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Vaccines in Pregnancy: A Review of Guidelines

Short Title: Vaccines in Pregnancy

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Abstract

Importance: Vaccination during pregnancy protects both the pregnant individual and the fetus from severe infectious diseases. Maternal immunization has expanded over the past decade, with new vaccines, robust safety data, and clear evidence of neonatal benefit through transplacental IgG transfer.

Objective: To summarize current evidence regarding the safety, efficacy, and clinical recommendations for vaccines administered before and during pregnancy, outline strategies to address vaccine hesitancy, and provide an updated reference of vaccines recommended and contraindicated during pregnancy.

Evidence Acquisition: Evidence synthesized from guidelines issued by the CDC, ACOG, SMFM, and major peer-reviewed publications including randomized trials, observational studies, vaccine safety surveillance systems, and meta-analyses. Literature informing disease burden, immune physiology, and perinatal outcomes associated with vaccine-preventable diseases also reviewed.

Results: Influenza, Tdap, and COVID-19 vaccines demonstrate strong maternal and neonatal protective effects with excellent safety profiles. The RSV vaccine offers additional infant protection against severe lower respiratory tract disease. Several other vaccines (e.g., hepatitis A and B, meningococcal, polio, rabies) can be administered in pregnancy when clinically indicated. Live-attenuated vaccines remain contraindicated. Maternal immunization is most effective when integrated into routine prenatal care with onsite availability. Vaccine hesitancy can be mitigated through evidence-based counseling, addressing safety concerns, and improving the provider-patient trust relationship.

Conclusion: Maternal immunization is safe, effective, and essential for preventing morbidity and mortality among pregnant individuals and infants.

Relevance: This review provides clinicians with an updated guide for counseling, administering, and optimizing vaccine use before, during, and after pregnancy.

Target Audience: Obstetricians and gynecologists, family physicians

Learning Objectives:

1. Understand the safety data, physiology, and maternal–fetal benefits of vaccines administered during pregnancy

2. Identify which vaccines are routinely recommended, recommended as needed, or contraindicated in pregnancy

3. Recognize evidence-based strategies for improving vaccine uptake and addressing vaccine hesitancy in the obstetric settings

Importance of Vaccines in Pregnancy

Pregnancy increases an individual's susceptibility to infection due to physiologic immune changes, cardiopulmonary changes, and altered cell-mediated immunity. A number of vaccine-preventable infectious diseases can have severe maternal consequences for pregnant individuals, including increased risks of hospitalization, respiratory compromise, sepsis, and mortality. Additionally, in the setting of maternal infection, the fetus can be placed at risk for both primary vertical infection and secondary pathophysiologic impacts of maternal illness, including preterm birth, fetal growth restriction, and stillbirth. These perinatal consequences are thought to be the result of innate maternal immune responses toward the pathogen, leading to inflammation and apoptosis at the maternal-fetal placental interface. Maternal immunization has been shown to provide a dual benefit: direct prevention against severe infection of the pregnant individual, which can also mitigate the risk of secondary impact on the pregnancy, along with passive immunization of the newborn via transplacental transfer of maternal IgG, as well as through breast milk, which is critical given the vulnerability of infants in the first months of life [1] . In addition, in cases of influenza and COVID-19, passive maternal antibody transfer is key in protecting at-risk newborns against these diseases, since childhood vaccines against these infections are not recommended until 6 months of age. A robust body of evidence regarding the safety and efficacy of maternal vaccination has led to endorsement by over 30 US medical societies, including ACOG, SMFM, AAP, and IDSA, supporting the critical role of routine prenatal vaccination against influenza, Tdap, COVID-19, and RSV in preventing severe maternal and neonatal illness [2][3].

Vaccine Safety in Pregnancy

Numerous large-scale experimental and real-world practice studies have provided consistent evidence demonstrating that inactivated, recombinant, toxoid, and mRNA vaccines administered during pregnancy have excellent safety profiles for both the pregnant individual and the fetus [4][5][6]. In addition, large cohort studies and surveillance systems—including the CDC's Vaccine Safety Datalink (VSD) and the V-safe pregnancy registry—have consistently shown no increased risk of congenital anomalies, miscarriage, preterm birth, fetal growth restriction, or maternal hypertensive disorders after receiving recommended vaccines during pregnancy [7][8][9]. Safety data for influenza vaccination, collected over several decades, have consistently demonstrated reductions in maternal morbidity without adverse fetal outcomes, and support its routine use in all trimesters [4][10]. Similarly, Tdap vaccination in pregnancy has been shown to be safe, with no association with stillbirth, preterm birth, or hypertensive disorders, while providing critical passive immunity to the newborn [4][11]. The introduction of novel mRNA COVID-19 vaccines was accompanied by contemporaneous safety surveillance registries, which similarly demonstrated consistent overall safety data regarding these vaccines' administration during pregnancy [6][7]. Furthermore, large recently published real-world COVID-19 vaccination reports have demonstrated no safety concerns in reports on over 700,000 pregnant women vaccinated globally and further support the neonatal benefit from maternal vaccination in pregnancy [12]. Studies in both Canada and Scandinavia also examined receipt of COVID-19 vaccine in pregnancy and found no safety concerns, along with significant reductions in severe

neonatal morbidity and mortality in infants delivered after maternal prenatal vaccination [13] [14].

National professional societies continue to affirm that recommended maternal vaccines pose no known harm and confer significant maternal and neonatal benefits, reinforcing the critical role of and the strong safety profile related to vaccination during pregnancy [2][3][15]. Live-attenuated vaccines (e.g., MMR, varicella, zoster, live attenuated influenza vaccine) remain contraindicated due to theoretical risks of fetal infection, though registries that have collated outcomes in the setting of inadvertent prenatal exposures have not shown any evidence of negative fetal impact [2][3].

