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Safety of the 9-valent human papillomavirus vaccine in pregnancy based on the vaccine adverse event reporting system

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Abstract

Current guidelines recommend against administering the 9-valent human papillomavirus (HPV) vaccine during pregnancy due to limited safety data. We examined adverse events reported in patients receiving the 9-valent HPV vaccine during pregnancy. The Vaccine Adverse Events Reporting System (VAERS) database was queried for "exposure during pregnancy" to the 9-valent HPV vaccine. Cases were excluded if there was no information on pregnancy in the report or the patient was not pregnant at the time of vaccination. Individual reports were reviewed and data were extracted on gestational age and adverse pregnancy events. From the 285 reports identified, 273 were included. 40.3% (110/273) of the reports stated that there were no adverse events following vaccination. There were eight reports of mild maternal reactions (most commonly injection site pain) and one report of a serious reaction (angioedema). The majority of reports (257/273, 94.1%) did not include the pregnancy outcome. There was one case of vaginal bleeding, four miscarriages, one elective abortion, no stillbirths, and two congenital anomalies. There were seven reports of live births. 61.5% (168/273) of the reports included gestational age at the time of vaccination. Few cases of pregnancy-related adverse events were identified following 9-valent HPV vaccine administration. The VAERS database is an electively reported database; thus, the incidence of events could not be determined, and many reports were incomplete. Despite these limitations, the low numbers of adverse events are reassuring. Clinical trials are warranted to conclusively examine the safety and efficacy of HPV vaccination during pregnancy.

Keywords: Human papillomavirus; Vaccination; Vaccine Adverse Events Reporting System; Pregnancy; Gestational age; Congenital vaccine exposure

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1. Introduction

The human papillomavirus (HPV) is the cause of various types of cancer, such as that of the cervix, vagina, vulva, anus, and oropharynx, as well as genital warts. Every year, over 500,000 individuals are diagnosed with cervical cancer, and over 300,000 cases of mortality are recorded worldwide.[1] In the United States (US) alone, there are approximately 10,800 cases of cervical cancer, 2,300 cases of oropharyngeal cancer,

5000 cases of anal cancer, 3000 cases of vulvar cancer, and 700 cases of vaginal cancer annually.[2] Every year, 4,000 of these women die of cervical cancer.[2]

A significant proportion of these deaths is preventable through vaccination. The quadrivalent HPV vaccine was approved by the US Food and Drug Administration (FDA) in 2006. It has since been replaced by the 9-valent HPV vaccine, which was approved by the FDA in December of 2014 and is now recommended for persons aged 9–11 with catch-up vaccination recommended until age 26, and shared decision-making regarding catch-up vaccination until age 45.[3-5] The 9-valent HPV vaccine protects against HPV types 16, 18, 6, 11, 31, 33, 45, 52, and 58, which are the most commonly associated with cervical cancer and genital warts. It has been shown to be highly protective against cervical neoplasia and cancer, with the potential to prevent 90% of cases of cervical cancer.[6,7] In addition to this high efficacy, the HPV vaccine has consistently shown a favorable safety profile, which has improved over time, with fewer adverse events reported with the 9-valent vaccine than previous formulations.[8]

Vaccination rates have risen since the HPV vaccine first debuted but remain stubbornly low, with only 61.4% of US adolescents vaccinated as of 2023.[9] Although many factors contribute to this deficit, infrequent adolescent healthcare visits are a significant reason.[10] In response to these statistics, the American College of Obstetricians and Gynecologists has stated that HPV vaccination rates in the US are unacceptably low and encourages catch-up vaccination in adults up to age 45.[11] Similarly, the Centers for Disease Control and Prevention (CDC) recommends vaccination up until age 26 and states that it should be discussed and offered up until age 45.[12] Although the optimal time for vaccination is before sexual debut, underpinning the recommended target age of 9–11 years, the HPV vaccine is still beneficial even when HPV vaccination does not occur until after exposure to the virus. It has been shown to provide a 30% reduction in high-grade cervical dysplasia (CIN2+) and 25% reduction in the need for excisional procedures.[13] Despite the recommendation for catch-up HPV vaccination, there are still low reported rates of vaccination in patients presenting for antenatal care.[14-16] Indeed, under current guidelines in which antepartum vaccination is contraindicated,[3,11] pregnancy has been identified as a barrier to completion of catch-up vaccination.[17] Postpartum vaccination rates are similarly low, with significant loss to follow-up after the first dose.[16,18] A challenge that has been identified in postpartum vaccination studies is that patients are often lost to follow-up until they become pregnant again[19] at which time the vaccine cannot be given until the postpartum period. While postpartum vaccination rates can be improved to up to 65% completion with targeted interventions,[16] this still leaves many women unvaccinated and susceptible to cervical cancer. Additional strategies are needed to ensure that access to the HPV vaccine is maximized.

