Environmental Scan: Considerations for Vaccine Implementation

Acknowledgements

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Scope

This environmental scan was started in March 2025 during a period of significant transition across the U.S. immunization landscape. This content reflects policies, systems, and practices as they existed at the time the scan began and does not include subsequent changes to the Advisory Committee on Immunization Practices (ACIP), the Food and Drug Administration (FDA), or other new recommendation bodies. This scan focuses primarily on the implementation of routine childhood and adult vaccines, excluding emergency or pandemic-specific products.

Although examples of vaccine implementation were included whenever possible, well-documented implementation experiences in the literature were limited. As a result, the monoclonal antibody (mAb), nirsevimab, which is recommended to protect infants from severe respiratory syncytial virus (RSV) disease, is used throughout the scan as a case study because detailed recent information is available both in the published literature and in the perspectives shared by subject matter experts. In a few select instances where no other information was available, COVID-19 vaccine implementation was referenced to illustrate processes that may be relevant to future routine vaccines. Additional examples were incorporated whenever possible, and the authors welcome information on additional documented implementation experiences related to other vaccines.

Support for this project was provided through unrestricted educational grants from vaccine manufacturers: GSK, Merck, Pfizer and Sanofi. Manufacturer representatives participated on the project advisory board; however, AIM maintained full independence and editorial control over the project design, analysis, report content, and final workplan. Participation on the advisory board was offered to representatives from all major vaccine manufacturers. AIM does not endorse specific brands, products, or companies.

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Executive Summary

This environmental scan, developed by the Association of Immunization Managers (AIM), provides a comprehensive overview of the routine processes, gaps, and promising practices associated with vaccine implementation in the United States. Initiated in early 2025, the scan is a foundational component of AIM's Vaccine Implementation Project, which seeks to improve readiness for, and implementation of, new immunization products and changes to existing recommendations in the U.S. This scan does not assess which vaccines should be recommended, or by whom. This environmental scan report and accompanying flowchart are intended to inform future work to streamline the implementation of any newly recommended immunization technology.

While the scan is a historical document which reflects conditions as of March 2025, it acknowledges the rapidly evolving immunization landscape and the need to adapt implementation strategies accordingly. This report serves as both a historical record of previous routine processes and a strategic tool to inform future planning, policy development, and collaborative efforts across the immunization community.

The report is organized sequentially around seven key stages of the vaccine implementation process, from research and development through post-recommendation public access and ongoing implementation responsibilities. Each stage outlines routine steps, documents gaps and promising practices, and presents considerations for partners, including members of AIM's Vaccine Implementation Advisory Board (Advisory Board), who give counsel on the project. Based on historical implementation experiences documented in this scan, these stages have involved multi-year scientific, regulatory, and policy processes and have engaged dozens of multidisciplinary partners across federal agencies, advisory committees, manufacturers, healthcare systems, and public health programs. The monoclonal antibody (mAb) nirsevimab, recommended for the prevention of severe respiratory syncytial virus (RSV) disease in infants, is used throughout the scan as a case study to illustrate real-world implementation successes, challenges, and opportunities.

Overview of the Vaccine Recommendation and Implementation Process

The environmental scan documents the routine vaccine recommendation and implementation process across seven stages (as it functioned prior to March 2025):

Stage 1. **Research and Development:** Early activities focus on identifying public health needs, advancing scientific research, and determining whether a vaccine or immunization product is feasible, warranted, and likely to move forward into clinical development.

Stage 2. **Clinical Trials:** Vaccine candidates undergo phased clinical trials to evaluate safety, efficacy, dosing, and target populations, generating the evidence needed for regulatory review and potential recommendation.

Stage 3. **FDA Review and Licensure:** The Food and Drug Administration (FDA) reviews clinical data to determine whether to license or authorize a product, while parallel activities such as the development of vaccine billing and administration codes begin to support future implementation.

Stage 4. **ACIP Review and Recommendation:** The Advisory Committee on Immunization Practices (ACIP) reviews available evidence and issues recommendations for use of the product, defining eligible populations, timing, and conditions for use, and forming the basis for national immunization policy.

Stage 5. **CDC Adoption:** Once ACIP recommendations are adopted by the Centers for Disease Control and Prevention (CDC) director, they are published in the Morbidity and Mortality Weekly Report (MMWR) as the official U.S. immunization schedule, triggering downstream activities related to vaccine distribution, insurance coverage, provider guidance, and public education.

