

Improving Maternal Immunization Status

**Working Toward Solutions to the Policy,
Data, and Implementation Challenges Driving
Suboptimal U.S. Maternal Vaccination Rates**

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Executive Summary

This white paper was written in an effort to better understand evolving challenges that undermine longstanding efforts to address the most persistent barriers to maternal immunization in the United States. Despite Centers for Disease Control and Prevention (CDC) recommendations around maternal immunization, well-documented evidence of the efficacy of vaccination for both mother and baby, and broad recognition of the barriers impeding vaccination among pregnant individuals—as well as myriad efforts to address these barriers—maternal immunization rates remain suboptimal across the general population. Further, gaps in vaccine coverage are even more pronounced among Black and Hispanic populations and among those living in low-income and rural settings and/or participating in Medicaid.

Additionally, like many other public health challenges, sub-optimal maternal immunization rates have been magnified and exacerbated by the COVID-19 pandemic. At the same time, the COVID-19 pandemic has also raised important conversations about pressing barriers to vaccination and prompted increased policy momentum and investment into resources and infrastructure related to immunization. As such, the current public health and legislative landscapes present a unique opportunity to further efforts aimed at improving maternal immunization.

With this context in mind, this white paper outlines factors that may be driving and contributing to the persistence of these longstanding barriers, despite the fact that maternal immunization barriers are well-understood and many legislative, programmatic and community level efforts to address them exist.



Stakeholder perspectives presented in this paper indicate that two primary evolving challenges are impacting and potentially impeding even the most robust efforts to close vaccination gaps. These are: 1) inadequate high-quality maternal immunization data, and 2) issues related to coordination and implementation of maternal immunization programs on the ground.”

Stakeholder perspectives presented in this paper indicate that two primary evolving challenges are impacting and potentially impeding even the most robust efforts to close vaccination gaps. These are: 1) inadequate high-quality maternal immunization data, and 2) issues related to coordination and implementation of maternal immunization programs on the ground. Furthermore, addressing these challenges, including through policy solutions, presents an opportunity to develop better informed and more effective solutions to the most persistent barriers, at a critical moment when interest in improving immunization rates is high.

What follows is an overview of the current landscape, limitations, and impacts of challenges related to maternal immunization data collection/reporting and implementation, as well as a discussion that details potential solutions that could strengthen existing efforts in place to address longstanding barriers to vaccinations among pregnant individuals.

SNAPSHOT:

Data and on-the-ground implementation gaps stand in the way of fully understanding and realizing path to gains in maternal immunization rates

Key Insights: High Quality Data, Monitoring and Reporting

- More effectively collecting, monitoring and reporting on maternal immunization data that leverages information technology will be critical to realizing meaningful progress against suboptimal vaccination rates among pregnant individuals.
- To achieve this goal, widely used vaccine registries or immunization information systems (IIS) with complete, high-quality data will be vital, as comprehensive IIS provide timely, accurate information on immunization, serving as a powerful tool for assessing current coverage rates, gaps and disparities, and enabling the development of effective and targeted efforts in areas with highest need.
- Several pieces of recent legislation—including the *21st Century Cures Act*, the proposed *Immunization Infrastructure Modernization Act* and *Black Maternal Health Momnibus Act*—include language aimed at expanding and improving data collection and interoperability, demonstrating some promising movement across the policy landscape.
- Additionally, the COVID-19 outbreak—and most recently the rollout of COVID-19 vaccines—have prompted renewed momentum around data collection and IIS among policymakers.

Key Insights: On-the-Ground Coordination and Implementation

- An emphasis on coordination between the programs being developed at the federal level and healthcare professionals (HCPs) who are implementing on the ground, and solutions that aim to address the most prominent access challenges will be critical to advancing maternal immunization efforts going forward.
- Solving for these on-the-ground implementation challenges will require prioritizing a range of diverse solutions. A handful of states have established some promising measures that should be looked to for evidence of the impact these changes can have on reducing gaps in maternal immunization. Forward-looking solutions to encourage maternal immunization currently underway in select states include:
 - Incentivizing payments in the managed care delivery system for HCPs who administered the Tdap vaccine as part of their prenatal care
 - Allowing HCPs to bill health plans outside of capitation rates
 - Providing Tdap starter doses to clinics and encouraging group purchasing of vaccines
 - Leveraging vaccination management services, or third-party technology platforms that provide end-to-end vaccine management

Background

Vaccines administered during pregnancy provide critical protection to pregnant individuals and their fetuses against potentially deadly infectious diseases and also help protect newborns from harmful pathogens during the “window of vulnerability” when infants are too young to receive their own vaccinations.¹ Because newborns are too young to receive most vaccines, maternal immunization plays a critical role in preventing potential hospitalizations, long-term health problems or even death.² To that end, maternal immunization is an essential part of prenatal care, offering important protection to both mother and baby.³

The barriers to maternal immunization in the United States—many of which are longstanding—are complex, interconnected, and they persist across patient, healthcare professional (HCP) and systems levels. While recent advances and promising strides have been made in addressing some of these barriers, suboptimal maternal immunization rates remain a challenge and like many other public health issues, have only been magnified and exacerbated by the COVID-19 pandemic.

Current guidelines from the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) recommend that pregnant individuals receive an inactivated influenza vaccine and a Tdap (tetanus, diphtheria, pertussis) vaccine during each pregnancy.⁴ These recommendations are supported by a broad range of medical associations including the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists and others, and are based on comprehensive research

that has consistently demonstrated the significant benefits associated with maternal vaccines for individuals who are pregnant and their newborns.⁵

The data that have led to maternal vaccination recommendations are compelling. Individuals who are pregnant and postpartum are more than twice as likely to be hospitalized for influenza than those who are not.⁶ Additionally, newborns whose mothers received an influenza vaccine are up to 81 percent less likely to be hospitalized with influenza in the first six months of life than those with mothers who did not receive a vaccine.⁷ Similarly, pertussis, also known as whooping cough, is a highly contagious disease and infants are at especially high risk for complications related to the disease in the first six months of life.⁸ While infants cannot receive vaccination against pertussis until they are two months old, a Tdap vaccination administered to a pregnant individual during the third trimester (as is recommended) has been found to reduce the risk of infants contracting pertussis in their first two months of life by 77.7 percent.⁹

Despite well-documented evidence of the efficacy, safety and benefits of maternal immunization, many individuals are not receiving the vaccines recommended during the course of pregnancy, leaving mothers and their babies vulnerable to potentially life-threatening complications associated with these diseases. According to the most recent CDC survey, the rate of vaccination among pregnant individuals between 2019 and 2020 was 61.2 percent and 56.6 percent for influenza and Tdap, respectively. Only 40.3 percent of pregnant individuals received both vaccines and in some populations these rates are far

lower.¹⁰ Assessments of maternal immunization rates among Black and Hispanic populations, for example, estimate that only 23 percent of Black individuals and 25.4 percent of Hispanic individuals received both recommended vaccines during the course of their pregnancy.¹¹ Additionally, research suggests there are further disparities in maternal immunization rates among pregnant individuals living in low-income and rural settings, and/or participating in Medicaid.¹²

While persistent barriers to maternal immunization have been well-documented, experts and stakeholders in the maternal health space are increasingly raising concerns around issues pertaining to a lack of comprehensive data, as well as gaps in the coordination and implementation of on-the-ground vaccination programs. Without better data collection, sharing and analysis, it is difficult to fully understand exactly who does not receive maternal vaccinations and why, and to determine how to best address the situation. Likewise, barriers to coordination between federal programs, HCPs, and immunization stakeholders working to carry out these programs within local communities creates implementation challenges that also impede efforts to improve maternal immunization rates.



Without better data collection, sharing and analysis, it is difficult to fully understand exactly who does not receive maternal vaccinations and why, and to determine how to best address the situation. Likewise, poor coordination between federal programs and the teams responsible for carrying out these programs within local communities creates implementation challenges that also impede efforts to improve maternal immunization rates.”

Existing research and literature on the barriers to maternal immunization make mention of data- and implementation-related challenges, but these topics have not historically been a central focus. The objective of this white paper is to evaluate the current landscape around maternal immunization data and implementation efforts, provide analysis of how data and implementation limitations and gaps intersect with and impact existing efforts to address maternal immunization barriers, and discuss opportunities and proposed approaches to addressing these issues.