While pregnancy has been considered a barrier to vaccination under current guidelines, it has the potential to present an opportunity for vaccination if vaccine safety can be demonstrated in pregnancy. During pregnancy, individuals who may not otherwise seek or have access to healthcare have increased access to medical insurance and frequent contact with healthcare providers. Pregnancy is also a time of high patient motivation that crosses racial and socioeconomic lines, mitigating some social and structural barriers to care.[20] Given active patient engagement with the healthcare system for prenatal care, pregnancy may be an ideal time to complete the full course of HPV vaccination, which would also reduce rates of incomplete vaccination due to loss to follow-up.[18,21,22] This may be particularly valuable in low- and middle-income countries where nearly 90% of cervical cancer-related deaths occurred and where vaccine coverage was only 15% in 2019.[23] In these settings, integration of HPV vaccination into existing health infrastructure has been proposed as a means of combating cervical cancer.[23] Nevertheless, it is worth noting that antenatal visit attendance is also lower in these settings and the HPV vaccine is not currently available in many of these countries.[24]

Safety concerns have been cited for national and international guidelines recommending against administering the 9-valent HPV vaccine in pregnancy. However, unlike vaccines against varicella or rubella, which are live attenuated vaccines and thus contraindicated in pregnancy due to a theoretical potential for crossing the placenta possibly causing congenital infection, the HPV vaccine does not contain live HPV virus. Instead, the HPV vaccine is comprised of recombinant virus-like particles with no risk of causing infection to the mother or the fetus.[25] Another potential safety concern during pregnancy is exposure to adjuvants which are used in vaccines to boost the immune response. The adjuvant in the 9-valent HPV vaccine is an aluminum salt. Aluminum salts are commonly used in vaccines, including the tetanus, diphtheria, and acellular pertussis (Tdap) vaccine, which is routinely administered during pregnancy.[26] Despite the low theoretical risk for harm, the ACOG, the Society for Maternal-Fetal Medicine (SMFM), the World Health Organization (WHO), and the CDC currently recommend against vaccination during pregnancy due to insufficient safety data.[3,11,27,28]

Given the concerns regarding inadequate safety data, we aimed to examine adverse events reported in the Vaccine Adverse Events Reporting System (VAERS) database, a nationally maintained database that accepts voluntary reports of adverse events following vaccine administration, for patients who inadvertently received the 9-valent HPV vaccine during pregnancy. We further aimed to review the existing literature on vaccine safety in pregnancy and interpret our results in the context of these other studies

2. Materials and methods

2.1. Study design

This is a retrospective observational cohort study of adverse events reported to the VAERS database.

2.2. Data collection

VAERS is a national database maintained by the CDC and FDA that accept adverse event reports following receipt of any US-licensed vaccine. The database goes back as far as 1990, although our data set begins in 2015 when the 9-valent HPV vaccine was licensed. VAERS reports are submitted on a voluntary basis by healthcare providers or members of the public.[29] Healthcare providers are required to report certain adverse events, and vaccine manufacturers are required to report all adverse events that they are aware of. VAERS is a passive reporting system and is not designed to assess causality but to help detect unusual patterns of adverse event reporting that may underlie a vaccine safety issue. An essential objective of the VAERS database is to identify possible vaccine safety signals, such as rare adverse events that may be missed in pre-licensure clinical trials. Reported events are often temporally associated with vaccination, and may or may not be causally related.