Addressing vaccine hesitancy in pregnancy

A systematic review conducted by the Vaccine Confidence Project in 2012 revealed that the main barriers to vaccination in pregnancy were concerns regarding vaccine safety, beliefs that vaccines were not needed or effective, a lack of a specific recommended from a healthcare provider, low knowledge levels surrounding vaccines, issues surrounding access and cost, and a perception of conflicting advice from a variety of sources [16]. Additionally, 59% of the articles cited in the Project's report showed lower rates of vaccination among ethnic minorities [16]. A clear and definitive provider recommendation remains one of the most influential factors in vaccine uptake in adults [17][18]. Motivational interviewing has also demonstrated effectiveness in addressing ambivalence, enabling clinicians to explore pregnant patients' values and concerns while guiding them toward evidence-based decisions [19].

Importantly, and as a directly actionable and correctable variable, the availability of on-site vaccination in the clinical setting where the patient is having a medical visit has been shown to significantly reduce missed opportunities that arise when the patient needs to leave and receive a vaccine at a separate location, even a pharmacy. On-site vaccine availability has been consistently associated with improved uptake in prenatal settings [18]. Current guidelines from major public health organizations affirm that the combination of strong provider recommendation, motivational interviewing, and point-of-care vaccine access creates the most effective approach to improving maternal vaccination coverage [17][18][19]. Other examples of adjunct interventions to improve prenatal vaccination have included: offering vaccines at all visits rather than only during scheduled immunization periods, nurse-driven immunization workflows with standing orders for vaccines, reminders integrated into electronic health records, and prenatal care quality metrics aligned with vaccination rates.

Preconception vaccines

Measles, Mumps, Rubella (MMR)

Measles (rubeola) virus is a highly contagious airborne disease transmitted through respiratory droplets and aerosols. One singular case can lead to 12-18 additional infections with exposure. Most recently, the CDC has reported a 5-fold increase in measles cases nationwide from 282

cases in 2024 to 2,242 cases in 2025. Roughly 92% of these cases involved unvaccinated individuals or those with unknown vaccination status. As a result of this rise, 3 measles-related deaths were reported [20][21]. Measles infection in pregnant individuals increases the risks for pneumonia, hospitalization, and overall maternal mortality. Measles has also been associated with increased rates of spontaneous abortion, premature delivery, low birth weight, and stillbirth [20].

Mumps virus (paramyxovirus) is transmitted through contact with saliva or respiratory droplets. The main symptoms involve swelling and pain of the parotid gland, but severe cases of mumps can result in viral pneumonia, cerebellar ataxia, encephalitis. The fetal impact of mumps infection during pregnancy, in contrast, is usually benign, without evidence of teratogenicity. However, studies from the 1960s, when mumps was more prevalent, show an association between mumps infection in the 1st trimester and spontaneous abortion and stillbirth [22].

Rubella (German measles) virus is an airborne RNA virus transmitted through respiratory droplets. If rubella infection is contracted in the first trimester or early 2nd trimester, the risk of miscarriage or severe congenital rubella syndrome is greater than 50%. However, if rubella infection is acquired in the late 2nd or 3rd trimester, the risk of congenital rubella syndrome is significantly reduced, the theory being that later in gestation, the fetus begins to develop its own immune response, in addition to maternal antibodies being transplacentally transferred [23].

Congenital rubella syndrome is characterized by cardiac (ventricular septal defects, patent ductus arteriosus, pulmonic stenosis and coarctation of the aorta), ocular (cataracts), auditory (deafness), growth restriction, and neurodevelopmental abnormalities (including microcephaly, developmental delay, encephalitis, and subacute sclerosing panencephalitis) [23] [24] [25]. Delayed complications in adults include glaucoma, retinopathy, diabetes mellitus, and thyroid dysfunction [23]. These risks underscore the importance of preconception vaccination to prevent the risk of maternal infection during any trimester of pregnancy. Immunization before pregnancy provides passive immunity to the newborn via IgG transfer through the placenta and through the breastmilk after birth, reducing the risk of neonatal infection and severe outcomes. Documented immunity to rubella, measles, and mumps should be established prior to conception; if absent, vaccination is recommended [26][27].
The safety profile of the MMR vaccine in the preconception period is well-established. MMR is a live attenuated vaccine and contraindicated during pregnancy due to theoretical fetal risk, but validated data registries have shown no increased risk of major birth defects, miscarriage, or congenital rubella syndrome in women vaccinated within 28-30 days prior to conception, or in early pregnancy [28]. Based on these data, inadvertent administration in the periconceptional period is not considered to be an indication for pregnancy termination. The vaccine is well tolerated, with rare serious adverse events and mild side effects, including fever or rash [26][29]. Current guidelines recommend that all nonpregnant women of childbearing age without documented immunity receive at least one dose of the MMR vaccine at least 28-30 days before attempting conception. Healthcare providers should assess immunity status and offer vaccination to eligible patients [26][27][29]. MMR should not be administered during pregnancy, but postpartum vaccination is recommended for nonimmune women, including those who are

breastfeeding, as MMR is safe in lactating individuals and does not adversely affect neonates [27][29][30].

Serologic screening is most useful for rubella, as documentation or establishment of immunity before conception is critical in preventing congenital rubella syndrome. Rubella IgG antibody testing is the standard; the presence of rubella IgG indicates durable immunity [31]. Women of childbearing age with 1 or 2 documented doses of rubella-containing vaccine and equivocal or negative rubella IgG should receive one additional dose of MMR (maximum 3 doses). No further serologic testing is needed after the third dose [32].