Evolving Data and Implementation Challenges in Commercial and Medicaid Contexts

Longstanding barriers to maternal immunization are complex and challenging to address despite the information, efforts, and proposed solutions that have been put forth by experts, stakeholders, and policymakers. While there is no single solution, or particular challenge that, if addressed, would solve for these persistent barriers, stakeholders have recently become more and more focused on understanding how two issues—shortcomings in data and reporting, and challenges related to program implementation—are exacerbating established obstacles and undermining ongoing efforts to address them across patient, HCP and systems-levels. Notably, these two issues are found within both the commercial and Medicaid contexts.

The subsequent section provides an overview of these dual evolving trends, presenting the current landscape, limitations, and impacts of challenges related to maternal immunization data collection/reporting and implementation.

Data and Reporting Challenges

The full extent of suboptimal maternal immunization rates—across the general population as well as within individual patient

communities—remains unclear because the United States lacks comprehensive immunization data and reporting systems. Barriers are exacerbated by the fact that while some maternal immunization data exist, the tools, resources and various systems currently in place to capture and report on rates of maternal immunization offer a disparate and incomplete picture, given the lack of real-time reporting and coordinated infrastructure to support such an effort.

In the United States there are several gaps and shortcomings related to current adult immunization vaccine registries or immunization information systems (IIS) that complicate and stand in the way of the process of capturing comprehensive maternal immunization data. Monitoring and reporting on immunization in the U.S. falls to the 62 individual IIS jurisdictions across the nation, many of which are in states that do not require HCPs to report immunizations to their IIS. While some jurisdictions have strong immunization data collection systems, each jurisdiction leverages different metrics and systems and has different levels of capacity with regard to capturing data on adult

Understanding Immunization Information Systems

Immunization information systems (IIS), otherwise known as registries, are confidential, population-based, computerized databases that record all immunization doses administered by participating healthcare professionals to persons residing within a given geopolitical area. They offer an opportunity for confidential, secure, centralized, and immediate authorized access to immunization records. IIS can be useful in identifying under- and over-immunized children, monitoring community immunization rates, identifying coverage gaps and improving vaccination rates.

Source: American Academy of Pediatrics. Immunization Information Systems. <https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunizations/Practice-Management/Pages/immunization-information-systems.aspx>

vaccination rates. Current limitations on the ability to share data across IIS platforms also create challenges—without interoperability, data are not portable which can lead to inconsistencies and an incomplete picture of maternal immunization rates that pose challenges for HCPs and health insurance plans, alike. In addition, health insurance plan access to IIS is uneven, and even excluded in some states. Adding to these challenges is the fact that a given IIS may not ask about pregnancy status, meaning even if vaccination status is captured, information about pregnancy may not be recorded. Taken together, these barriers make the realization of a comprehensive and real-time evaluation of maternal immunization currently impossible.¹³

Furthermore, while the National Vaccine Advisory Committee (NVAC) recommends that all HCPs have access to each patient's full immunization status at each medical encounter, which can be made possible through IIS integration with electronic health records (EHRs), recent surveys have shown that many HCPs are either unaware of the existence of IIS or unable to access them.¹⁴

The insights that are available on rates of vaccination among pregnant individuals are primarily drawn from two sources—the CDC's maternal vaccination internet survey panels, and private insurance and Medicaid claims databases—both of which have unique and significant limitations.^{15,16} Moreover, a reliance on disparate data sources with varying data collection processes, metrics of interest, reporting methods and degrees of portability presents challenges and gaps that impede a comprehensive understanding of the current maternal immunization landscape.

One of the most widely available and leveraged resources for data on U.S. maternal

immunization is the CDC's annual Morbidity and Mortality Weekly Report on *Influenza and Tdap Vaccination Coverage Among Pregnant Women in the United States*.¹⁷ The report evaluates a range of metrics including age, race/ethnicity, education and income level, marital and employment status, residence, insurance status, number of HCP visits, and whether or not an HCP offered/recommended maternal vaccines. In the wake of the COVID-19 vaccine the CDC also established the “v-safe COVID-19 Vaccine Pregnancy Registry”, which collects health information from those who received the COVID-19 vaccine in the periconception phase or during pregnancy and voluntarily opt-in to the registry.¹⁷

CDC surveys are largely seen as the most accessible and comprehensive resource on maternal vaccination coverage in the United States, yet the shortfalls of its data and reporting on vaccine coverage rates during pregnancy are meaningful – and undoubtedly interfere with the ability to fully understand the current maternal immunization landscape. The data collected are gathered exclusively from voluntary, online survey panels—a method with a range of limitations including:

- Data samples that aren't representative of all pregnant individuals in the United States, as surveys are conducted among smaller groups of volunteers who have already enrolled in general population-level survey panels rather than conducted across a randomly selected panel of individuals
- Biases related to the exclusion of individuals who do not have reliable internet access, as well as the self-selection processes for entry into the internet panel and the survey itself
- Survey results that are self-reported and not verified through medical record review

- Unequal sub-population representation with some sub-populations having smaller sample sizes than others
- Biases related to respondent recall of vaccination, with recent surveys reporting that 13 percent of participants did not know their vaccination status
- Published data are retrospective from the year prior, meaning the most recently released data does not capture real-time vaccination rates¹⁸

In addition to the CDC’s maternal immunization surveys and reports, information on maternal vaccine coverage can also be captured using medical claims data from both commercial insurers and Medicaid.¹⁹ These data are derived from claims submitted by HCPs to obtain payment for services rendered, which can include vaccines administered during pregnancy.²⁰

Unlike the CDC surveys, these databases can offer large sample sizes from geographically diverse regions and more accurately capture vaccination status because data collection is not based on self-reporting.²¹ Still, this method of data collection and reporting presents its own challenges including:

- Not being widely available or publicly accessible; rather claims data is primarily available for purchase and therefore availability and insights are reliant on third-party interests, as well as third-party data analysis and publication (often carried out by academic groups)
- Data is inherently bifurcated by plan (commercial vs. Medicaid), which can be helpful if there is interest in comparing measures across plan type—but presents challenges for comparing across other metrics and makes it difficult to assess

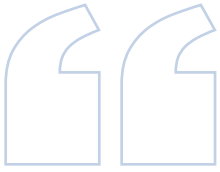
the comprehensive landscape (i.e., maternal immunization rates across the full population regardless of plan type)

- While more accurate than self-reporting, claims data still only offer a sample rather than a full database reporting out real-time, up-to-date maternal immunization statistics
- The inability to account for and capture immunization that takes place outside of a traditional HCP setting (i.e., retail pharmacy or community health center) or immunization within uninsured populations. Furthermore, claims data do not include vaccination services provided through public health programs that do not bill a patient’s health coverage.

The barriers resulting from a system that lacks comprehensive data collection, monitoring, and reporting on maternal immunization have been identified by stakeholders in the maternal health space as one of the most significant challenges to improving rates of maternal immunization.²² Without representative, quality data that reflect real-time vaccination rates among pregnant individuals, stakeholders are unable to understand the full scope of the problem, making it difficult to:

- Accurately identify key areas of concern;
- Fully assess the severity and extent of coverage gaps; and,
- Effectively evaluate, develop, and advocate for the solutions most needed and best equipped to address the most pressing barriers to maternal immunization.

In short, shortcomings in quality data collection, monitoring, and reporting are undermining even some of the most robust efforts to address longstanding barriers contributing to persistent, suboptimal maternal immunization rates.



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Implementation Challenges

In addition to the challenges stemming from a lack of high-quality comprehensive data, issues with on-the-ground implementation of programmatic efforts to reduce gaps in maternal immunization coverage are also a key challenge to improving vaccination rates. Specifically, stakeholders are pointing to issues of coordination between federal and state-level programs and the HCPs interfacing with and delivering prenatal care to patients.

It is important to note that the term “HCP” refers to a diverse range of practitioners responsible for delivering pregnant individuals care, including medical doctors, nurse practitioners, certified nurse midwives, registered nurses, physician assistants and others, and conversations concerning challenges and solutions must consider all of these roles.