We queried the VAERS database on July 27, 2022, with the following query parameters: Sex: Female; State/Territory: The United States/Territories/Unknown; Symptoms: EXPOSURE DURING PREGNANCY; Vaccine Products: HUMAN PAPILLOMAVIRUS (TYPES 6, 11,16, 18, 31, 33, 45, 52, 58) RECOMBINANT VACCINE (HPV9); VAERS ID: All; Group By: VAERS ID; Show Totals: False; Show Zero Values: False.[30] Cases were excluded if there was no information on pregnancy in the report, or the patient was stated not to be pregnant at the time of the vaccination. Thus, preconception exposure was excluded. Individual reports were reviewed, and data were extracted on pregnancy status, gestational age at time of vaccination, adverse events, and pregnancy outcome. Report severity is determined on the basis of criteria established by the Code of Federal Regulations. Serious adverse events include those that result in death, life-threatening illness, hospitalization, prolongation of hospitalization, disability or permanent damage, congenital anomaly, or other medically important condition. Demographic characteristics of cases were not routinely reported in the database and could not be collected.

2.3. Outcomes

Adverse events were characterized as pregnancy-related or unrelated. Pregnancy-related adverse events included miscarriage, vaginal bleeding, elective abortion, stillbirth, and congenital anomaly. Miscarriage was defined as occurring before 20-week gestational age. Stillbirth was defined as occurring at 20-week gestational age or later. Since most reports in VAERS documented gestational age in whole weeks (*e.g.*, 15 weeks rather than 15.29 weeks or 15 weeks and 2 days), gestational age was treated as a categorical variable. Gestational age was determined from the report or calculated from the last menstrual period (LMP) or estimated due date stated in the report, rounding to the number of weeks of gestation completed. Gestational age abstracted from VAERS was categorized by trimester for analysis. The first trimester was defined as less than 14-week gestational age, the second trimester was defined as 14–27-week gestational age, and the third trimester was defined as 28-week gestational age or more.

2.4. Analysis

Frequencies and proportions were calculated using Microsoft Excel 2019. Graphs were generated in Microsoft Excel 2019. Causality between vaccination and adverse events could not be assessed due to the nature of the VAERS reporting system.

Because VAERS is a publicly available database, this study was exempted from institutional review board (IRB) review under federal regulation 45 CFR 46.104, and informed consent is not required.

3. Results

There were 285 reports identified in the VAERS system under our search criteria, with the earliest in 2015 less than 1 year after licensing of the 9-valent HPV vaccine. After excluding those reports in which the patient was not pregnant at the time of vaccination, or pregnancy status could not be determined from the report, 273 were included in this analysis (Figure 1). Among these, 110 (40.3%) reports expressly stated that there were no adverse events following vaccination and the reason for submission of the report was vaccine exposure during pregnancy. Of the remaining 163 reports, there were 21 reports of mild adverse events. The most common adverse event (n = 8) was injection site pain. Other adverse events, as reported in VAERS, included urinary tract infection,

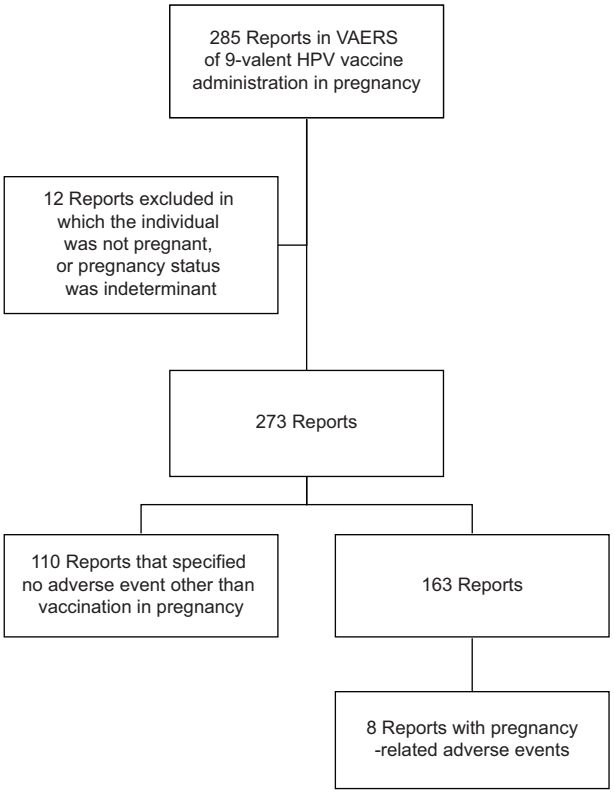

Figure 1. Flow diagram of Vaccine Adverse Events Reporting System database. The initial query identified 285 reports of exposure to the 9-valent human papillomavirus vaccine during pregnancy. On review, 12 reports were excluded due to the vaccine exposure happening outside of pregnancy, or at an indeterminate time in relation to the pregnancy. Of the remaining 273 reports, 110 specified that there was no adverse event other than administration during pregnancy. Of the remaining 163 reports, 7 reported adverse pregnancy events.

abdominal pain, nausea, fatigue, nasal congestion, weakness, discomfort, syncope, headache, injection site swelling, irregular menses, testing positive for HPV, and weight gain. There was one report of a serious maternal reaction (angioedema). There were no reports of maternal death.