For measles and mumps, immunity is typically established by documented vaccination, but IgG serology may be used if records are unavailable. However, commercial IgG assays for measles and mumps may have suboptimal sensitivity and can occasionally fail to detect preexisting immunity, so a positive result is definitive, but a negative result may not exclude immunity [31]. If a woman has 2 documented doses of measles- or mumps-containing vaccine and serology is negative or equivocal, she should still be considered immune; additional doses are not recommended [31][32].

Pregnant individuals who have been exposed to measles without documented immunity status should receive postexposure prophylaxis with intravenous immunoglobulin treatment (IVIG), at a dose of 400 mg/kg, within six days of measles exposure. If exposure occurs preconceptionally or postpartum, postexposure prophylaxis with the MMR vaccine within 72 hours of exposure should be offered [30].

Varicella

Varicella infection during pregnancy poses substantial risks to both the pregnant individual and fetus. Maternal complications include a 10-20% risk of developing varicella pneumonia, carrying a maternal mortality rate as high as 40%. The virus can also cross the placenta and lead to fetal infection, resulting in serious fetal consequences depending on the timing of maternal infection [33]. Infection during the first half of pregnancy can cause varying aspects of the congenital varicella syndrome, with 1st-trimester exposure impacting development most severely. Congenital varicella is characterized by limb hypoplasia, skin scarring, eye abnormalities, and neurological defects. When maternal infection occurs in the 3rd trimester, neonatal varicella infection is associated with high neonatal mortality rates. These severe complications underscore the critical importance of establishing immunity before conception [33]. Vaccination before pregnancy provides protection against these potentially devastating outcomes, as well as conferring passive immunity to the newborn through transplacental transfer of maternal IgG antibodies, which increases markedly during the last 4-6 weeks of gestation. Additionally, maternal IgG antibodies transferred in breast milk from vaccinated women provide additional passive immunity to the newborn [34].

Preconception varicella vaccination prevents maternal infection as well as the risk of fetal infection and complications described above, and strongly protects against serious maternal complications of illness, protecting both the mother and the fetus [34]. The vaccine provides passive immunity to newborns through maternal antibody transfer, offering protection during the

vulnerable early months of life before the infant can receive its first varicella vaccine dose, at 12 months of age. Varicella vaccine effectiveness is approximately 80% after one dose and 92-95% after two doses [34].

Data from the VARIVAX Pregnancy Registry (1995-2013) provide reassurance regarding periconceptional exposure. Among 905 pregnancies with known outcomes following inadvertent vaccination during pregnancy or within three months prior to conception, the miscarriage rate was 10% and major birth defects occurred in 2.6% of live births—rates consistent with background population estimates. Critically, no cases of congenital varicella syndrome were identified among any registry participants, and no defects consistent with congenital varicella were observed [35]. Still, the vaccine remains contraindicated during pregnancy since it is based on immunity produced in response to a live attenuated virus, though, like the MMR vaccine, can be safely administered after delivery to susceptible individuals, even while breastfeeding [35].

The American Society for Reproductive Medicine recommends that all adults planning pregnancy should be assessed for varicella immunity, defined by documentation of previous varicella infection or vaccination. Those without evidence of immunity should receive two doses of single-antigen varicella vaccine administered at least 4 weeks apart. If only one dose was previously received, a second dose should be administered [27][34]. Pregnancy should be avoided for one month after each varicella vaccination. For postexposure prophylaxis, if a nonimmune individual is exposed to varicella before pregnancy, the vaccine should be administered: ideally within 96 hours of exposure, but up to 10 days after, and pregnancy should be avoided [34][36]. Pregnant individuals found to be nonimmune should receive the first dose of varicella vaccine upon completion of pregnancy and before discharge from a healthcare facility, with the second dose administered 4-8 weeks later. The vaccine may be administered during lactation [27][33]. However, immunizations should ideally be completed prior to conception because live attenuated vaccines are contraindicated in pregnancy.

Hepatitis A

Hepatitis A virus (HAV) infection can present significant risks during pregnancy, particularly for women with underlying conditions or specific exposures. Pregnant women with chronic liver disease or HIV infection are at risk for severe outcomes from HAV infection [37]. Additionally, certain behavioral and occupational factors increase infection risk, including sexual contact, international travel, close contact with international individuals, and homelessness [37].

Vaccination during the preconception period or pregnancy prevents HAV infection in at-risk women, thereby avoiding potential severe maternal complications. By preventing maternal infection, vaccination also protects the fetus from the consequences of maternal illness and potential vertical transmission risks [37].

The Advisory Committee on Immunization Practices (ACIP) recommends hepatitis A vaccination for pregnant women when indicated, reflecting the vaccine's acceptable safety profile during pregnancy [37]. Pregnant women should be vaccinated for the same indications as nonpregnant women, indicating no additional safety concerns that would contraindicate use during pregnancy [37] (Table 1).

The ACIP recommends that pregnant women identified to be at risk for HAV infection or severe outcomes should be vaccinated during pregnancy if not previously vaccinated [37]. The HAV vaccine is administered in 2 doses with second dose 6 to 18 months after first dose (Table 1). The combined Hepatitis A and B vaccine (Twinrix®) follows a 3-dose schedule (0, 1, 6 months) or an accelerated 4-dose schedule (0, 7, 21-30 days, then a booster at 12 months). Postexposure prophylaxis (PEP) with hepatitis A vaccine is recommended for individuals age >12 months to prevent infection with hepatitis A virus (HAV) when administered within 2 weeks of exposure. Immunoglobulin (dosage 0.1 mL/kg), in addition to hepatitis A vaccine, may be administered to persons age >40 years for postexposure prophylaxis depending on risk factors [38]. Unvaccinated or partially vaccinated pregnant adolescents should receive catch-up vaccination [37]. The guidelines emphasize that pregnant women at risk should also receive counseling on additional prevention methods, such as hand hygiene [37].