There is broad awareness and a large body of evidence to demonstrate that when pregnant individuals receive influenza and Tdap vaccines, the risk of infection and complications associated with these diseases is greatly reduced for both mother and

baby.²³ Maternal immunizations work, yet current gaps in coordination are impeding critical efforts to address some of the most challenging barriers to maternal immunization.

General consensus among stakeholders is that at the HCP level, there is a strong amount of education and awareness of current CDC maternal immunization recommendations. However, there are still reported gaps in HCPs communicating these recommendations to their pregnant patients. For example, a study evaluating 133 New York state obstetrician-gynecologists (OB-GYNs) found that even though 92 percent reported knowledge of ACIP’s recommendation that pregnant individuals receive a Tdap vaccine, only 80 percent actually recommended the vaccine and 67 percent reported stocking the vaccine in their offices.²⁴ Another national study of 353 OB-GYNs found that in instances where a vaccine was not stocked in their office, only 56 percent referred patients to their primary care provider and 25 percent referred to a local pharmacy.²⁵



Whether a result of inadequate reimbursement, competing priorities, lack of digital prompt via EHR or IIS system, or some combination thereof, these challenges are further exacerbated by the lack of coordination between programs at the federal level and on-the-ground implementation.”

Whether a result of inadequate reimbursement, competing priorities, lack of digital prompt via EHR or IIS system, or some combination thereof, these challenges are exacerbated by the lack of coordination between proposals and programs at the federal level and on-the-ground implementation. The recommendation that pregnant individuals receive influenza and Tdap vaccines has been in place since 2004 and 2012, respectively, and while there are some nuances, HCPs delivering care to pregnant individuals recognize and appreciate that their patients should be receiving these vaccines.^{26,27} Rather, the current challenge ties back to implementation of policy proposals focused on addressing maternal immunization barriers that are currently undermined by a lack of coordination at state, regional and community levels.

Reimbursement rates and costs of purchasing, stocking, and administering vaccines have also been identified as barriers to maternal vaccination.^{28, 29}

These challenges have, to an extent, been recognized at the legislative level and there have been a number of proposals put forth regarding quality measurement guidance and better incentivizing HCPs to administer vaccines

to individuals who are pregnant. For example, in 2019, the Prenatal Immunization Status was added as a new measure to the Healthcare Effectiveness Data and Information Set (HEDIS), as a means of better assessing the receipt of important prenatal vaccines and improving the visibility of vaccination recommendations.³⁰

That said, despite growing momentum with regards to this issue at the federal level, there is a notable lack of coordination between policy conversations and on-the-ground implementation beyond education and awareness campaigns at the state and HCP level. In the case of HEDIS, for instance, despite the addition of the prenatal immunization measure, implementation gaps have led to continued discrepancies in HCP recommendation and administration of maternal vaccination, with many citing reimbursement and financial risk of vaccine stocking as key barriers.

To ensure the programs, legislation and activities established to address gaps in maternal vaccine coverage are carried out efficiently and effectively, and that objectives are translated into practice, these implementation discrepancies need to be addressed, ideally holistically and systemically.

Longstanding Barriers to Maternal Immunization

Longstanding barriers to maternal immunization have been extensively studied, with findings reflecting obstacles across federal-, state-, HCP-, and patient-levels. The dynamics between these multi-sectoral challenges have all been reported to contribute to suboptimal rates of recommended maternal immunizations. Many of these challenges, such as disparate access to and receipt of vaccines and inadequate data collection, have been exacerbated by the COVID-19 pandemic and brought to the forefront of national dialogue.

While the focus of this paper is centered on the evolving challenges undermining efforts to address longstanding barriers to maternal immunization, the following section provides a summary of these barriers for context. Additional information on the current landscape and relevant legislative activity related to maternal immunization can be found in the [Appendix](#).

Federal- and State-Level Barriers

There are persistent barriers to maternal immunizations at the federal level. Concerns regarding Medicaid funding are frequently discussed, often in conjunction with the variation in state-by-state coverage.³¹ The *Maternal Immunization Coverage Act*, was introduced in the Senate in the spring of 2021 in an attempt to address these concerns by amending the Social Security Act to require Medicaid coverage of recommended vaccines for pregnant individuals.³² Underrepresentation of both pregnant individuals and communities of color in clinical research presents another challenge in increasing rates of maternal immunization, as this has the potential to translate into

vaccine hesitancy among underrepresented groups or could lead to interventions that are not as safe or efficacious in particular populations.^{33,34} Lastly, the nationwide underutilization of EHRs and IIS limits the data available to inform a better understanding of trends in maternal immunization—and ultimately design and implement impactful solutions.³⁵

To help expand access and eliminate financial barriers to COVID-19 vaccines, *The American Rescue Plan Act of 2021*, a COVID-19 relief package, became law in March 2021 and contains a number of provisions aimed at increasing coverage, expanding benefits, and adjusting federal financing for state Medicaid programs. One element of the law establishes that all COVID-19 vaccines and their administration are covered without cost-sharing for Medicaid enrollees and provides 100 percent federal matching funds for this coverage.³⁶ Broad elimination of financial barriers to COVID-19 vaccines has been seen as vitally important. To that end, advocates are calling for all ACIP-recommended maternal immunizations to similarly be covered without cost-sharing under both the Medicaid program and across commercial plans and that vaccine manufacturers continue to ensure that ACIP-recommended vaccines are made available at reasonable prices.

COVID-19 has also highlighted the need for pregnant individuals to be included in clinical trials, particularly as clinical trials are currently underway to evaluate COVID-19 vaccines in pregnant individuals.³⁷ Beyond the scope of the pandemic, opportunities to mitigate the challenges associated with participation of pregnant individuals and communities of color in clinical research

include leveraging a multipronged approach that encompasses community outreach programs, greater representation in medical schools and clinical trial databases, reimbursement for indirect healthcare costs and dialogue within communities of color about the barriers they experience.³⁸

To address underutilization of data collection platforms, legislation has been proposed, including the *Black Maternal Health Momnibus Act of 2021* and the *Immunization Infrastructure Modernization Act of 2021*, both of which are aimed, in part, at improving maternal health data collection, reporting and sharing processes.^{39,40}

Recent legislative efforts have been made to address financial barriers associated with variable state-by-state Medicaid coverage. *The Maternal Immunization Coverage Act*, introduced in April 2021, would require state Medicaid programs to cover certain vaccines recommended for pregnant individuals without cost-sharing.⁴¹ Additionally, the *Mothers and Offspring Mortality and Morbidity Awareness (MOMMA's) Act* was introduced in the Senate in February of 2021 and in the House in May of 2021; if passed into law, this bill would establish a series of programs and requirements to address maternal mortality including expanding coverage under Medicaid and Children's Health Insurance Program (CHIP) for pregnant and postpartum individuals.⁴² A report from the U.S. Government Accountability Office (GAO) is also currently underway and will review vaccination coverage under Medicaid and how states cover vaccinations for children and adults with a focus on any resulting racial, ethnic or geographic disparities in immunization rates that may be related to gaps in coverage.⁴³

Additionally, the state-by-state approach to Medicaid program implementation, driven

in part by differences in policy between managed care organizations supporting state Medicaid programs, result in discrepancies in access to vaccination services and can exacerbate current inequities and disparities in rates of maternal immunization.⁴⁴ Challenges related to coordination across existing resources, programs and relevant stakeholders can also inhibit on-the-ground efforts to improve maternal vaccine coverage.

