase uptake of recommended vaccines during pregnancy. Pregnant patients should be able to have open communication with their healthcare provider and be confidently offered appropriate vaccines prior to and during pregnancy (American College of Obstetricians and Gynecologists 2024a). Healthcare providers should receive up-to-date training on vaccination and learn how to support their patient through the decision-making process (Wilson et al. 2015). It is important to ensure that time is available for providers to discuss individual patient concerns and answer questions to allow the patient to make an informed decision.

As noted above, uptake of influenza, Tdap, and COVID-19 vaccines is higher among pregnant persons who reported receipt of an offer or referral for vaccination from their healthcare provider. However, in the recent internet panel survey (Centers for Disease Control and Prevention 2024b), over 40% of pregnant patients reported not receiving a recommendation for an updated 2023–2024 COVID-19 vaccination. Similarly, over 20% of patients reported that they had not received a recommendation to receive influenza and Tdap vaccines. The ACOG has recommended that obstetricians–gynecologists and other healthcare providers develop a routine process for recommending and providing vaccines, along with stocking and administering recommended vaccines in their offices (American College of Obstetricians and Gynecologists 2019). Healthcare providers should use patient-centric language to discuss evidence-based literature regarding the known safety of vaccinations during pregnancy. Given that marginalized populations have decreased vaccination uptake, more research is needed to understand how to best reach and support these populations (Adeyanju et al. 2021).

Despite the ongoing evidence of the success of vaccines in improving children's health cited earlier, vaccination rates among children also continue to be less than optimal. Following 10 years of nationwide vaccination coverage with measles, mumps, and rubella (MMR) vaccine, diphtheria, tetanus, and acellular pertussis vaccine (DTaP), poliovirus vaccine, and varicella vaccine for close to 95% of children enrolling in kindergarten in the United States, following the COVID-19 pandemic, childhood vaccination

rates for these vaccines fell to approximately 93% for the 2020–21, 2021–22, and 2022–23 school years, and to <93% for all reported vaccines for the 2023–24 school year (Seither et al. 2024). The rate of vaccine exemptions increased from 2.6% during the 2021–2022 school year to 3.3% during the 2023–24 school year. As vaccine coverage decreases, increased outbreaks of vaccine-preventable diseases such as pertussis and measles have been observed (Mathis et al. 2024; Rubin 2024; World Health Organization 2024).

One factor that hinders efforts to reduce vaccine-preventable diseases is the threat posed by misinformation and disinformation (Ruggeri et al. 2024). Misinformation is defined as "inaccurate information that is unintentionally presented as fact," while disinformation is a form of misinformation that involves "deliberately spreading false information to cause harm" (Ruggeri et al. 2024; Whitehead et al. 2023). While misinformation and disinformation about vaccination has existed since vaccines were first developed, the COVID-19 pandemic exacerbated the problem (Whitehead et al. 2023). Additionally, the use of social media as a primary source of information allows easy dissemination of misinformation or disinformation (Puri et al. 2020). While there were attempts by some social media platforms to limit the spread of inaccurate information about COVID-19 vaccination during the pandemic, increasing circulation of and exposure to misinformation and disinformation has been linked to higher levels of vaccine hesitancy (Whitehead et al. 2023). Unfortunately, the social and political issues that became associated with the COVID-19 vaccine also resulted in reduced confidence in other vaccinations administered to children and/or adults. This continues to be a challenge as vaccine misinformation continues at a rate that can override information campaigns and other public health interventions intended to counter the false claims presented (Ruggeri et al. 2024).

4 | Progress on New Vaccines to Benefit Pregnant Persons and Their Infants

Numerous vaccines are currently in development that could provide benefit to pregnant persons and infants. Here, we focus on two vaccines that have significant potential impact on maternal and fetal health outcomes: vaccines against cytomegalovirus (CMV) and Group B streptococcus (GBS). Congenital CMV infections occur in approximately one in 200 babies in high-income countries (Khalil et al. 2024), and approximately 20% of those cases will result in birth defects or other long-term adverse outcomes (Centers for Disease Control and Prevention 2024a; Davis, King, and Kourtis 2017; Khalil et al. 2024). Prenatal CMV infection is a major cause of sensorineural hearing loss in children with estimates as high as 20% of all cases (Goderis et al. 2014). Multiple CMV vaccines are in development, with several being tested in Phase 2 or 3 clinical trials (Liberati et al. 2024). Results from a Phase 1 study for mRNA-1647 showed that CMV vaccine to successfully elicit both humoral and cellular immune responses with no serious adverse effects (Fierro et al. 2024). A Phase 3 clinical trial of the mRNA-1647 vaccine in CMV-seronegative female participants is in progress (ClinicalTrials.gov 2024).

GBS is the most common cause of newborn infections with nearly 20 million women globally estimated to be colonized, resulting in 231,000 early-onset cases and 162,000 late-onset cases in addition to 46,000 stillbirths (Goncalves et al. 2022). An estimated 91,000 infant deaths result from meningitis, pneumonia, and sepsis that result from GBS infections (Trotter et al. 2023). Although intrapartum antibiotic prophylaxis (IAP) is commonly used in high-income countries to reduce the risks from GBS, the value of a widely available and effective vaccine would significantly reduce infant deaths and stillbirths (Trotter et al. 2023). A related analysis estimated that maternal GBS vaccinations could prevent 127,000 early-onset cases and 87,300 late-onset cases (Procter et al. 2023). GBS vaccine development has shifted from monovalent and bivalent vaccines designed against polysaccharides to hexavalent conjugates and protein-based vaccines, but all have been tested in pregnant persons with two moving into Phase 3 trials (Paul et al. 2023). In a recent review of five maternal GBS vaccination trials, high variability was seen in the immune responses and maternal-to-infant antibody levels (Kokori et al. 2024). The majority of side effects were non-severe, but the authors cautioned that additional safety testing and a better understanding of the variability in response to different serotypes are needed. A wider review of clinical trials including healthy adults and pregnant persons concluded that conjugated capsular polysaccharide vaccines induced a strong immunogenic response without severe adverse effects (Bjerkhaug et al. 2024). Importantly, transfer of GBS antibodies across the placenta to the infant was documented, although the rate of transfer varied across studies.

5 | Conclusions

In summary, BDRP and OTIS continue to strongly support the use of vaccines to decrease morbidity and mortality associated with infectious diseases, including vaccine-preventable birth defects and adverse pregnancy and infant outcomes. BDRP and OTIS recognize that the spread of vaccine mis- and disinformation through social media and other sources has increased vaccine hesitancy. We will: (a) continue our efforts to educate healthcare providers and the general public about the effectiveness and safety of vaccines; (b) support the development of new vaccines, especially those that prevent infections that adversely affect maternal and child health; (c) conduct and support studies to understand ways to improve vaccine uptake and work to address barriers to the use of these important public health tools; and (d) conduct and support studies on vaccine safety surveillance and research so that public concerns about vaccine safety can be appropriately addressed.

Conflicts of Interest

S.A.R. serves on scientific advisory committees for several pregnancy registries, including registries for Harmony Biosciences, Axsome Pharmaceuticals, Biohaven Pharmaceuticals (recently acquired by Pfizer), Myovant Sciences, and Novo Nordisk. The other authors declare no conflicts of interest.

Data Availability Statement

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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