Hepatitis B

Hepatitis B virus infection affects an estimated 800,000 to 1.8 million people in the United States and over 290 million worldwide, with a prevalence of 0.7% to 0.9% among pregnant individuals in the United States, resulting in more than 25,000 infants born annually at risk for chronic infection. The disease burden is particularly severe when transmission occurs perinatally, as up to 90% of perinatally exposed neonates who do not receive appropriate immunoprophylaxis will develop chronic hepatitis B infection, compared to only 5% to 10% of exposed immunocompetent adults [39]. Among all individuals with chronic HBV infection, 20% will eventually die of complications including cirrhosis, end-stage liver disease, and hepatocellular carcinoma, with chronic HBV being the major source of hepatocellular carcinoma globally. Approximately two-thirds of people with hepatitis B are unaware of their infection, and only

one-fourth of U.S. adults have received a complete hepatitis B vaccination series, highlighting the critical gap in prevention [39][40].

Universal hepatitis B vaccination provides both immediate and long-term protection for women of reproductive age and their future offspring. Vaccination prevents acquisition of HBV during pregnancy, thereby eliminating the risk of perinatal transmission, which is responsible for up to 50% of HBV infections worldwide. For women planning pregnancy, achieving immunity before conception ensures protection throughout gestation and eliminates the need for accelerated vaccination schedules during prenatal care [39]. Additionally, vaccinated women who achieve immunity can safely breastfeed without concern for transmission, as breastfeeding is recommended for HBV-infected individuals only after infant immunoprophylaxis [39].

Hepatitis B vaccination is safe and effective in pregnancy, with seroconversion rates exceeding 90%, similar to rates observed outside of pregnancy, and no vaccine-specific adverse outcomes reported across thousands of pregnancies. The vaccine contains noninfectious DNA particles and poses no known risk to the fetus. Studies have demonstrated that vaccination series completion rates are high in pregnancy due to the frequent nature of prenatal care, and an accelerated vaccination schedule (0, 1, and 4 months rather than 0, 1, and 6 months) has shown similar immunogenicity. The vaccines recommended for use in pregnancy include the 3-dose vaccines RECOMBIVAX HB (Merck), ENGERIX-B (GlaxoSmithKline), and TWINRIX (GlaxoSmithKline), which combines hepatitis A and B antigens as well as the 2-dose vaccine HEPLISAV-B. The 3-antigen vaccine PreHevbrio has insufficient data to inform use in pregnant persons [34][39] (Table 1).

The Society for Maternal-Fetal Medicine recommends hepatitis B vaccination in pregnancy for all individuals without serologic evidence of immunity or documented history of vaccination. This recommendation aligns with the 2022 ACIP guidance for universal hepatitis B vaccination in all adults aged 19 to 59 years, which removes the need for risk factor-based screening. The American Society for Reproductive Medicine recommends hepatitis B vaccine for women at high risk, including healthcare workers exposed to blood products, individuals receiving hemodialysis, intravenous drug users, those with sexually transmitted infections or multiple sexual partners, travelers to high-prevalence countries, and household contacts of infected individuals [34][39].
USPSTF recommends universal Hepatitis B screening with HBsAg with each pregnancy at the initial prenatal visit regardless of previous HBV vaccination or previous negative HBsAg test results [41]. For women with chronic HBV infection who become pregnant, vaccination against hepatitis A is recommended if they are susceptible, as coinfection poses additional hepatotoxic risks. Vaccination in pregnancy is cost-effective given the lifelong burden of disease that may be avoidable, and prenatal care represents a unique opportunity to complete vaccination series due to high compliance rates [39][40].

Tetanus, Diphtheria, Pertussis

Tetanus, diphtheria and pertussis are three bacterial infections that can lead to serious complications in adults and children. Most of the morbidity and mortality is related to pertussis, which is a highly contagious and frequently fatal illness. The majority of infants contract pertussis from infected family members and caregivers, particularly mothers and older siblings. The 2012 pertussis epidemic in the United States, with nearly 42,000 reported cases, underscored the ongoing burden of disease, with the highest incidence and most severe complications continuing to affect infants age 6 months and younger [42][43][44]. Tetanus and diphtheria, while less common due to adequate vaccination, remain serious threats. Tetanus can cause severe muscle spasms and death, while diphtheria can lead to respiratory failure, heart failure, and death. Maternal vaccination provides protection against all three diseases during the vulnerable neonatal period.

Maternal Tdap vaccination during pregnancy provides passive immunity to newborns via maternal antibody transfer through the placenta and breastmilk, offering protection during the critical first weeks of life before infants can receive their own vaccines at 2 months of age (earliest at 6 weeks). Studies demonstrate that the incidence of pertussis in infants significantly decreased following the implementation of maternal Tdap vaccination during pregnancy. Vaccine effectiveness estimates range from 91% to 93%, in several studies [45][46]. Even when maternal vaccination is not completely protective, infants whose mothers received Tdap during pregnancy experience significantly reduced morbidity, including lower rates of hospitalization and intensive care unit admission. Adequate active transport of maternal IgG occurs after 30 weeks of gestation and requires a minimum of 2 weeks to mount an immune response after receiving Tdap vaccine. Vaccinating between 27-36 weeks gestation maximizes maternal antibody response and passive antibody transfer to the fetus [42][43][47].