Practice-Level Barriers

At the HCP-level, financial barriers such as prohibitive administration costs and inadequate reimbursement can dissuade practitioners from stocking and offering recommended vaccines to their obstetric patients.⁴⁵ Compounding financial concerns, insufficient bandwidth among HCPs and HCP staff, and a recognized gap among some HCPs in providing culturally competent care are also reported barriers to providing influenza and Tdap vaccinations.^{46,47} Additionally, even when all the aforementioned barriers are accounted for, HCPs may still encounter pregnant patients who refuse vaccination despite recommendations.⁴⁸

Further, despite the benefits of using electronic data collection methods, many HCPs delivering care to pregnant and postpartum individuals, underutilize or do not use IIS, which can be further exacerbated by costs associated with establishing these systems especially among smaller practices often serving rural or underserved populations.⁴⁹ Underutilization and lack of access to IIS also creates issues for health insurance plans, limiting plans' ability to understand which members of their populations have and have not received vaccinations and subsequently hindering their ability to conduct effective outreach and education. Overall interoperability between health information technology

platforms is lacking and there are gaps in data that could help improve monitoring of vaccine preventable disease and vaccine coverage rates in real time at a population level.⁵⁰ More HCPs enrolling in and transmitting maternal immunization data to their jurisdictions' IIS, and ensuring IIS access for health insurance plans is essential to improving availability and accessibility of maternal health data and ultimately improve maternal immunization rates.

To address cost concerns, education on the long-term benefits of implementing vaccine services, as well as potential cost-saving business practices may help overcome financial deterrents.⁵¹ That said, leading advocacy organizations underscore that without improved reimbursement for preventive health services (which includes immunization) that acknowledges the cost aspects of counseling and administering vaccines to pregnant individuals, these education efforts alone fall short.⁵²

Current approaches to mitigating bandwidth issues largely focus on appointing in-office vaccine champions and instituting standing orders or established processes for assessing, documenting, recommending and administering vaccines.⁵³ Training all patient-facing staff on the importance and benefit of vaccination for pregnant individuals and how to deliver an impactful vaccine recommendation can also help fill the reported gap in HCP recommendations. In addition to training staff on the importance of vaccination, bipartisan legislation, including the *Black Maternal Health Omnibus Act of 2021*, has been introduced with language that aims to help expand and strengthen culturally competent care for pregnant individuals.⁵⁴

Beyond office-centric initiatives, advocates have identified incentivizing the adoption

of the HEDIS Prenatal Immunization Status quality measure as an opportunity to increase rates of maternal immunization.⁵⁵ Language within the *Maternal Immunization Enhancement Act*, introduced to the Senate in April of 2021, aims to solidify quality measures. The legislation would add a quality measure that accounts for perinatal vaccination status for pregnant individuals under Medicaid and CHIP.⁵⁶ The U.S. Department of Health and Human Services (HHS) has also included increasing Tdap vaccinations in pregnant individuals as a development objective under the Healthy People 2030 program.⁵⁷

Patient-Level Barriers

At the patient-level, pregnant individuals continue to encounter barriers to receiving recommended influenza and Tdap vaccinations. Inadequate access to care and out-of-pocket costs can inhibit uptake of maternal immunizations, especially among populations who are un- or under-insured or covered by Medicaid.^{58,59} Further, because not all pregnant individuals have insurance coverage and there is no comprehensive analysis of how maternal immunization is covered it is impossible to determine the full extent of this coverage gap.

One proposed solution to alleviate patient-level financial barriers is to eliminate cost-sharing for maternal immunizations. Currently in states with traditional Medicaid coverage, the individual Medicaid program is responsible for determining whether maternal vaccinations are provided to pregnant individuals with or without cost-sharing.⁶⁰ Federal legislation has been proposed to require state Medicaid programs to cover maternal immunizations without cost-sharing.^{61,62} This is a promising step although maternal health advocates and experts

recommend that the elimination of cost-sharing for maternal immunization extend beyond Medicaid and be applied to all plans, public and commercial. Additionally, other pieces of legislation have been introduced and are aimed at increasing maternal vaccination awareness and equity, particularly for communities with disproportionately high rates of unvaccinated individuals.⁶³ Moreover, not all patients may have the appropriate education or awareness regarding maternal immunizations, which alone or

coupled with vaccine hesitancy and/or a lack of culturally competent care, can contribute to particularly low rates of vaccination.⁶⁴ Educating not just the mother, but also partners and family members on the positive health benefits of recommended vaccines can help fill the gap in knowledge and reduce hesitancy and echo leading obstetric groups' call to increase open and fact-based dialogue on the safety and efficacy of vaccines for pregnant individuals.^{65,66}

Discussion

As this paper lays out, stakeholders have identified the lack of comprehensive data around maternal immunization rates, and gaps in coordination and implementation on-the-ground as two underlying issues hindering the programs and activities in place to tackle persistent barriers to maternal immunization. The remainder of this section provides a discussion of a range of promising solutions that have been put forth and their potential impacts.

Existing and Proposed Solutions: High-Quality Data Collection, Monitoring and Reporting

More effectively collecting, monitoring and reporting on maternal immunization data that leverages information technology will be critical to improving maternal vaccination rates. To achieve this goal, widely used vaccine registries or immunization information systems (IIS) that collect comprehensive, high-quality data and allow for electronic data exchange are vital.⁶⁷ IIS with complete, real-time, high-quality data provide timely, accurate information on immunization, serving

as a powerful tool for assessing current coverage rates, gaps and disparities and also enabling the development of effective and targeted efforts in areas with greatest need.⁶⁸

Some states have begun to recognize the power and importance of comprehensive and high-quality IIS in improving maternal immunization, providing promising models for other states. In California, for example, Medi-Cal—the state's Medicaid program—not only requires that health plans ensure timely provision of all vaccines recommend by ACIP, but also requires that complete data on the administration of these vaccines is reported to the California Immunization Registry. In 2019, California also made it mandatory for pharmacists to report immunizations, giving HCPs and stakeholders insight into whether or not vaccine referrals were successful.⁶⁹

Colorado and Wisconsin have also taken steps to strengthen and leverage the collection and monitoring of vaccine coverage data.^{70,71} Both states are using data matching to match patient medical records with the records

of their states' IIS, allowing each state to map maternal immunization rates against a variety of demographic metrics, assess vaccine coverage gaps, and identify areas of highest need to inform effective intervention programs.⁷² Learnings from work to improve the collection, monitoring and reporting of maternal immunization data should be looked to as a valuable framework that should be leveraged by other states across the country.

At the federal level, the Centers for Medicare & Medicaid Services (CMS) issued rules under the *21st Century Cures Act* to improve and streamline health data interoperability between HCPs, patients and health insurance plans in an effort to encourage more coordinated and complete care.⁷³ Additionally, the COVID-19 outbreak—and most recently the rollout of COVID-19 vaccines—have prompted renewed momentum around data collection and IIS among policymakers. Recently proposed legislation includes the *Immunization Infrastructure Modernization Act*, which includes provisions to improve immunization data systems and information exchange, and the *Black Maternal Health Omnibus Act*, which is focused on improving data collection for maternal health indicators specifically. These efforts have the potential to meaningfully and drastically improve data infrastructure for capturing adult immunizations if passed.^{74,75}

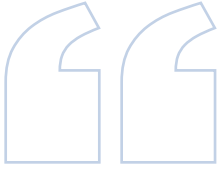
Furthermore the COVID-19-related funds and efforts that have been put in place to provide real-time surveillance of infection and vaccination rates (e.g., the CDC's development of a standardized approach to reporting and monitoring COVID-19 cases) have the potential to serve as a foundation for broader-reaching future efforts.⁷⁶ In other words, the data and surveillance systems created in response to COVID-19 can and should be leveraged to capture comprehensive data for

adult vaccination coverage, including maternal immunization rates.

Notably, in addition to allocating these funds and making this infrastructure available, oversight ensuring states are effectively and appropriately carrying out this data collection and meeting specified standards will also be critical. To that end, the National Vaccine Advisory Committee (NVAC), the American Immunization Registry Association (AIRA) and others should be activated to identify and lay out standards and guardrails to help make certain that adequate and appropriate participation and compliance is occurring at the state level. Importantly, these standards must be accompanied by appropriate and adequate resources to enable any necessary training for HCPs and staff on the use of IIS.

Existing and Proposed Solutions: On-the-Ground Coordination and Implementation

In addition to strengthening high-quality data collection and monitoring and reporting, operationalizing approaches to ensure that HCPs are able to offer vaccinations and that patients are able to access them, is essential to improving vaccine coverage rates among pregnant individuals. While recognition of sub-optimal maternal immunization rates by policymakers is critical to realizing improvements, the efficacy of policy and programmatic activities only goes as far as the ability of these efforts to be implemented. An emphasis on coordination between the programs being developed at the legislative level and HCPs who are implementing on the ground, and solutions that aim to address the most prominent access challenges will be critical to advancing maternal immunization efforts going forward.



