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EDITORIAL

Joint position statement on vaccines from the Society for Birth Defects Research and Prevention and the Organization of Teratology Information Specialists

In this joint position statement, the Society for Birth Defects Research and Prevention (BDRP) and the Organization of Teratology Information Specialists (OTIS) acknowledge the important role that vaccines play in improving public health, including the health of mothers and children. Vaccines have substantially reduced the morbidity, mortality, and healthcare costs associated with vaccine-preventable diseases (Centers for Disease Control and Prevention, 2011a, 2011b). Vaccines are increasingly used during pregnancy to prevent maternal infection and to provide protection for the newborn through passive immunization (Lindley et al., 2019). However, despite strong evidence related to the efficacy and safety of vaccines, vaccine hesitancy (the reluctance or refusal to vaccinate) could reverse some of the progress made. Vaccine hesitancy has led to increased outbreaks of infectious disease in the United States (Patel et al., 2019) and globally (Abad & Safdar, 2015). Pregnant women often cite concern about the effects on their fetus as a common reason for nonvaccination (Lindley et al., 2019). Addressing the drivers of vaccine hesitancy will sustain progress in public health achievements in vaccine-preventable diseases (Lo & Hotez, 2017). In addition, removal of financial barriers will be important given that uninsured children, adolescents, and adults are less likely than those who are insured to receive recommended vaccines (Chan, Chang, Erickson, & Wang, 2019; Hill, Elam-Evans, Yankey, Singleton, & Kang, 2018; Lu et al., 2018). BDRP and OTIS advocate for the continued use of vaccines to improve health, development of new vaccines, removal of barriers to vaccination in developed and developing countries including addressing drivers of vaccine hesitancy and barriers related to costs, and continued support of vaccine safety studies to address concerns raised by the public.

The effects of vaccines on public health are well documented. Vaccines are considered by the Centers for Disease Control and Prevention (CDC) to be one of the 10 great public health achievements in the United States and worldwide for 2001–2010 (Centers for Disease & Prevention, 2011a, Centers for Disease & Prevention, 2011b). Vaccination led to the eradication of smallpox, a major cause of global morbidity and mortality. In 1967, the first year of the smallpox eradication program, 43 countries reported cases of smallpox, with at least 10 million cases and 2 million deaths; in 1977, a little over 10 years later, the last known case of smallpox was reported in Somalia (Henderson, 2011). Childhood vaccination has a significant impact on childhood morbidity and mortality; an analysis performed in 2014 showed that 322 million illnesses; 21 million hospitalizations; and 732,000 deaths were estimated to be prevented by vaccines among children born during 1994–2013 over the course of their lifetimes (Whitney et al., 2014).

The development of new vaccines has led to continued disease prevention. The human papillomavirus (HPV) vaccination was first recommended for adolescent females in 2006 (recommendations were later extended to males) to prevent cervical and other HPV-associated cancers. Despite the fact that only about half of adolescents in the United States had completed the HPV vaccination series (Walker et al., 2019), substantial decreases in rates of high-grade cervical lesions (cervical cancer precursors) have been observed since the introduction of the vaccine (Benard et al., 2017; Flagg, Torrone, & Weinstock, 2016; Gargano et al., 2019). Rotavirus vaccine is another example: Gastroenteritis due to rotavirus led to up to 70,000 hospitalizations annually before the introduction of the rotavirus vaccine into the infant vaccination schedule in the United States in 2006. Since its introduction, dramatic reductions in the number of hospitalizations, emergency department visits, and physician office visits due to rotavirus have been observed in children <5 years of age (Curns et al., 2010; Shah, Tate, Steiner, & Parashar, 2016; Tate et al., 2010; Wang, Mast, Glass, Loughlin, & Seeger, 2010). Of note, decreases in rotavirus hospitalizations were seen across age groups even among persons who were too old to be vaccinated, demonstrating the indirect effect of vaccinating infants on the health of the entire population, given the importance of young children in disease transmission (Baker et al., 2019; Baker, Dahl, Cubilo, Parashar, & Lopman, 2019). These direct and indirect effects have also been observed globally (Tate et al., 2010).