Tdap vaccination during pregnancy has a reassuring safety profile with no evidence of adverse fetal effects from inactivated vaccines or toxoids. A randomized controlled trial demonstrated that Tdap vaccination in the third trimester was well tolerated, with injection site and systemic symptoms in pregnant women not significantly different from those in postpartum or nonpregnant women. Additionally, no Tdap vaccine-related adverse pregnancy outcomes were observed [42][44]. A large cohort study of 16,606 pairs of Tdap recipients and unexposed pregnant women found no increased risks of fetal growth restriction, preterm delivery, rupture of membranes, stillbirth, placental abruption, or neonatal death [48]. Safety data remain reassuring even when women receive successive Tdap immunizations over relatively short intervals due to closely spaced pregnancies. Administration of Tdap with other indicated inactivated vaccines during pregnancy (such as influenza vaccine) is acceptable and safe. Tdap vaccines do not contain thimerosal, and no evidence exists suggesting any vaccine is associated with increased risk of adverse effects from trace mercury-containing preservatives [42].

The American College of Obstetricians and Gynecologists (ACOG) and the Advisory Committee on Immunization Practices (ACIP) recommend that Tdap be administered during each pregnancy, irrespective of prior history of receiving Tdap. The recommended timing is between

27 weeks and 36 weeks of gestation, with vaccination as early as possible in this window to maximize maternal antibody response and passive antibody transfer to the newborn [42][43][47]. Tdap may be safely administered at any time during pregnancy if needed for wound management, pertussis outbreaks, or other extenuating circumstances. For women who have never received Tdap and did not receive it during pregnancy, it should be administered immediately postpartum to reduce transmission risk to newborns. However, women who previously received Tdap as adolescents, adults, or during prior pregnancies but not during their most recent pregnancy should not receive Tdap postpartum [34][42]. Adolescent and adult family members and caregivers who have not previously received Tdap and who have or anticipate having close contact with an infant younger than 12 months are recommended to receive a single dose at least 2 weeks before planned infant contact [42][43].

Respiratory Virus Vaccinations

COVID

Coronavirus disease (COVID) is a respiratory infection caused by the SARS-CoV-2 virus, which emerged as a new infectious agent resulting in a global pandemic in early 2020, with ongoing case rates still currently at higher than desirable levels. Clinical severity related to COVID infection has been comprehensively described and ranges from mild or asymptomatic infection to severe respiratory compromise requiring inpatient hospitalization and critical care management. Long-term symptomatology has also been described in up to 39% of patients who recover from acute infection, but are ultimately diagnosed with "long COVID" [49][50]. Pregnancy confers increased susceptibility to novel respiratory viruses, including SARS-CoV-2, due to adaptive maternal changes in immune responses, along with alterations in cardiopulmonary physiology in pregnant patients [51].

COVID infection during pregnancy is associated with significantly increased rates of maternal morbidity and mortality. Pregnant individuals with COVID have an increased risk of veno-thromboembolism, a 5-fold higher risk of intensive care unit admission, higher risks of mechanical ventilation and need for extracorporeal membrane oxygenation, and up to a 20-fold increased risk of maternal mortality, compared to non-pregnant individuals [52][53][54]. Other severe complications of infection have also been shown to occur more frequently during pregnancy compared to morbidity in matched non-pregnant women [52][53]. COVID infection has also been associated with higher incidences of hypertensive disorders of pregnancy, including preeclampsia and eclampsia [52][53][55]. Patients with pre-existing medical comorbidities such as cardiovascular disease, diabetes, and obesity have been shown to experience even higher rates of severe COVID-related symptoms and complications [56]. COVID infection in pregnancy is not limited to maternal risk and has also been strongly associated with increased rates of neonatal morbidity and mortality. Reported adverse fetal and neonatal outcomes include a significant increase in preterm delivery, NICU admission, and severe neonatal and longer-term morbidities [52] [53][57]. Affected pregnancies also demonstrate higher rates of stillbirth, fetal growth restriction, low birthweight, low Apgar score, and perinatal mortality [53] [58]. COVID infections also result in severe illness in post-neonatal

pediatric populations, with infants younger than 6 months demonstrating the highest hospitalization rates among all pediatric age groups [59][60].

The primary aims of COVID vaccination for all patients are to mitigate the risk of an infection's progression to severe disease and to reduce rates of COVID-related hospitalizations and death [61]. Notably, while maternal COVID infection has not been associated with vertical transmission and fetal infection, increasing maternal disease severity has been strongly associated with greater neonatal risks and morbidity, particularly related to resulting spontaneous or medically-indicated preterm deliveries [57], underscoring the role of maternal vaccination in lowering the risks for adverse outcomes both for mothers and their newborns.
Current evidence unequivocally supports both the efficacy and safety of COVID vaccination during pregnancy [12][13][62][63]. Maternal vaccination has been strongly and consistently associated with reduced risks of severe COVID related illness, hospitalization, and intensive care unit admission in pregnant vaccinated patients [12][62]. Available data do not demonstrate an increased risk of adverse maternal outcomes, including hypertensive disorders of pregnancy, pulmonary embolism, postpartum hemorrhage, maternal death, or intensive care unit admission, among individuals vaccinated during pregnancy [53][64].