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A handful of promising programs have been established in some states, which can be looked to for evidence of the impacts these interventions have on reducing gaps in vaccination coverage among pregnant individuals. California’s 2020 budget, for example, included incentive payments in the managed care delivery system for HCPs who administered the Tdap vaccine as part of their prenatal care.⁷⁷ Additionally, in an effort to lower the financial barriers associated with vaccine administration, several of Medi-Cal’s managed care plans have allowed HCPs to bill the health plan outside of capitation rates, and are providing Tdap starter doses to clinics and encouraging group purchasing of vaccines.^{78,79}

At the federal level, the *Mothers and Offspring Mortality and Morbidity Awareness (MOMMA’s)* Act, introduced in early 2021, also aims to address coordination and implementation barriers through a range of proposed activities including: establishing national obstetric emergency protocols, standardizing data collection and reporting related to maternal health, improving pregnant individuals’ access to culturally competent care, providing

options for states to adopt and pay for doula services, and expanding Medicaid coverage for new mothers across the entire postpartum period (1 year).⁸⁰

Another approach to reducing implementation barriers to maternal vaccination on-the-ground is through the use of vaccination management services, or third-party technology platforms that provide end-to-end vaccine management by helping HCPs facilitate purchasing, logistics, and billing related to vaccines. Third party vaccine management services—which are now available in 22 states—provide vaccines to HCPs at no cost, automate restocking and inventory management, provide technology enabled and user-friendly onsite tools that document vaccinations into EHR and state immunization registries, where permitted, while also coordinating vaccine billing and administration fees.

By streamlining the challenges HCPs face related to administering immunizations, these services give practices the ability to consistently administer vaccines to their patients. For example, often practices’ inventory of the influenza vaccine will run low as the season progresses and ordering additional vaccines that may not be used poses a financial risk, which can also leave patients unvaccinated. By allowing for a quick restock of needed doses and the ability to return unused doses, vaccine management services help ensure practices have the vaccinations their patients need onsite, when they need them while limiting financial risk.

In the absence of being able to provide maternal vaccines on-site, providing transportation to encourage and support pregnant individuals who have been referred to a secondary vaccination site is another

solution that might be explored. Models for this have been initiated in the context of COVID-19, where ride sharing services have partnered with Medicaid and health systems to provide transportation at no-cost to patients.⁸¹ Establishing programs, incentives and partnerships that help provide transportation for pregnant individuals who may not have access to reliable transportation means to vaccine sites has the potential to address gaps that arise when patients are referred elsewhere for maternal immunizations.

Lastly stakeholders in the maternal health space are also proposing that research into how HCPs are communicating about maternal vaccinations to their pregnant patients be undertaken to gain better insight into whether or not there are HCP-patient communication and education challenges that can be addressed and if so, how they might be best approached. One example that may serve as a model is the CDC's You are the Key to HPV Cancer Prevention program which offered continuing education credits to HCPs who took courses that supported them in making effective vaccine recommendations and answering patient questions and concerns.⁸²

Conclusion

For many years, stakeholders, experts, and policymakers have worked to identify the most challenging barriers to maternal immunization in the United States and develop a range of solutions to address the obstacles that exist across the spectrum from patients and HCPs, to the state and federal levels. The persistence of these issues has, in recent years, prompted stakeholders to reevaluate some of the evolving challenges that are impeding existing efforts to close maternal vaccination coverage gaps.

The analysis presented demonstrates the harmful impacts these challenges have on progress, and like so many other health challenges, the longstanding and evolving barriers that have been magnified by the COVID-19 pandemic.

COVID-19 has also brought many of these barriers to light and spurred renewed interest in immunization infrastructure and the implementation resources needed to successfully close vaccine coverage gaps.

As a result, maternal health stakeholders are currently in a unique position to highlight and advance meaningful solutions that stand to strengthen data and implementation efforts to improve rates of maternal immunization.



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Appendix

Relevant Federal Legislative Activity			
NAME OF LEGISLATION	STATUS	AIM OF LEGISLATION	IMPLICATIONS FOR MATERNAL IMMUNIZATION RATES
Immunization Infrastructure Modernization Act of 2021⁸³	Introduced to the House on 1/28/2021	<p>To amend the Public Health Service Act with respect to immunization system data modernization and expansion, including:</p> <ul style="list-style-type: none"> • An assessment of current capabilities and gaps among immunization practitioners • Expand enrollment and training of immunization practitioners • Support real-time immunization record data exchange and reporting • Improve secure data collection, transmission, bidirectional exchange, maintenance, and analysis of immunization information • Enhance security of bidirectional exchange of immunization record data and interoperability of immunization information systems with health information technology platforms; and • Enhance data exchange interoperability with other jurisdictions. 	Widespread implementation of immunization systems as confidential, population-based resources helps record maternal immunizations administered by participating practitioners. Data captured can help identify areas of need, can be exchanged among HCPs, and help improve vaccination rates.
The Black Maternal Health Momnibus Act of 2021^{84,85} (including the Maternal Vaccinations Act)⁸⁶	<p>Introduced to the House on 2/8/2021</p> <p>Introduced to the Senate on 2/22/2021</p>	<p>Build on existing legislation to comprehensively address every dimension of the maternal health crisis in America. Specifically, with respect to maternal health and uptake of immunizations, the Act includes calls to action to:</p> <ul style="list-style-type: none"> • Provide funding to community-based organizations that are working to improve maternal health outcomes and promote equity. • Grow and diversify the perinatal workforce to ensure that every mom in America receives culturally congruent maternity care and support. • Improve data collection processes and quality measures to better understand the causes of the maternal health crisis in the United States and inform solutions to address it. • Invest in digital tools like telehealth to improve maternal health outcomes in underserved areas. • Promote innovative payment models to incentivize high-quality maternity care and non-clinical perinatal support. • Promote maternal vaccinations to protect the health and safety of moms and babies. 	The Momnibus Act encompasses a range of identified opportunities to overcome reported barriers to quality maternal health care and maternal immunizations, such as improving equity and access, fostering a more diverse and culturally congruent workforce, expanding data collection processes, promoting innovative payment models and encouraging maternal vaccinations.

Relevant Federal Legislative Activity

NAME OF LEGISLATION	STATUS	AIM OF LEGISLATION	IMPLICATIONS FOR MATERNAL IMMUNIZATION RATES
<p>Maternal Immunization Enhancement Act⁸⁷</p>	<p>Introduced to the Senate on 4/14/2021</p>	<p>Establishes several administrative requirements relating to vaccination rates among pregnant individuals enrolled in Medicaid.</p> <p>The Centers for Medicare and Medicaid Services must issue guidance to states with best practices for increasing vaccination rates for certain vaccines that are recommended by the Centers for Disease Control and Prevention and include a quality measure regarding prenatal immunization status for pregnant individuals under Medicaid.</p> <p>Additionally, the Government Accountability Office must report on vaccination rates among pregnant individuals enrolled in Medicaid, including barriers and demographic data.</p>	<p>The Maternal Immunization Enhancement Act recognizes the importance of improving the visibility of recommended maternal immunizations through the inclusion of the prenatal immunization status quality measure. This Act also highlights the gap in data that currently exists among pregnant individuals enrolled in Medicaid, calling for the Government Accountability Office to report on vaccination rates among pregnant individuals on Medicaid, respective barriers and demographic data.</p>
<p>Maternal Immunization Coverage Act⁸⁸</p>	<p>Introduced to the Senate on 4/14/2021</p>	<p>Requires state Medicaid programs to cover, without cost-sharing, certain vaccines that are recommended for pregnant individuals by the Centers for Disease Control and Prevention.</p>	<p>Passing of the Maternal Immunization Coverage Act would help to eliminate the frequently cited financial burden to receiving recommended maternal immunizations among pregnant individuals with Medicaid coverage, creating more access and opportunity for increased receipt of Tdap and influenza vaccinations.</p>
<p>Mother and Newborn Success Act^{89,90}</p>	<p>Introduced to the Senate on 7/22/2020</p>	<p>Seeks to address ongoing maternal health crisis through enhanced public health programs, improved care for underserved populations and research focused on maternal health.</p>	<p>Includes component calling for an evidence-based public and provider awareness campaign that includes a focus on the safety and effectiveness of vaccines for pregnant women and their children with a focus on communities with low rates of vaccination with a goal of improved vaccine confidence and reduced hesitancy among pregnant individuals to decrease disparities in maternal health across racial, ethnic and geographic demographics.</p>