Vaccination has an impact on disease among infants born to women who have been vaccinated, either through: (a) vaccines given during pregnancy for which there is decreased infant morbidity and mortality due to transplacental transmission of maternal antibodies and (b) vaccines given before pregnancy that prevent disease of pathogens that cause birth defects when a woman is infected during pregnancy. Currently, two vaccines are recommended for pregnant women in the United States by the Advisory Committee on Immunization Practices (Grohskopf et al., 2019; Liang et al., 2018): (a) the inactivated influenza vaccine and (b) the combined tetanus toxoid, reduced diphtheria toxoid, acellular pertussis (Tdap) vaccine. Pregnant women are at an increased risk of influenza-associated complications (Mertz et al., 2017). Infants younger than 6 months of age have the highest incidence of influenza-associated pediatric deaths and are unable to be vaccinated until 6 months of age (Shang, Blanton, Brammer, Olsen, & Fry, 2018). Pertussis-related morbidity and mortality are the highest among infants younger than 1 year of age (Skoff, Hadler, & Hariri, 2019), with the highest percentage of hospitalizations and deaths in infants aged younger than 2 months old (Liang et al., 2018), and the first dose of the pertussis-containing vaccine series is not recommended until 2 months of age. Vaccinating pregnant women with influenza and Tdap vaccines reduces the risk of influenza and pertussis illness among infants during the first few months of life due to transplacentally transferred antibodies, referred to as passive immunity (Campbell et al., 2018; Nunes & Madhi, 2018; Omer et al., 2018). The Advisory Committee on Immunization Practices has recommendations regarding influenza and Tdap vaccination during pregnancy: (a) Influenza vaccine is recommended for all women who are or will be pregnant during the influenza season and can be administered at any time during pregnancy (Grohskopf et al., 2019), and (b) Tdap vaccine is recommended during each pregnancy, preferably during the early part of the third trimester of pregnancy (Havers, Moro, Hunter, Hariri, & Bernstein, 2020).

Because of routine vaccination in childhood with tetanus-containing vaccines in developed countries, maternal and neonatal tetanus is rarely seen. However, maternal and neonatal tetanus remains a substantial cause of death in some developing countries (Thwaites, Beeching, & Newton, 2015). The Maternal and Neonatal Tetanus Elimination Initiative, organized by the World Health Organization (WHO) and its partners, focuses on immunization (including two doses of tetanus toxoid 4 weeks apart for pregnant women who were incompletely or never vaccinated), clean delivery and umbilical cord care practices, and surveillance (Raza & Avan, 2019). While progress has been made through this program, 14 countries have yet to eliminate maternal and neonatal tetanus (Raza & Avan, 2019).

In addition to vaccines given to women during pregnancy to improve the health of their infants through passive immunization, vaccination programs have improved infant health through the prevention of infectious diseases that result in birth defects. The best example of this is the rubella vaccination program. Rubella was considered a relatively minor infection of childhood until its teratogenicity was recognized in 1941 (Gregg, 1941). Major outbreaks of rubella in Europe and the United States in the early 1960s were followed by the births of infants with the congenital rubella syndrome characterized by cataracts and other causes of visual impairment, hearing loss, congenital heart disease, and intellectual disability. The 1964–1965 rubella epidemic in the United States is estimated to have resulted in 20,000 cases of congenital rubella syndrome and over 5,000 pregnancy terminations (Plotkin, 2001; Reef & Cochi, 2006). This outbreak led to the development of a vaccine, with the first recommendation for its use in the United States in 1969. The rubella vaccination program in the United States initially focused on the vaccination of children to decrease rubella virus circulation, later expanding to the vaccination of adolescent girls and adult women. Rubella-containing vaccine is contraindicated during pregnancy because of the theoretical risk that the attenuated virus could cross the placenta and adversely affect the fetus, although data on inadvertently exposed pregnant women have been reassuring (Centers for Disease Control, 1989; Plotkin, 2001). In 2004, data on rubella epidemiology were reviewed by an independent panel of experts, and it was determined that rubella and congenital rubella syndrome had been eliminated in the United States (Reef & Cochi, 2006).