As previously noted, infants under 6 months of age experience the highest COVID hospitalization rates among all pediatric age groups [59][60]. Vaccination during pregnancy is particularly important because it confers passive immunity to the infant through transplacental transfer of maternal antibodies, as well as after delivery in breast milk. Vaccinated pregnant individuals demonstrate significantly higher antibody titers at delivery and in the postpartum period compared with those who acquire SARS-CoV-2 infection during the latter half of pregnancy [65]. Maternal antibody levels correlate directly with antibody titers in infants at six months of age, with the majority of exposed neonates retaining detectable antibodies, compared with fewer than 10% of infants born to mothers with infection alone [65]. Since infants are not eligible for vaccination until 6 months of age, maternal vaccination provides critical protection against COVID-19 during the first months after birth. COVID vaccination during pregnancy is associated with a reduced risk of severe SARS-CoV-2 infection requiring hospitalization in infants during the first six months of life [66] [67]. Vaccination in pregnancy has not been associated with an increased risk of pregnancy loss or stillbirth: available data, in fact, suggest a significant reduction in the risk of stillbirth in pregnancies during which the mother received a COVID vaccine [62]. Maternal COVID vaccination has not been associated with increased risks for preterm birth, small for gestational age at birth, or neonatal ICU admission [12][53] [64][68]. In addition, no associations have been identified as associated with maternal COVID vaccination in the first trimester and increased risks for congenital anomalies [69][70].

Maternal COVID vaccination continues to be associated with lower rates of neonatal morbidity and mortality compared to outcomes in infants whose mothers were not vaccinated during pregnancy in more recent studies, even after the peak of the pandemic. Infants under 6 months of age continue to be hospitalized for COVID-19 at higher rates than all age groups except adults

75 years and older [71]. In a stark demonstration of the benefits of maternal COVID vaccination, an analysis of US neonatal outcomes during the 2023-24 respiratory virus season showed that less than 5% of mothers whose infants were hospitalized for COVID-19 had been vaccinated during those newborns' pregnancies [60]. In addition, maternal COVID-19 booster vaccination during pregnancy has been shown to reduce the infant's risk of acquiring symptomatic COVID-19 in the first 6 months by 56% (95% CI 8%–79%, P = .03) relative to no boosting [66].
As a result of the cumulative efficacy and safety data related to COVID vaccination during pregnancy [12][13][14], the overwhelming majority of national medical societies continue to support and reinforce guidance statements in favor of maternal and childhood vaccination policies. These organizations include the American College of Obstetricians and Gynecologists (ACOG), the Society for Maternal-Fetal Medicine (SMFM), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP), among dozens of others. These groups' ongoing practice guidance statements have continued to strongly support maternal and childhood vaccination in the face of increasing political, rather than science-based, resistance on the federal level.

Even in the setting of prior vaccination or infection, updated COVID-19 re-vaccination remains necessary to sustain protection against severe disease [66][72][73]. Similar to protocols undertaken to ensure season-specific virus strain matching for annual influenza vaccines, updated COVID-19 vaccines are designed to address continuing emergence of new coronavirus variants. Infants born to mothers who received a updated, "boosted" dose demonstrated significantly higher antibody titers at delivery compared with infants of non-boosted mothers, and a lower risk of SARS-CoV-2 infection during the first six months of life [66]. As our national societies have emphasized, COVID vaccinations are an important component of perinatal preventive care for both mothers and newborns and can be administered at any point in pregnancy. They can also be given in conjunction with other vaccines routinely administered in pregnancy, such as Tdap, influenza, and RSV.

Respiratory Syncytial Virus

Respiratory syncytial virus (RSV) is a common respiratory pathogen. It is a leading cause of pediatric respiratory illness and is responsible for annual seasonal epidemics affecting individuals across all age groups [74]. RSV typically manifests as a self-limited upper respiratory infection but can lead to significant lower respiratory tract disease, including bronchiolitis and pneumonia, particularly in infants.

Respiratory syncytial virus (RSV) represents a substantial healthcare burden in the pediatric population and is the leading cause of hospitalization among infants under 6 months of age in the United States (US) [75]. Each year, approximately 60,000–80,000 children younger than 5 years are hospitalized with RSV infection in the United States, many of whom require respiratory support, including intensive care and mechanical ventilation, with an estimated 200–300 deaths occurring annually [76] [77][78]. Infants under 6 months demonstrate the highest morbidity and mortality [79], and account for 3% of all infant hospitalizations annually [74][80][81][82]. In

infants under 1 year of age, mortality from RSV is nearly fivefold greater than that from influenza [82].

Approximately 80% of infants hospitalized with RSV were previously healthy and born at term. However, infants born preterm were nearly three times more likely to be hospitalized due to RSV-related complications compared with those born at term [83]. This highlights the substantial burden of RSV among even otherwise healthy term infants, and the markedly higher risk faced by those born preterm.

The primary goal of RSV vaccination during pregnancy is to confer passive immunity to the infant and to reduce their risk of severe RSV-associated lower respiratory tract disease, hospitalization, and death. Although pregnant women are susceptible to RSV infection and pregnancy increases vulnerability to respiratory illnesses in general, currently available data are not sufficient to establish a significant maternal benefit from RSV vaccination [81]. Maternal RSV vaccination is considered both effective and safe for both the mother and newborn. In the clinical trial setting, maternal RSV vaccination demonstrated 70%–80% efficacy in reducing severe RSV-associated lower respiratory tract infection and approximately 60% efficacy in preventing RSV-related hospitalization among infants aged 0–6 months [84]. These findings have been supported by several large global studies, which have described similar real-world effectiveness in this age group [85][86][87]. Among infants who did develop severe RSV infection, those whose mothers were vaccinated during pregnancy was associated with shorter durations of respiratory support and hospitalization [86].

Maternal adverse effects from the RSV vaccine have been reported to be generally mild, consisting mostly of self-limited local and systemic reactions, most commonly injection-site pain, headache, myalgias, and nausea [88]. Maternal RSV vaccination was associated with numerically higher but non–statistically significant increases in late-preterm birth and mild hypertensive disorders of pregnancy in some analyses, though no biologically plausible mechanism or causal relationship has been established [74][81][89]. The U.S. Food and Drug Administration, along with national obstetric, pediatric, and other medical societies, continues to conclude that the benefits of RSV vaccination during pregnancy outweigh these theoretical risks. As a precaution, the FDA selected a dosing window of 32 weeks' gestation or later to mitigate a theoretical associated risk of preterm birth [81].