The majority of reports (257, 94.1%) did not include the pregnancy outcome. Of pregnancy-related events, there was one report of pre-eclampsia, one case of vaginal bleeding, four reported miscarriages, one elective abortion, no stillbirths, and two congenital anomalies (Table 1). One of the congenital anomalies was reported as Trisomy 18, and the other did not have details reported. Of note, this unspecified congenital anomaly was also associated with a miscarriage. There were seven reports of live births.

Gestational age at the time of vaccination was included in 168 (61.5%) reports. Vaccination occurred in all trimesters of pregnancy and ranged from 1 to 38 weeks of gestational age (Figure 2). Among those exposures with reported gestational ages, 54.8% occurred in the first trimester, 13.7% occurred in the second trimester, and 31.5% occurred in the third trimester. The average gestational age at time of vaccination was 15.6 weeks, the median gestational age at vaccination was 11 weeks and the most common week of vaccination was 28-week gestational age.

Table 1. Adverse pregnancy-related events and gestational age at vaccination

Adverse event	Gestational age at time of vaccination
Vaginal bleeding	7 weeks
Miscarriage	6 weeks
Miscarriage*	Unreported
Miscarriage	Unreported
Miscarriage	Unreported
Elective abortion	Unreported
Congenital anomaly (Trisomy 18)	3 weeks
Congenital anomaly (Unreported type)*	Unreported
Pre-eclampsia	4 weeks

Note: *These two adverse events occurred in the same pregnancy.

While HPV vaccine exposures occurred across all gestational ages, the data demonstrate a bimodal vaccine administration distribution. Many patients received the HPV vaccine in the first trimester before they were aware of the pregnancy. These exposures were often reported as the urine pregnancy test came back positive after the vaccine was administered. A second spike occurred around the time of the 28-week visit when the Tdap vaccine is administered. Many of these reports stated that the provider inadvertently administered the 9-valent HPV vaccine rather than the Tdap vaccine.

4. Discussion

We identified few cases of pregnancy-related adverse events among the 273 reports in the VAERS database following administration of the 9-valent HPV vaccine during pregnancy. The most common adverse event was injection site pain (n = 8) which is a known side effect of the vaccine, and the most common pregnancy-related adverse event was miscarriage (n = 4). Many of the reported adverse events were likely only temporally related and others may have been symptoms of pregnancy, such as nausea and fatigue. Only two cases of congenital anomalies were identified. Miscarriage is a common early pregnancy outcome, seen in approximately 10% of pregnancies, and these numbers were not higher than would be expected. Likewise, congenital anomalies complicate roughly 3% of pregnancies, and rates observed were not higher than

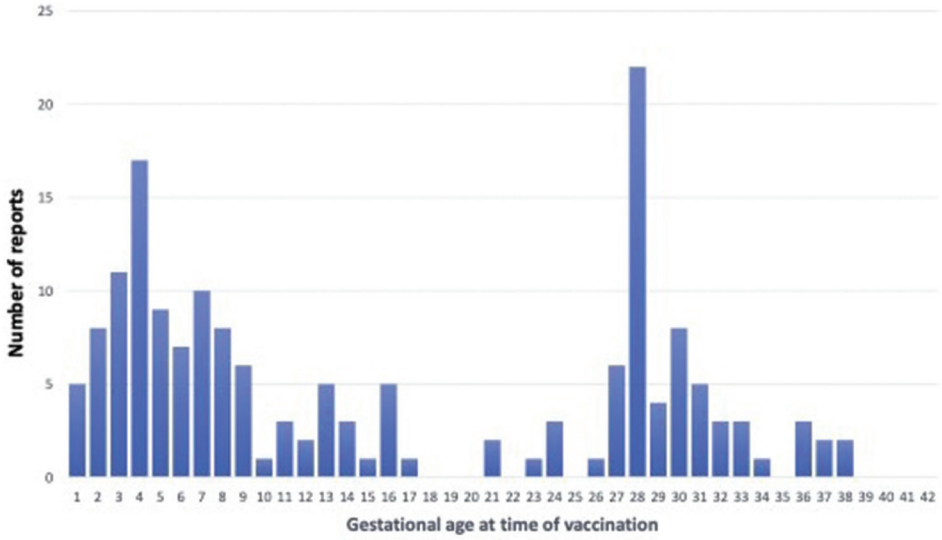

Figure 2. Distribution of timing of inadvertent 9-valent human papillomavirus vaccination during pregnancy. There were 168 reports with data available on gestational age at the time of vaccine exposure. Gestational age is reported as weeks completed.