Unfortunately, the use of vaccination to prevent birth defects has not been extended globally. A progress report published in 2019 showed that 81 (42%) of the countries in the WHO have achieved rubella elimination. The number of WHO countries with rubella-containing vaccine in their immunization schedules increased from 99 (52%) in 2000 to 168 (87%) in 2018, translating to 69% of the world's infants receiving a rubella-containing vaccine in 2018 (Grant, Desai, Dumolard, Kretsinger, & Reef, 2019).

Childhood varicella (chicken pox) vaccination also prevents birth defects. Congenital varicella infection is a rare complication of infection with varicella during the first 20 weeks of pregnancy and is characterized by cicatricial scars, neurological defects, unilateral limb defects, and gastrointestinal abnormalities (Centers for Disease Control and Prevention, 2011a; Tan & Koren, 2006). Similar to rubella vaccine, the varicella vaccine is contraindicated during pregnancy due to the theoretical risk

of passing the attenuated vaccine strain across the placenta; however, data suggest that the risk associated with inadvertent exposure is low (Wilson et al., 2008).

Vaccines that are on the horizon to decrease birth defects by preventing infectious disease include vaccines against cytomegalovirus (CMV) and Zika virus (Bialas & Permar, 2016; Diamond, Ledgerwood, & Pierson, 2019), both causes of birth defects and developmental disabilities. Other vaccines in development that would improve infant health through the prevention of infant infection include vaccines against group B streptococcal infection and the respiratory syncytial virus (RSV) (Giersing, Karron, Vekemans, Kaslow, & Moorthy, 2019; Kobayashi et al., 2019). BDRP and OTIS encourage the development of these and other vaccines with the potential to improve maternal and infant health.

Despite the evidence of the effectiveness and safety of vaccines, uptake of vaccines has been less than ideal, in part due to vaccine hesitancy. Vaccine hesitancy was identified by the WHO as one of the top 10 threats to global health in 2019 (World Health Organization, 2019). Vaccine hesitancy not only increases the risk of adding to the global burden of vaccine-preventable diseases but has the potential to reverse the progress that has already been achieved by reducing herd immunity. Individual, group, and contextual influences drive hesitancy. According to the Global Vaccine Action Plan Strategic Advisory Group of Experts on Immunization, key reasons why people hesitate to vaccinate include complacency, inconvenience in accessing vaccines, and lack of confidence. Currently, only about a third of all countries worldwide collect data on this issue, and these data show a wide variation on prevalence and what prompts vaccine hesitancy by region and country income level (World Health Organization, 2017). Guidelines to best address vaccine hesitancy emphasize trust building, active hesitancy prevention, regular national assessments of concerns, and crisis response planning (World Health Organization, 2017).

An example of vaccine hesitancy and its subsequent impact in the United States is the decrease in measles-mumps-rubella (MMR) vaccination rates below the 92–94% threshold needed to maintain herd immunity (MMR vaccination coverage was 91.5% in 2017) (Hill et al., 2018; Orenstein & Seib, 2014). Lower coverage in some communities (e.g., New York's Orthodox Jewish community) has resulted in outbreaks of measles (McDonald et al., 2019), an infection that was considered to be eliminated in the United States in 2000 (Katz & Hinman, 2004). Some of the concerns related to MMR vaccine were initially raised by a paper published in 1998, which suggested that the MMR vaccine might be associated with an increased risk for autism. The study had a small sample size and lack of controls, and many studies since that time have shown no connection (Maglione et al., 2014). The paper was retracted in 2010 by the journal because of issues with subject recruitment and financial conflicts of interest (Leask, Booy, & McIntyre, 2010). However, concerns among many parents about this possible link remain, despite overwhelming evidence to the contrary (DeStefano & Shimabukuro, 2019).