Of the RSV vaccines currently on the market, only Pfizer's bivalent RSVpreF vaccine (Abrysvo®) is currently approved for use in pregnancy. ACOG [89], SMFM [81], and the CDC [75] recommend administration of a single dose of Abrysvo to pregnant individuals between 32 0/7 and 36 6/7 weeks of gestation during periods of increased RSV circulation, provided they do not have a planned delivery within 14 days of vaccination and have not previously received the maternal RSV vaccine in a prior pregnancy. Notably, current guidance does *not* recommend the repeat administration of the maternal RSV vaccine in a subsequent pregnancy for individuals who have already received vaccination. The RSV vaccine can be safely co-administered with

other vaccines routinely administered in pregnancy, such as Tdap, influenza, and COVID vaccines [81][89].

The annual period of RSV circulation—typically September 1 through January 31 in most areas of the continental United States—may vary by region and year. Therefore, ACOG & the CDC recommend clinicians align maternal vaccination timing with local RSV surveillance data to optimize infant protection [74][75].

Infants younger than 8 months of age who were not optimally protected against RSV infection through maternal vaccination — whether due to maternal vaccine declination, limited access to prenatal care, receipt of the maternal RSV vaccine in a prior pregnancy, or maternal vaccination occurring fewer than 14 days prior to delivery—should receive passive immunization with one of the two available RSV monoclonal antibodies [75][89]. Nirsevimab (Beyfortus) and clesrovimab (Enflonsia) are the RSV monoclonal antibodies currently approved to reduce the severity of RSV-associated lower respiratory tract infection in infants [90][91]. Monoclonal antibody prophylaxis is recommended within the first week of life [74]. Both maternal vaccination during pregnancy and postnatal administration of RSV monoclonal antibodies are safe and effective strategies to prevent severe RSV disease in infants. However, clinicians should counsel families that reliance on postnatal monoclonal antibody prophylaxis may be affected by supply-chain limitations, delays in administration, and higher associated treatment cost [74][76][81].

Influenza

Influenza is an acute viral respiratory infection caused by influenza A and B viruses that circulate seasonally. Its clinical presentation can range from asymptomatic infection to severe cardiopulmonary collapse requiring intensive care.

Pregnancy confers increased susceptibility to respiratory viruses like influenza, due to adaptive maternal changes in immune responses, along with alterations in cardiopulmonary physiology in pregnant individuals [92][93][94]. Pregnant individuals with comorbidities such as cardiovascular disease, asthma, diabetes, and obesity have been shown to have higher rates of more severe complications of influenza infection [94]. These include increased risks of pneumonia, asthma exacerbation, bronchitis, and sepsis, as well as a greater need for advanced respiratory support, intensive care unit admission, and death [94][95]. Severe maternal influenza infection is also associated with higher rates of obstetric complications, including a twofold increase in preterm birth and an increased risk of fetal death [94]. Influenza-related maternal morbidity and mortality also rise with each advancing trimester in the absence of vaccination: compared to matched non-pregnant individuals, pregnant patients with no comorbidities have higher rates of illness and hospitalization that rise from a relative risk of 1.7 in the first trimester to 5.5 in the third trimester. When maternal medical comorbidities are present, that increased risk is reported as a relative risk of 2.9 in the first trimester, and increases to 7.9 in the third trimester [94][96].

Infants, particularly those younger than 6 months, have the highest rates of influenza-related hospitalization among pediatric populations, accounting for approximately 20,000 hospitalizations annually [96]. Severe complications of influenza infection in infancy include pneumonia, myocarditis, pericarditis, and a spectrum of neurologic manifestations. Among these, influenza-associated encephalopathy or encephalitis (IAE) is a rare but devastating sequela of infection in infants, which showed a historic rise in incidence in the 2024-25 respiratory season in the US. This rise in cases was described in the MMWR, detailing 109 reported cases and 21 deaths, including 37 cases of severe acute necrotizing encephalopathy (ANE). Many affected infants were previously healthy, with 74% requiring ICU care. In addition, influenza vaccination coverage among affected children was low, at only 16% [97]. This highlights the substantial burden of influenza among even otherwise healthy term infants, and the higher risk faced by infants with existing comorbidities.

The primary aims of influenza vaccination are to mitigate the risk of an infection's progression to severe disease and to reduce rates of influenza-related hospitalizations and death in both pregnant individuals and neonates.

Extensive data support the safety and efficacy of influenza vaccination during pregnancy for both maternal and neonatal outcomes. To date, no associations have been identified with early pregnancy loss, stillbirth, congenital anomalies, preterm delivery, or low birthweight [98]. Maternal vaccination has not been linked to autism spectrum or other neurodevelopmental disorders in offspring [99].

Vaccinated pregnant women experience a significant reduction in influenza-related acute respiratory illness [100]. The rate of respiratory infection with fever was 4% lower in the vaccinated group compared to the unvaccinated group [100]. Additionally, vaccination was associate with fewer clinic visits [100].

As previously noted, infants younger than 6 months experience the highest hospitalization rates among pediatric age groups. Vaccination during pregnancy is particularly important, as it provides passive immunity to the infant through transplacental antibody transfer and, after delivery, through breast milk [96]. Because infants are not eligible for influenza vaccination until 6 months of age, maternal immunization offers critical protection during the early postnatal period.

Maternal influenza vaccination during pregnancy is demonstrated to be 50 -90% effective in preventing influenza–related hospitalizations in infants. This potentially translates to over 10,000 fewer influenza-attributable hospitalizations among infants younger than 6 months annually [96] [100].