expected. The only serious adverse event reported was angioedema, which was not a pregnancy-specific adverse event. Overall, these findings provide reassuring data on the safety of the 9-valent HPV vaccine in pregnancy.

Our data are consistent with prior reports from both the quadrivalent and 9-valent vaccines, supporting the safety of vaccination in pregnancy. In a voluntary post-marketing registry from Merck of the quadrivalent HPV vaccine, rates of spontaneous abortion and major birth defects were no greater than the general population.[31] Similarly, in a study of VAERS reports for the quadrivalent HPV vaccine inadvertently administered during pregnancy, there were no unexpected patterns of adverse maternal or fetal outcomes. The most common pregnancy-specific adverse event was miscarriage, and the most common adverse event overall was maternal fever.[32] Neonatal anomalies included one each of absence of lower extremities, total anomalous pulmonary venous return, and Trisomy 21. A positive safety profile was also seen in a retrospective study using data from a national registry in Denmark, in which women exposed to the quadrivalent HPV vaccine in pregnancy showed no increased risk of spontaneous abortion, preterm birth, small-for-gestational-age neonate, or stillbirth.[33] In a combined analysis of five phase III clinical trials of the quadrivalent HPV vaccine, there was also no increased risk of fetal loss, spontaneous abortion, or congenital anomalies.[34] A meta-analysis of 11 clinical trials and cohort studies including the 2-, 4-, and 9-valent vaccine showed no association with stillbirth, preterm birth, birth defects, small-for-gestational-age newborn, or ectopic pregnancy.[35] Similarly, pre-licensure studies of pregnant individuals who were inadvertently vaccinated with the 9-valent HPV vaccine showed good safety.[25,36] A post-marketing surveillance study from China noted 50 cases of exposure during pregnancy, with no cases of stillbirth.[37] A recent cohort study of 1,493 patients from seven Vaccine Safety Datalink sites found that the 9-valent HPV vaccine was not associated with spontaneous abortion, preterm birth, small-for-gestational-age birth, or birth defects.[38] There was no pattern to the identified birth defects, which included ventricular septal defects, microcephaly, cleft palate, septo-optic dysplasia, encephalocele, renal agenesis, and pyloric stenosis. However, this study only examined vaccination up to 19-week gestation. Consistent with these data, in a meta-analysis of phase III clinical trials of the 9-valent HPV vaccine, rates of spontaneous abortion, stillbirth, and congenital anomalies were similar to the general population.[36] Fetal anomalies that were identified were diverse across organ systems and showed no pattern. The most common adverse events reported were injection site-related, including pain, swelling, and erythema, similar to the common adverse events seen in our VAERS data.

Other studies, in addition to ours, have examined the VAERS data on the 9-valent HPV vaccine in pregnancy. A prior study by Landazabal *et al.*[39] examining VAERS reports from 2014 to 2017 identified 82 reports of 9-valent HPV vaccine administration during pregnancy, compared to the 273 cases reported here. Our data overlapped with Landazabal *et al.*'s study,[39] but we included more recent reports and many more reports of vaccination occurring in the third trimester. A more recent retrospective pharmacovigilance analysis of VAERS reports from 2015 to

2024 for the 9-valent HPV vaccine using disproportionality analyses to detect potential safety signals by Liu *et al.*[40] found no positive signals for reports in pregnant individuals. Of note, despite a time frame that overlapped that of our study and the study by Landazabal *et al.*,[39] Liu *et al.*[40] only identified reports from 18 pregnant individuals. This discrepancy is likely due to differences in VAERS search parameters. While the study did not delineate the full set of search parameters used, they did note that they included reports involving "GARDASIL 9" in the vaccine name field. It is also possible that their exclusion criteria were more stringent than those employed by us or Landazabal *et al.*[39] Interestingly, the authors identified four cases of fetal cardiac disorders, which were not identified in our analysis and did not mention the congenital anomalies that we noted (Trisomy 18 and an unspecified anomaly). It is possible that the cardiac cases were all seen after July 27, 2022, when our data collection occurred. Alternatively, different search criteria may have been responsible. Landazabal *et al.*[39] did not note any congenital anomalies in their results. Despite the differences in sample size and fetal effects for our studies, our conclusions regarding the safety of the vaccine in pregnancy are consistent.