Vaccine hesitancy is also observed among pregnant women for vaccinations recommended during pregnancy. Despite recommendations by the CDC (Grohskopf et al., 2019; Havers et al., 2020) and American College of Obstetricians and Gynecologists (ACOG) (American College of Obstetricians and Gynecologists Committee on Obstetric Practice, 2018; Committee on Obstetric Practice & Emerging Infections Expert Work, 2017), uptake of influenza and Tdap vaccines among pregnant women in the United States remains low at 53.7 and 54.9%, respectively, as of April 2019 (Lindley et al., 2019). Other high-income countries report a similar phenomenon. A recent study in France reported 7.4% coverage of influenza vaccination during pregnancy, with only 25% receiving a healthcare provider recommendation for vaccination (Descamps, Launay, Bonnet, & Blondel, in press). Similarly, in Australia, 46% of mothers reported receiving the influenza vaccine and 82% reported receiving the pertussis vaccine when they were pregnant. The most common barrier to vaccination was that the vaccine was not offered in the prenatal clinic. The Australian study also found that most vaccine decision-making begins prenatally for vaccinating children postdelivery (Danchin et al., 2018). Vaccine hesitancy in low- and middle-income countries, where data are lacking, should be prioritized under global efforts such as the Advancing Maternal Immunization project and the WHO's Maternal Immunization and Antenatal Care Situation Analysis project. Vaccine hesitancy during pregnancy should be tackled at individual, provider, health system, and national levels while addressing minority groups and those with limited healthcare access (Krishnaswamy, Lambach, & Giles, 2019; Salmon, Dudley, Glanz, & Omer, 2015). In 2018, among women in the United States who did not receive the flu vaccine before or during pregnancy, about 20% declined vaccination due to a belief that the vaccine is not effective, while lack of knowledge about the need to be vaccinated during every pregnancy was cited as the most common reason for pregnant women not receiving the Tdap vaccine (Kahn et al., 2018). Healthcare provider recommendation and offer of vaccine are associated with higher vaccination coverage (Gorman, Brewer, Wang, & Chambers, 2012; Kahn et al., 2018). Effective strategies to increase vaccine coverage during pregnancy need a multipronged approach, including: (a) reminders prompting conversations and standing orders at health systems level; (b) education and training of health

professionals on vaccine efficacy, safety, benefits, and timing; and (c) education for individuals through information sharing at prenatal clinics and healthcare facilities by healthcare staff and providing referral to sites where vaccines are available (Rasmussen & Jamieson, 2019).

Healthcare providers play a role in effectively addressing vaccine hesitancy among pregnant women by emphasizing to them that not receiving influenza vaccines puts their fetus or newborn at risk of adverse outcomes (O'Leary et al., 2019). Hesitancy can be addressed at population-level immunization programs and among individuals (Bisset & Paterson, 2018). Strategies to address hesitancy at programmatic levels delve into detecting hesitancy in populations, healthcare professional knowledge and practices, effective communication, and collaboration, while strategies to address hesitancy at the individual level include not dismissing hesitancy, using clear language, reinforcing the important role of vaccination in community-level protection, and addressing pain at immunization (MacDonald, Butler, & Dube, 2018). In addition, understanding social media influences on vaccine hesitancy is equally important both in the context of childhood and pregnancy vaccinations (Getman et al., 2018; Schmidt, Zollo, Scala, Betsch, & Quattrociocchi, 2018). Vaccine hesitancy is shown to be deeply ingrained in one's perceptions, moral values, and motivation; thus, understanding root causes of vaccine hesitancy attitudes can guide vaccine promotion strategies among parents and pregnant women (Amin et al., 2017; Hornsey, Harris, & Fielding, 2018). Persuasion and education about the value of vaccines and trust in health professionals, along with a stable, accessible, and affordable supply of vaccines, have been proposed to improve vaccine uptake and prevent hesitancy (Colgrove, 2016). Policy analysis of vaccine needs among vulnerable populations, including refugees and asylum seekers, should be considered for special scenarios, and strategies should be integrated into current immunization programs to reduce vaccine hesitancy due to a uniquely different set of reasons compared to those discussed above in select populations (Giambi et al., 2019; Louka et al., 2019).