ACOG [93], AAP [99], SMFM, and other national medical organizations continue to recommend annual influenza vaccination for individuals who are pregnant, planning pregnancy, or lactating to protect both mother and infant from severe influenza–related complications. The inactivated or recombinant influenza vaccine is approved for pregnancy, can be given at any trimester, and can be safely co-administered with other vaccines routinely administered in

pregnancy, such as Tdap, RSV, and COVID vaccines. The annual period of influenza circulation —typically September through April in most areas of the continental United States—may vary by region and year. Therefore, ACOG [93] and other national medical organizations recommend clinicians align maternal vaccination timing with local influenza surveillance data to optimize maternal and infant protection. Of note, the live-attenuated intranasal influenza vaccine, including self-administered formulations, is not approved for use in pregnant individuals but can be safely given postpartum [92].

Conclusion

Maternal immunization remains an important preventive care tool, offering dual protection for both pregnant individuals and their infants. As discussed, strong evidence supports the safety and efficacy of routinely recommended vaccines—including Tdap, COVID-19, influenza, and RSV, while highlighting the continued contraindication of live-attenuated vaccines. Integrating vaccination into standard prenatal care, coupled with tailored counseling to address hesitancy, optimizes uptake and strengthens maternal and neonatal outcomes. By equipping clinicians with updated guidance on vaccine indications, contraindications, and strategies to improve acceptance, this review underscores the vital role of maternal immunization in reducing maternal morbidity and mortality.

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Table 1. Vaccines in Pregnancy If Indicated

Vaccine	Type	Indications for Use	Vaccine Regimen	Safety in Pregnancy
Hepatitis A	Inactivated virus	High-risk individuals: chronic liver disease, clotting-factor concentrates recipients, laboratory workers with HAV, travelers to endemic areas, IV drug users	2-dose series (Havrix or Vaqta); doses at 0 and 6 months	**Safe; no known risk to fetus**. ACIP recommends vaccination for pregnant patients with indication. Association with small-for-gestational-age infants
Hepatitis B	Recombinant (inactivated DNA particles)	All adults <60 years; adults ≥ 60 years at risk (chronic liver disease, HIV, sexual exposure, IV drug use, incarceration, travel to endemic areas); all pregnant patients	3-dose series (0, 1, 6 months) for Engerix-B, Recombivax HB, Twinrix; 2-dose series (0, 1 month) for Heplisav-B. Note: PreHevbrio not recommended in pregnancy	**Safe; can be administered during pregnancy**. No known risk to fetus. PreHevbrio lacks safety data in pregnancy
Meningococcal	Polysaccharide and conjugate vaccines available	High-risk pregnant women (exposure risk or serious illness risk)	Varies by vaccine type (MenACWY, MenB)	**Probably safe**. RCTs comparing to other vaccines support safety. Recommended for high-risk pregnant women
Poliovirus	Inactivated (IPV)	High-risk pregnant women (exposure risk); travelers to endemic areas	Primary series: 3 doses; booster if needed	**No evidence of adverse outcomes** in limited data. Used in high-risk pregnant women
Cholera	Live attenuated or inactivated (varies by formulation)	Travelers to endemic areas with cholera outbreaks	Varies by vaccine formulation	Limited safety data in pregnancy
Q fever (Coxiella burnetii)	Inactivated whole-cell vaccine	High-risk occupational exposure (veterinarians, abattoir workers, laboratory personnel)	Single dose	Limited data; not routinely available in US
Haemophilus	Conjugate	High-risk pregnant	1 dose if not	**Limited Safety**

Vaccine	Type	Indications for Use	Vaccine Regimen	Safety in Pregnancy
influenzae type b (Hib)	vaccine	women (asplenia, immunocompromised)	previously vaccinated	**data in pregnancy**
Japanese encephalitis	Inactivated virus	Travelers to endemic areas in Asia; laboratory workers	2-dose series (days 0 and 28)	**Generally avoided unless high risk**. Limited safety data; theoretical risk minimal with inactivated vaccine
Rabies	Inactivated virus	Post-exposure prophylaxis; pre-exposure for high-risk individuals (veterinarians, laboratory workers, travelers to endemic areas)	Pre-exposure: 3 doses (days 0, 7, 21-28); post-exposure: 4-5 doses depending on immune status	**Safe**. Observational data support safety. Recommended for high-risk/post-exposure in pregnant women
Pneumococcal	Polysaccharide (PPSV23) and conjugate (PCV15, PCV20)	High-risk pregnant women (chronic disease, immunocompromised)	Varies: PCV followed by PPSV23, or PCV20 alone	**Limited safety data**. No recommendations.
Tick-borne encephalitis	Inactivated virus	Travelers to endemic areas in Europe and Asia; high-risk occupational exposure	3-dose series (0, 1-3 months, 5-12 months); accelerated schedules available	**Generally avoided unless high risk**. Limited data; recommended for high-risk pregnant travelers
Typhoid	Live attenuated (oral Ty21a) or polysaccharide (injectable Vi)	Travelers to endemic areas; laboratory workers with Salmonella typhi	Oral: 4 doses every other day; Injectable: single dose	**Injectable preferred if needed**; live oral vaccine contraindicated. Limited safety data for injectable form
Yellow fever	Live attenuated virus	Travelers to endemic areas in Africa and South America	Single dose: booster generally not needed	**Generally contraindicated but may be given if travel to high-risk area unavoidable**. Observational data suggest safety, but live vaccine theoretically poses risk

Centers for Disease Control and Prevention, & Advisory Committee on Immunization Practices. *Guidelines for Vaccinating Pregnant Women. CDC; July 2012*.