There are two notable exceptions to the overall positive safety data. The first is a meta-analysis which included two randomized controlled trials (RCTs) with the 9-valent HPV vaccine and found that vaccination during the period from 90 days before the LMP to 45 days after LMP seemed to be related to an increased risk of spontaneous abortion (RR = 2.04, 95% CI: 1.28–3.24).[35] This was based on the results of four RCTs, only one of which, Moreira *et al.*[36] showed an increased risk of spontaneous abortion, while the others trended toward a decreased risk of spontaneous abortion. Interestingly, from their own data, Moreira *et al.*[36] concluded that they observed increased rates of spontaneous abortion with the 9-valent as compared to the quadrivalent vaccine, but that both rates were similar to those in the general population. The authors of the systematic review noted that given the paucity of studies, their findings should be interpreted with caution. Only four miscarriages were noted in our study, although we did not examine the preconception time period, possibly omitting some miscarriages that would have been included in the meta-analysis. Thus, further research is indicated on periconception exposure to the 9-valent HPV vaccine, and patients with exposure during this period should be counseled on the insufficient data on the risk of miscarriage. For recommendations regarding vaccination during pregnancy, it may be reasonable to suggest waiting until after the first trimester. The other study that identified potential safety signals reviewed VAERS data for the quadrivalent HPV vaccine and raised concerns for increased risk of venous thromboemboli,[41] especially in pregnant women. This is of particular concern because pregnancy is at baseline a prothrombotic state, and increased risk of thromboembolism could have significant health ramifications. However, this concern was not borne out in population-based studies.[41,42] Consistent with these population-based studies, we saw no cases of venous thromboembolism among the 273 reports reviewed.

We further considered our data in the context of other vaccines that are administered in pregnancy. Safety data from VAERS on the 9-valent HPV vaccine are similar to those reported for the COVID-19 vaccines, with most adverse events being unrelated to pregnancy, and the most common pregnancy-related adverse event being miscarriage.[43] Conversely, pregnant women vaccinated with cell-based influenza vaccines were more likely to report pregnancy-related adverse events in VAERS, and the most commonly reported adverse event was premature delivery.[44]

Our results have implications for future research. While our data and the studies reviewed above are reassuring, further research is warranted on HPV vaccination in pregnancy. First, it will be critical to assess patient and provider acceptance of HPV vaccination in pregnancy. The acceptance rate of vaccines varies during pregnancy; for example, the acceptance rate of influenza, Tdap, and COVID vaccines during pregnancy is 61.2%, 56.6%, and 28.5%, respectively.[45,46] One study of patient attitudes surrounding antepartum vaccination showed that one-third of patients would accept the HPV vaccine during pregnancy if recommended by their obstetrician.[14] However, this study was from over a decade ago, and attitudes toward vaccination have changed since the COVID-19 pandemic. In addition, patients may be more familiar with the HPV vaccine since it has been on the market longer, and more vaccines are now recommended during pregnancy, which could both alter patient perceptions of antepartum HPV vaccination. Second, it would be valuable to gather population-level data on individuals inadvertently vaccinated with the 9-valent HPV vaccine during pregnancy, as has been done for the quadrivalent vaccine.[33] Long-term follow-up of the children born to these pregnancies would also be of value and is becoming feasible now that the 9-valent vaccine has been in circulation for a decade. Large databases such as national records maintained in Europe or the Kaiser system in California could help to provide further reassurance of the safety of the 9-valent vaccine. Third, it will be important to demonstrate the immunogenicity of the vaccine when administered during pregnancy. This could be done through retrospective serology studies of women who were inadvertently exposed, or ideally with