Finally, negative beliefs about vaccine safety, both outside of and during pregnancy, need to be addressed using effective strategies. In the United States, concerns about the safety of vaccines was the second most common reason why women did not receive influenza or Tdap vaccines at an appropriate time during pregnancy (Lindley et al., 2019). Strong levels of evidence support the safety of influenza and Tdap vaccines during pregnancy, including two studies conducted by the research arm of OTIS (Chambers et al., 2016; Louik et al., 2016). In a recent systematic review that identified two randomized controlled trials and 14 observational studies that included a total of 634,253 pregnant women, no associations were seen between influenza vaccines and the following outcomes: stillbirths, infant deaths, fetal growth restriction, risk of small- or large-for-gestational age births, preterm birth, low birth weight, need for mechanical ventilation at birth, respiratory distress syndrome, congenital malformations, cesarean delivery, admission to the neonatal intensive care unit, or low Apgar scores (Nasser et al., 2019). With regard to the safety of the Tdap vaccine, the systematic review by Nasser et al. (2019) identified four randomized controlled trials and 12 observational studies that included 377,432 pregnant women, and no increase in risk of maternal or newborn adverse outcomes was identified to be associated with the vaccine. While concerns have been raised about passively acquired antibodies interfering with the infant's response to their own pertussis-containing vaccine series (Zimmermann et al., 2019), the significance of small differences in antibody concentrations is unclear given that antibody levels may not directly correlate with levels of protection. In addition, no increased risk of pertussis has been seen among infants whose mothers were vaccinated during pregnancy in several studies (Campbell et al., 2018).

Healthcare providers need to be familiar with these safety data to adequately address pregnant women's concerns. When a 2017 study identified a possible association between influenza vaccination given very early in pregnancy during the 2010–2011 and 2011–2012 influenza seasons and spontaneous abortion among women who had received a pandemic H1N1 influenza vaccination the previous season (Donahue et al., 2017), ACOG developed a commentary that placed this single study in context for obstetric health providers (Sperling, Riley, & Immunization and Emerging Infections Expert Work Group, 2018). In their commentary, they emphasized the small number of subjects included in the study by Donahue et al., the previous studies that had not observed this association, and the lack of a biologically plausible mechanism for the observed association. This association between influenza vaccine and spontaneous abortion has not been seen in later studies, including one conducted by the same group during the 2012–2013, 2013–2014, and 2014–2015 seasons (Donahue et al., 2019).

In summary, BDRP and OTIS will continue to act and advocate for the use of vaccines to decrease morbidity and mortality from infectious diseases, including vaccine-preventable birth defects, and to improve the health of mothers and babies. Identifying ways to increase the use of vaccines globally (e.g., rubella-containing vaccines) is needed to extend the successes in the United States and other developed countries to the rest of the world. BDRP and OTIS will: (a) continue to educate healthcare providers and the general public about the efficacy and safety of vaccines to improve vaccine uptake and work to address

barriers to this important health intervention; (b) support the development of vaccines to prevent other causes of birth defects (e.g., CMV and Zika virus), to improve infant health (e.g., vaccines against group B streptococcal infection and RSV), and to address newly emerging infections (e.g., coronavirus disease 2019 (COVID-19); (c) support studies to understand what drives vaccine hesitancy and ways to address this issue; and (d) provide support in identifying funding for vaccine safety surveillance and research to ensure that public concerns about vaccine safety can be appropriately addressed.

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CONFLICT OF INTEREST

Dr S. A. Rasmussen is a member of the Jazz Pharmaceuticals Pregnancy Registry Advisory Committee, Teva Pregnancy Registry Advisory Committee, and the Steering Committee for the Gilenya Pregnancy Registry. She also serves as a litigation consultant on behalf of Hoffmann-La Roche for a product liability claim regarding an alleged birth defect. All other authors do not have any conflicts of interest to declare.

DATA AVAILABILITY STATEMENT

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

Sonja A. Rasmussen[1,2]
Vijaya Kancherla[3]
Elizabeth Conover[4]

[1]*Department of Pediatrics, University of Florida College of Medicine, Gainesville, Florida*
[2]*Department of Epidemiology, University of Florida College of Public Health and Health Professions and College of Medicine, Gainesville, Florida*
[3]*Department of Epidemiology, Rollins School of Public Health, Emory University, Atlanta, Georgia*
[4]*Department of Genetic Medicine, Munroe Meyer Institute, University of Nebraska Medical Center Omaha, Omaha, Nebraska*

Correspondence
Sonja A. Rasmussen, Department of Pediatrics, University of Florida College of Medicine, 1600 SW Archer Road, PO box 100296, Gainesville, FL 32610.
Email: skr9@ufl.edu

ORCID

Sonja A. Rasmussen https://orcid.org/0000-0002-0574-4928
Vijaya Kancherla https://orcid.org/0000-0002-2803-8030

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