Relevant Federal Legislative Activity

NAME OF LEGISLATION	STATUS	AIM OF LEGISLATION	IMPLICATIONS FOR MATERNAL IMMUNIZATION RATES
<p>Mothers and Offspring Mortality and Morbidity Awareness (MOMMA's) Act⁹¹</p>	<p>Introduced to the Senate on 02/24/2021</p> <p>Introduced to the House on 05/20/2021</p>	<p>Seeks to reduce America's rising maternal and infant mortality rate, especially for moms and babies of color who are significantly more likely to die during or in the year year after pregnancy through a multi-pronged set of activities including:</p> <ul style="list-style-type: none"> • Establishing national obstetric emergency protocols through a federal expert committee, • Ensuring dissemination of best shared practices and coordination amongst maternal mortality review committees, • Standardizing data collection and reporting, • Improving access to culturally competent care throughout the care continuum, • Providing guidance and options for states to adopt and pay for doula support services, and • Expanding Medicaid coverage to new mom's across the entire postpartum period (1 year). 	<p>Standardizing data collection around maternal indicators, including immunization status, helps to understand the full picture of maternal immunization and identify gaps to build more informed and targeted programs to encourage vaccine uptake. Bolstering culturally competent care may also help address the impacts a lack of culturally competent care can have on immunization (e.g. vaccine hesitancy or lack of HCPs who can explain the importance of vaccination to pregnant individuals who do not speak English as a first language).</p>
<p>American Rescue Plan Act of 2021⁹²</p>	<p>Became law on 3/11/2021</p>	<p>Contains a number of provisions aimed at increasing coverage, expanding benefits, and adjusting federal financing for state Medicaid programs. One element of the law establishes that all COVID-19 vaccines and administration are covered without cost-sharing for Medicaid enrollees and provides 100% federal matching funds for this coverage. The bill also provides a new option for states to extend Medicaid coverage to 12 months postpartum.</p>	<p>The importance of eliminating financial barriers, like cost-sharing has been acknowledged by the passing of this Act. With COVID-19 bringing to the forefront national dialogue around reducing barriers to immunizations, advocates in the maternal health space are calling for all ACIP-recommended maternal immunizations to similarly be covered without cost-sharing under the Medicaid program.</p>
<p>Maternal Health Quality Improvement Act</p>	<p>Approved by the Senate Committee on Health, Education, Labor and Pensions on 05/25/21</p> <p>Introduced to the House on 7/9/2021</p> <p>Approved by the House Energy and Commerce Health Subcommittee on 7/15/2021</p>	<p>Authorizes funding for several public health programs to address the maternal health crisis and improve the quality of maternal health care in the United States, including through:</p> <ul style="list-style-type: none"> • Disseminating best practices for maternal healthcare, • Implicit bias training for health care providers, • Integrating health care services for pregnant and postpartum individuals, and • Public awareness campaigns about the safety and effectiveness of vaccines to prevent disease in pregnant and postpartum individuals and in infants. 	<p>The maternal vaccination section of this bill directs the Centers for Disease Control and Prevention to take into consideration as part of its vaccination public awareness campaigns the importance of increasing awareness and knowledge of the safety and effectiveness of vaccines to prevent disease in pregnant and postpartum individuals and in infants and the need to improve vaccination rates in communities and populations with low rates of vaccination.</p>

Longstanding Barriers – Current Challenges and Landscape

BARRIER	CHALLENGES	CURRENT LANDSCAPE
Practice Level Barriers		
Inventory and Reimbursement	<p>Financial barriers frequently stand in the way of administering maternal immunizations. Administration costs, combined with inadequate reimbursement rates, are deterrents to HCPs offering immunizations to their pregnant patients.⁹³ Due to the increased time needed to appropriately counsel patients, administer the vaccine, and plan and manage vaccine supplies, OB-GYNs and other HCPs responsible for delivering care to pregnant individuals often have a higher median cost of vaccination than other practitioners.⁹⁴ Costs related to administering vaccines have also risen over time, which may lead practitioners in solo or small practices to be less likely to offer vaccines than HCPs in larger health care systems, where the distribution of related expenses may help offset the financial burden.⁹⁵</p> <p>Inadequate reimbursement is also a widely reported financial challenge. Due to constrained budgets, many Medicaid agencies often set low reimbursement rates for vaccine purchasing and administration.⁹⁶ Private insurance plans generally have a larger budget than Medicaid, but reimbursement is often capitated, resulting in similar financial challenges.⁹⁷ Additionally, reimbursement rates often do not include consideration for the time, training, and resources required to stock and administer vaccines.⁹⁸ In a 2016-2017 study of 353 nationally-representative OB-GYN HCPs in the U.S., 53 percent reported inadequate reimbursement for vaccine purchase and 45 percent reported inadequate reimbursement for vaccine administration as barriers to stocking or administering maternal vaccines.⁹⁹</p>	<p>Educating HCPs on the long-term benefits of implementing vaccine services as well as potential cost-saving business practices may help overcome financial concerns. Payer contracting for immunization services, appropriate billing for vaccination services and participation in vaccine purchasing groups can help HCPs implement vaccination services.¹⁰⁰ While some best practices have been identified to alleviate financial barriers, leading advocacy organizations recognize the continued need for improved reimbursement for immunization services that acknowledges the cost aspects of counseling and administering vaccines to pregnant individuals, and call for cross-sectoral action to help increase uptake of recommended vaccines among pregnant individuals.¹⁰¹</p>
Resources and Bandwidth	<p>Competing demands and insufficient bandwidth to administer vaccines in-clinic while also providing routine medical care are also reported barriers among obstetric HCPs.¹⁰² In one survey of OB-GYNs, 47 percent of respondents cited other medical services taking precedence over vaccination as a major or moderate barrier to stocking or administering vaccine.¹⁰³ In many cases, OB-GYN practices have less automated processes in place for ordering, tracking and storing vaccines and as a result, the logistical burden can deter HCPs from administering vaccines to their pregnant patients.¹⁰⁴</p>	<p>Delegating the responsibilities associated with organizing and maintaining in-office vaccine stock to an individual or team of staff can help alleviate over-burdening HCPs and create a work environment where staff is invested in vaccine promotion.¹⁰⁵ Implementing standing orders, where allowed by state and appropriate to the practice, can also help streamline the vaccine stocking process and allow qualified health professionals such as nurses, other than OB-GYNs, to assess the need for and administer vaccines. If standing orders are not feasible, standardizing the roles and responsibilities of staff in the immunization process can also help lessen capacity challenges.¹⁰⁶</p>