prospective clinical trials. It is possible that immunologic changes of pregnancy could alter the efficacy or durability of vaccination during this time. Moreover, immunogenicity may vary with gestational age. Sex steroid hormone levels are thought to be responsible for sex differences in vaccine immune responses.[47] However, data from other vaccines administered in pregnancy are reassuring. The hepatitis B,[48] Tdap,[49] H1N1 influenza,[50] quadrivalent inactivated influenza,[51] COVID-19,[52] and respiratory syncytial virus (RSV)[53] vaccines have all demonstrated high immunogenicity during pregnancy. Moreover, postpartum vaccination data show high immunogenicity even with a modified two-dose regimen.[54] Finally, cost-effectiveness studies would also be valuable. The direct medical costs of cervical dysplasia have been estimated at over eight billion dollars annually.[55] Increased vaccine uptake during pregnancy has the potential to reduce these costs. Other vaccines in pregnancy have benefited from cost-effectiveness analyses. Screening and vaccinating for hepatitis B has been shown to be cost-effective during pregnancy[56] and helped to reshape SMFM guidance on vaccination during pregnancy.[57]

Beyond future research implications, our results have significant clinical implications as well. First, this study still has clinical value in counseling patients who were inadvertently exposed to the 9-valent HPV vaccine during pregnancy. While ACOG recommends against administration of the HPV vaccine during pregnancy, it also advises against pregnancy testing before administration of the HPV vaccine.[11] Thus, there will continue to be women who are inadvertently vaccinated before pregnancy. Patients may feel anxious having received a contraindicated vaccine during pregnancy. Providers can provide reassurance that our data, along with previous studies, do not show an elevated risk of severe adverse maternal or fetal effects and that the most common adverse events are mild, related to the injection site, and not pregnancy-specific. Another important clinical implication of our data is the finding of a spike in inadvertent vaccine administration around 28-week gestation when pregnant women receive the Tdap vaccine. This was by far the most frequent timing of vaccine administration. In the case of wrong vaccine administration with the 9-valent HPV vaccine, the risks to the pregnant patient are minimal, but it may result in anxiety or mistrust of the healthcare system, which can hopefully be ameliorated with counseling as previously discussed. However, misadministration of live-attenuated vaccines poses a greater potential risk. It is reasonable to assume that wrong vaccine administration during around 28-week gestation is not limited to the HPV vaccine but may include other vaccines that providers stock. Identifying this common timing of vaccine administration errors creates an opportunity for targeted intervention. Quality improvement initiatives in clinics and pharmacies where vaccines are administered have the potential to reduce these mistakes and improve patient care. This is increasingly important as more vaccines are recommended during pregnancy, such as the RSV vaccine and other vaccines that are currently in development. Perhaps, the greatest clinical implication of our data is its contribution to the growing body of literature on the safety of the 9-valent HPV vaccine in pregnancy. Safety data may ultimately lead to a revision of the national and international guidelines that contraindicate vaccination with the 9-valent HPV vaccine in pregnancy. If guidelines were less restrictive, pregnancy presents an opportunity to complete vaccination. Lack of frequent contact with the healthcare system has been proposed as a reason for poor vaccine uptake among adolescents. Given active engagement with the healthcare system during pregnancy, it may be an ideal time to complete the full course of HPV vaccination, which would also reduce rates of incomplete vaccination due to loss to follow-up.[18] Indeed, SMFM now recommends vaccination for hepatitis B during pregnancy for women who are non-immune or who have not previously been vaccinated, due to the fact that prenatal care presents an opportunity to complete a multi-dose vaccine series[57] and compliance rates for vaccine completion are high in pregnancy.[58] Underscoring the importance of VAERS data in guideline development, safety data from VAERS studies were used in the decision-making process for the updated hepatitis B vaccine recommendations.[57,59] While one of the great potential benefits of vaccination during pregnancy is the chance to administer a multiple-shot vaccine, it is important to note that studies examining the efficacy of single-dose HPV vaccination are currently being performed. Thus far, these studies have focused on adolescents,[60-63] but it is possible that they could be extended to pregnancy. Studies have already demonstrated the immunogenicity of a two-shot series postpartum. If a single-shot regimen was found to be effective in adult women, the single dose could be administered postpartum, obviating the benefit of frequent healthcare contact during pregnancy for completion of the three-shot series. While earlier vaccination is ideal, and many patients may prefer to wait until postpartum for vaccination, vaccination during pregnancy still represents an opportunity to increase vaccine coverage and improve the health of women. Indeed, the WHO lists safety and efficacy in pregnant women as a desirable HPV vaccine characteristic under its considerations for vaccine implementation.[64] Furthermore, it is possible that there may still be benefits to vaccination antepartum. HPV

vaccination has been shown to reduce the risk of preterm birth and small-for-gestational-age infants.[65,66] However, these data should be interpreted cautiously as they were from women who were vaccinated in adolescence rather than antepartum. Further research is needed on any pregnancy-specific benefits of antepartum vaccination.

Our study has multiple strengths. First, it is a contemporary evaluation of the currently utilized 9-valent HPV vaccine. Data are uploaded to the system in near real time, so there was no lag in data collection from the time of entry to our data pull. To our knowledge, this is the most comprehensive analysis of the VAERS database for 9-valent HPV administration during pregnancy, encompassing 273 reports. Second, we present data not only on reported adverse events but also on the timing of vaccination in pregnancy. This allowed us to identify peak times of inadvertent vaccine administration and note the high rates of wrong vaccine administration around 28-week gestation. This is a novel and highly clinically relevant finding. Third, we included exposures that occurred at any gestational age. Prior studies focused on preconception and early gestation. However, adverse events are not limited to early pregnancy and may vary over the course of pregnancy due to physiologic adaptations of the pregnant woman and fetus. It is well known that drugs can have different impacts on a pregnancy in different trimesters. While miscarriage and congenital anomalies occur early in gestation, some adverse events, such as fetal growth restriction, may be more impacted by exposures later in pregnancy. In addition, any deliberate vaccination campaign during pregnancy would likely be implemented in the second and third trimesters, making it critical to collect these data.[21]

There are several limitations to note from our study. Many of these limitations are inherent to the design of the VAERS database. Many of the features that allow the VAERS database to quickly identify adverse events and capture rare events are associated with some drawbacks. As a voluntary reporting system, VAERS is at risk of both over- and underreporting; reporting bias; incomplete, coincidental, or inaccurate data; unverified reports; and inconsistent quality of reports.[29] Since there are no data on the total number of pregnant persons vaccinated in VAERS, the incidence of adverse events cannot be calculated nor can causation be determined. Events close to the time of the vaccination are more likely to be reported than remote events. Consequently, few reports included information on the delivery outcome. In addition, data on how many doses of the vaccine the patient received during pregnancy were lacking. Finally, due to the nature of the data, it was not possible to access medical records for verification of the exposure and the adverse event, or follow-up from the event. Despite these limitations, our study adds to the literature and should be viewed in the context of the aforementioned studies which also favor the safety of the vaccine in pregnancy. To this effect, ACOG and the CDC do not advise pregnancy testing before vaccination and report that existing safety data in pregnant persons who are inadvertently vaccinated is reassuring.[3,11]

5. Conclusion

HPV is a significant cause of morbidity and mortality, and despite the availability of a highly effective vaccine, vaccination remains underutilized in the target adolescent population. Vaccination during pregnancy has been proposed as a time to reach patients when they are highly engaged with the healthcare system. Our study examined the currently utilized 9-valent vaccine and did not identify concerning rates of adverse events, pregnancy-related, or otherwise. These findings, in the context of the existing literature, can provide reassurance to women inadvertently vaccinated during pregnancy. Phase I clinical trials are warranted to demonstrate immunogenicity of the vaccine in pregnancy, and national databases should be examined for the safety of the 9-valent HPV vaccine in pregnancy, similar to those completed for the quadrivalent vaccine. Qualitative research on patient and provider attitudes regarding HPV vaccination is also warranted to comprehensively evaluate the possible risks and benefits of 9-valent HPV vaccination during pregnancy. Given the increasingly large body of literature showing reassuring safety data among women inadvertently exposed to the 9-valent HPV vaccine during pregnancy, the high efficacy of the vaccine, the significant morbidity, mortality, and cost from cervical cancer, as well as the fact that for some women pregnancy may be a rare touchpoint with the healthcare system, we argue that national and international bodies should consider adopting guidelines that permit catch-up vaccination during pregnancy, using shared decision-making to weigh the risks and benefits of vaccination antepartum versus waiting until the postpartum period.

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Conflict of interest

The authors declare that they have no competing interests.

Author contributions

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Investigation: Sarah Boudova
Methodology: Sarah Boudova
Writing–original draft: Sarah Boudova
Writing–review & editing: Sarah Boudova, Christopher V. Chambers

Ethical approval and consent to participate

Not applicable.

Consent for publication

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Availability of data

Data are available from the corresponding author upon reasonable request.

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