Longstanding Barriers – Current Challenges and Landscape

BARRIER	CHALLENGES	CURRENT LANDSCAPE
Practice Level Barriers		
Provision of Culturally Competent Care	A recognized gap among some HCPs in providing culturally competent care can discourage patient acceptance of maternal immunizations. The historic lack of diversity and representation in the HCP workforce, due to systemic issues both within and beyond the healthcare system, still remains and can create a disconnect in offering respectful, culturally congruent maternity care. ¹⁰⁷ As mistrust and vaccine hesitancy shape patients' willingness to receive influenza and Tdap vaccines, especially among communities of color and underrepresented populations, HCP-patient relationships are key in facilitating uptake of maternal vaccinations. ¹⁰⁸	The Black Maternal Health Momnibus Act of 2021 is a proposed package of 12 bills aimed at addressing the drivers of poor maternal health outcomes and ending racial and ethnic disparities. One section of this legislation recommends establishing "Respectful Maternity Care Compliance Programs" to address racism, bias and discrimination in maternity care settings to promote respectful, culturally congruent maternity care. ¹⁰⁹ Furthermore, the Act calls for the Secretary of the U.S. Department of Health & Human Services to issue guidance to promote the recruitment of racially, ethnically and professionally diverse maternity care teams that provide respectful, culturally congruent care. ¹¹⁰
Discrepancies in HCP Recommendations	A strong recommendation from an OB-GYN is one of the largest influencers on patient acceptance of immunization. When an obstetric HCP directly recommends and stocks maternal immunizations, the odds of vaccine acceptance and receipt are up to 50-fold higher. ¹¹¹ And while obstetric care HCPs are advised to vaccinate all pregnant patients against influenza and pertussis during each pregnancy, there are still discrepancies between this knowledge, the recommendation and offer to the patient and the actual vaccine administration. For example, in a 2015 study of 133 New York state OB-GYNs, 92 percent reported knowing Tdap vaccination was recommended for all pregnant individuals, while only 80 percent communicated this recommendation to their pregnant patients – and only 67 percent stocked Tdap vaccines. ¹¹² This disconnect between knowledge and recommendation is echoed in other studies and findings, including low rates of maternal vaccination following referrals to primary care HCPs and local pharmacies, and illustrates the continued opportunity to maximize OB-GYN recommendation and administration to increase vaccination rates among pregnant individuals. ¹¹³	To operationalize, language can be built into intake and check-in/check-out forms to remind practitioners to recommend vaccines as appropriate. HCPs may also consider linking Tdap vaccination to other maternal care services to create a natural prompt for recommendation. Furthermore, other healthcare professionals, such as physician assistants, nurse practitioners, pharmacists, doulas and Lamaze class facilitators, can play an important role in consistently communicating the importance of receiving influenza and Tdap vaccinations.
Underutilization of EHR and IIS	Underutilization of electronic health records (EHRs) and immunization information systems (IIS) is also a reported barrier to vaccination. ¹¹⁴ IIS, operated by every state and many large cities, are confidential, population-based, computerized systems that have the ability to record all vaccine doses administered by participating HCPs – as well as exchange data with multiple HCPs and allow HCPs to automate their vaccine inventory. Population-level data collected in IIS can be aggregated to track coverage and identify areas of need where there are low immunization rates. ¹¹⁵	<i>The National Vaccine Advisory Committee: Reducing Patient and Provider Barriers to Maternal Immunizations</i> identified increasing use of these data collection platforms among obstetric HCPs as a method to increase rates of maternal immunizations. ¹¹⁶ Additionally, given the bidirectional data exchange between IIS and EHRs, OB-GYN practices are also advised to implement steps to ensure consistent immunization documentation in their EHRs.

Longstanding Barriers – Current Challenges and Landscape

BARRIER	CHALLENGES	CURRENT LANDSCAPE
Patient-Level Barriers		
Access to Care and Cost Concerns	<p>Access issues among pregnant patients can be shaped by various social determinants of health, such as an individual's level of education, geographic location and access to transportation, as well as insurance status and type of coverage.¹¹⁷ Based on a 2019-2020 Internet panel survey conducted by the CDC, rates of both influenza and Tdap vaccines were lower among pregnant individuals with a high school diploma or less when compared to those with a two- or four-year college degree. Additionally, only 18.9 percent of pregnant individuals living in rural settings received both influenza and Tdap vaccines while 81.1 percent of nonrural dwelling pregnant individuals received both recommended vaccines.¹¹⁸</p> <p>Pregnant populations who are un- or under-insured or covered by Medicaid may experience increased financial barriers to receiving maternal immunizations.¹¹⁹ Rates of vaccination are historically lower among recipients of state-administered Medicaid health insurance when compared to pregnant individuals with private coverage.^{120,121} For example, among pregnant individuals who delivered at a Florida health system between 2016 and 2018, 13.4% of those covered by Medicaid received a Tdap vaccine compared to 68.6% with private insurance. Similarly, 35% of those with Medicaid coverage received an influenza vaccine compared to 70.4% with private coverage.¹²²</p>	<p>One proposed solution to alleviate patient-level financial barriers is to eliminate cost-sharing burden in Medicaid for maternal immunizations.¹²³ Cost-sharing refers to the share of costs covered by insurance that is paid out of pocket by the patient and can include deductibles, coinsurance and copayments.¹²⁴ Cost-sharing has been found to reduce use of medical care, especially among low-income and disadvantaged populations.¹²⁵ The Maternal Immunization Coverage Act, introduced in April 2021, would require state Medicaid programs to cover maternal immunizations without cost-sharing, as recommended by the Centers for Disease Control and Prevention.¹²⁶</p>
Lack of awareness about maternal vaccines	<p>Despite existing educational efforts, a lack of knowledge of risks and benefits associated with maternal immunizations remains a reported patient barrier to vaccination.¹²⁷ The most commonly cited reason by pregnant patients for not receiving a Tdap vaccine was not knowing that vaccination is needed during each pregnancy.¹²⁸ In another survey of OB-GYNs, patient attitudes were commonly reported as a major or moderate barrier to vaccination, with 52 percent citing that patients refuse vaccines because of safety concerns and 40 percent citing patients refuse vaccines because they do not believe they are at risk for a vaccine-preventable disease.¹²⁹</p>	<p>Lack of awareness or education, coupled with other reported barriers like attitudes, beliefs, demographic background, previous experience with the healthcare system and health literacy, contribute to low rates of maternal immunization.¹³⁰ The Black Maternal Health Momnibus Act of 2021 – Title XII focuses on increasing maternal vaccination awareness and equity through a national campaign, particularly for communities with disproportionately high rates of unvaccinated individuals.¹³¹ The Momnibus Act also calls for engaging with individuals in underserved communities to develop resources and relationships to increase rates of acceptance and receipt of recommended maternal vaccinations.¹³² Language from the maternal vaccination title of the Momnibus Act was included in the Maternal Health Quality Improvement Act, which was approved by the Senate Committee on Health, Education, Labor and Pensions in May 2021.</p>

Longstanding Barriers – Current Challenges and Landscape

BARRIER	CHALLENGES	CURRENT LANDSCAPE
Patient-Level Barriers		
Vaccine Hesitancy	<p>Vaccine hesitancy among pregnant individuals, while not a new concept, has been exacerbated by the COVID-19 pandemic. Concerns over vaccine safety for both mother and child have been shown to influence whether or not pregnant individuals decide to be vaccinated against COVID-19.¹³³ With hesitancy around vaccination dominating national dialogue, the pandemic has also created an opportunity to showcase the importance of receiving life-saving vaccines.</p> <p>For example, current CDC guidance states that any of the authorized COVID-19 vaccines can be offered to people who are pregnant.¹³⁴ The American College of Obstetricians and Gynecologists recommends that COVID-19 vaccines should not be withheld from pregnant individuals and leading medical groups have issued a consensus statement on the importance of making COVID-19 vaccines available to pregnant individuals.¹³⁵ With continued education and guidance on COVID-19 vaccination during pregnancy, as of April 5, 2021, nearly 78,000 pregnant individuals have enrolled in v-safe, CDC’s smartphone-based tool used to provide health check-ins post-COVID-19 vaccination.¹³⁶ However, hesitancy around vaccination is not limited to the pandemic and has historically contributed to low rates of immunization, especially among communities of color.¹³⁷</p>	<p>Educating not just the mother, but also partners and family members on the positive health benefits of recommended vaccines can help fill the gap in knowledge and reduce hesitancy. At the federal level, the Mothers and Newborns Success Act allocates funds for a public and HCP awareness campaign promoting maternal health, including increasing awareness and knowledge of the safety and effectiveness of vaccines for pregnant individuals and their children and providing evidence-based, culturally and linguistically appropriate resources to pregnant individuals with the goal of decreasing disparities in maternal health across racial, ethnic and geographic demographics.¹³⁸ This bill language is similar to the maternal vaccination section of both the Black Maternal Health Momnibus Act of 2021 and the Maternal Health Quality Improvement Act.</p> <p>The Maternal Immunization Task Force, a coalition of leading obstetric HCP groups, has affirmed the importance of HCPs recommending and advocating for maternal immunization, calling for their members to commit to making a strong recommendation and open and fact-based dialogue to improve vaccine uptake.¹³⁹</p>

Longstanding Barriers – Current Challenges and Landscape

BARRIER	CHALLENGES	CURRENT LANDSCAPE
Federal-Level Barriers		
<p>Federal Allocation and Funding of Medicaid</p>	<p>Medicaid represents about \$1 out of every \$6 spent on health care in the U.S. and is the major source of funding for states to provide maternity coverage to their eligible residents.¹⁴⁰ In 2018, approximately 45 percent of all births in the United States were funded by Medicaid with a larger share of coverage for births in rural areas and among people of color.¹⁴¹ While Medicaid covers individuals eligible for services and allocates to states for federal matching based on state spending and program need, adult vaccination services are not a federally mandated benefit for traditionally eligible beneficiaries. Outside of certain federally mandated Medicaid benefits, states have the authority to determine how their Medicaid programs are implemented and which optional benefits are covered.¹⁴² Additionally, under Medicaid expansion, benefit packages for adults are required to cover adult immunizations with no cost-sharing, but to date, only 38 states and DC have adopted Medicaid expansion.¹⁴³</p> <p>Obstetric HCPs at Federally Qualified Health Centers (FQHCs) echo that financial barriers interfere with providing maternal immunizations to pregnant patients.¹⁴⁴ FQHCs most frequently cite a lack of Medicaid reimbursement as a barrier to increasing adult immunization rates. While Medicaid does pay FQHCs for vaccines via small reimbursement amounts with every per-visit payment under the Prospective Payment System (PPS), many immunization visits do not result in a PPS pay-per visit payment.¹⁴⁵ This capitated payment approach is challenging to amend and must be addressed through federal legislation.</p>	<p>The American Rescue Plan Act of 2021, a COVID-19 relief package, became law in March 2021 and contains a number of provisions aimed at increasing coverage, expanding benefits, and adjusting federal financing for state Medicaid programs. One element of the law provides a temporary financial incentive to encourage non-expansion states to adopt the Affordable Care Act Medicaid expansion. Additionally, this law establishes that all COVID-19 vaccines and administration are covered without cost-sharing for Medicaid enrollees and provides 100% federal matching funds for this coverage.¹⁴⁶ While broad elimination of financial barriers to COVID-19 vaccines is important, advocates are calling for all ACIP-recommended maternal immunizations to similarly be covered without cost-sharing under the Medicaid program.</p>

Longstanding Barriers – Current Challenges and Landscape

BARRIER	CHALLENGES	CURRENT LANDSCAPE
Federal-Level Barriers		
<p>Lack of representation of pregnant individuals and communities of color in clinical research</p>	<p>Over 4 million individuals in the United States give birth annually and approximately 64 percent are prescribed one or more medications during their pregnancy. However, few drugs are approved for use in pregnancy and most drug labels have little pregnancy data to inform prescribing decisions.¹⁴⁷ In a study of factors related to HCPs recommending vaccines, concerns were raised about the lack of studies conducted specifically with pregnant individuals and subsequent ambiguity in administration guidelines.¹⁴⁸ Common barriers to inclusion of pregnant individuals in clinical trials include clinical trial protocols and ethical considerations, lack of awareness about research and investigator outreach, transportation issues, especially among low-income individuals, the role of social approval, and time constraints.¹⁴⁹</p> <p>In addition to the exclusion of pregnant individuals, there is also historic underrepresentation of communities of color in clinical trials. The U.S. Food and Drug Administration (FDA) reports that white individuals account for 83 percent of research participants, while Black individuals make up only 5 percent of clinical trial participants and Hispanic individuals represent less than 1 percent of participants.¹⁵⁰</p>	<p>While the National Institutes of Health has longstanding inclusion guidance for clinical research, there have also been specific efforts focused on COVID-19 vaccine trials. Inclusion of pregnant individuals in clinical trials has received more national attention as a result of the COVID-19 pandemic and the desire for specific safety and efficacy information for this population. Currently, clinical trials are underway to evaluate COVID-19 vaccines in pregnant individuals.¹⁵¹ Beyond the scope of the pandemic, opportunities to mitigate the challenges associated with participation of pregnant individuals and communities of color in clinical research include leveraging a multipronged approach that encompasses community outreach programs, greater representation in medical schools and clinical trial databases, reimbursement for indirect health care costs and dialogue with minorities about the barriers they experience.¹⁵² The United States can also work to implement the recommendations of the federal Task Force on Research Specific to Pregnant Women and Lactating Women.¹⁵³</p>
<p>Challenges in nationwide use of IIS</p>	<p>Despite investment in immunization infrastructure, such as the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act, utilization of IIS systems remains low, especially across OB-GYN practices.^{154,155} While the cost of implementing an EHR system is often cited as an obstacle, lost revenue from months of preparation, planning, training and redesigning workflow also may play a role.¹⁵⁶ Additionally, since implementation of data collection and sharing platforms is inconsistent across states and health systems, utilizing IIS remains challenging and interoperability is lacking. Recent recommendations and legislation call for increased utilization of EHRs and IIS since gaps in vaccination data collection make disparities across different racial and geographic populations difficult to track and ultimately reduce.¹⁵⁷</p>	<p>In April 2020, the Adult Vaccine Access Coalition (AVAC) responded to the Senate Finance Committee's request for evidence-based proposals to improve maternal health. Among their recommendations was a call for improved data collection and reporting on maternal immunizations, including strengthening IIS interoperability and reporting and Medicaid data reporting on coverage and access to immunization services on a national level. Since then, additional legislation that addresses the underutilization of data collection platforms has been proposed.</p> <p>The Black Maternal Health Momnibus Act of 2021 focuses on ways to improve maternal health data collection and reporting processes.¹⁵⁸ Additionally, the Immunization Infrastructure Modernization Act of 2021 allocates substantial funding for improved and expanded information-sharing between state and federal governments and public and private HCPs.¹⁵⁹ This includes support for real-time immunization record data exchange and reporting, as well as improved secure data collection, transmission, bidirectional exchange, maintenance, and analysis of immunization information.</p> <p>Lastly, the National Strategic Plan for Vaccines 2021-2025 includes three developmental indicators that align with the Healthy People 2030 Immunization and Infectious Disease objectives. These indicators focus on the need to develop data sources and collect critical data to monitor U.S. vaccination rates.¹⁶⁰</p>

Longstanding Barriers – Current Challenges and Landscape

BARRIER	CHALLENGES	CURRENT LANDSCAPE
State-Level Barriers		
State-by-state approach to Medicaid	<p>While the federal government establishes certain mandatory Medicaid benefits, each state has the jurisdiction to administer its own program and determine which optional benefits are covered for adult beneficiaries.¹⁶¹ For example, in a survey of Medicaid programs conducted between June 2018 to June 2019, only 22 of 51 programs covered all 13 adult vaccines recommended by ACIP for both fee-for-service and managed care organization enrollees.¹⁶²</p> <p>Cost-sharing for pregnancy-related services is prohibited through Medicaid, but whether to permit cost-sharing for other maternal services provided, including vaccination, is at the discretion of each state program.¹⁶³ Medicaid expansion states, however, cover all ACIP-recommended vaccines without cost-sharing.¹⁶⁴</p>	<p>The Maternal Immunization Coverage Act would require state Medicaid programs to cover certain vaccines recommended for pregnant individuals without cost-sharing.¹⁶⁵ Additionally, a report from the U.S. Government Accountability Office on vaccination coverage under Medicaid and how states cover vaccinations for children and adults is currently underway. This report will also focus on any resulting racial, ethnic or geographic disparities in immunization rates that may result from gaps in coverage.¹⁶⁶</p>
Issues related to coordination across programs	<p>Stakeholders and advocates in the adult and maternal vaccination space have created resources and programs aimed at helping to increase rates of maternal immunization. However, these services often operate in silos and can be disconnected from one another, despite shared goals. As a result, gaps may persist in on the ground services.</p>	<p>Learnings from existent initiatives can help inform future activities to increase coordination and ultimately rates of maternal immunizations. See Existing and Proposed Solutions: High Quality Data Collection, Monitoring and Reporting</p>

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