Stage 6. **Post-recommendation to Public Access:** Following adoption, immunization programs and partners work to operationalize recommendations through vaccine supply management, distribution, administration, safety monitoring, and liability considerations to support vaccine delivery and ensure access.

Stage 7. **Ongoing Responsibilities:** After initial rollout, immunization programs and partners continue activities related to provider and public education, vaccine safety monitoring, vaccine uptake, systems and guidance updates, evolving evidence, policy changes, and implementation challenges.

Recurring Themes Shaping Vaccine Implementation

The sections below summarize key findings by eight topic areas. Although the report is organized chronologically, many gaps and promising practices occur across multiple stages. Fragmented documentation across partners and phases limited the ability to consistently trace implementation decisions, timelines, and lessons learned across products and over time. The thematic organization that follows highlights the most consistent cross-cutting patterns identified through the scan, including siloed communication, limited time for readiness, barriers related to payment and access, and downstream implementation implications of decisions made well before product recommendation. These sections are intended to help partners identify recurring challenges, retain lessons learned, and plan for stronger future implementation.

Vaccine Research and Development Prioritization

The absence of a centralized U.S. body to direct or prioritize vaccine development limits the alignment of product innovation with public health implementation needs. The National Institutes of Health (NIH), academic, and manufacturer partners help shape directions for new vaccines and biologics. Tools such as SMART Vaccines offer data-driven approaches for aligning development with public health priorities. However, no entity is responsible for using them to

guide national vaccine development priorities. The National Vaccine Advisory Committee's Innovation in Immunization Subcommittee, was expected to fill this gap but has not published a report and has had its meetings lapse. This leaves manufacturers without structured, ongoing guidance on which products are highest priority.

Early Product Information

Decisions made during Phase 2 and Phase 3 clinical trials, combined with siloed and uneven communication during regulatory review, can significantly affect downstream implementation for immunization programs and providers. During the period between Phase 2 and Phase 3 clinical trials, manufacturers begin making pivotal decisions about pricing, packaging, storage, and handling that have substantial downstream implications. Although manufacturers may convene advisory boards, these discussions are company-specific and do not consistently reflect downstream implementation needs. Later during FDA review, manufacturers may populate Pre-Approval Information Exchange (PIE) dossiers to share select clinical and economic information with health care decision makers prior to FDA approval, which can support earlier payer planning and inform coverage decisions. However, this engagement is guided by company-specific policies, is not uniformly transparent, and often does not include the broader range of partners who are legally permitted to receive such information. This limits jurisdictions' and providers' ability to anticipate implementation needs such as storage and handling and to prepare for provider education and onboarding. Demand for new vaccines may begin immediately after CDC adoption, yet immunization programs often have limited time and flexibility to address logistical barriers when guidance on cost, distribution, packaging, storage, and specialty provider enrollment arrives just before or even after ordering opens, slowing early access in key settings and reducing public trust.

Health Information Technology (IT) Systems

Limited time for technological readiness can impede vaccine rollout, particularly when new products require modifications across multiple health information systems. Time and resources are needed to incorporate new products into forecasting tools, vaccine ordering and documentation systems, electronic health records (EHRs), payer systems, and public dashboards. Many of these systems depend on finalized code sets that may not be available until after FDA licensure. Immunization information systems (IIS) and EHRs face particular challenges with novel products. Consider nirsevimab for example, its weight-based dosing led to deduplication problems, its classification as a drug required extra work to ensure IIS could accept messages, and maternal RSV vaccination highlighted the lack of linkage between maternal and infant records, limiting forecasting effectiveness. These examples underscore that complex coding, interoperability gaps, and evolving product types can strain health IT infrastructure and require earlier, more coordinated planning.

Payment and Coverage

Barriers related to upfront costs and payment uncertainties can create significant barriers to timely vaccine access. The upfront cost of stocking new vaccines is a well-documented implementation barrier, especially for small provider practices. This has contributed to two-tiered systems during early implementation, in which only children eligible for the Vaccines for Children (VFC) program, a federally funded program that provides vaccines at no cost to eligible children, received higher cost products such as the 7-valent pneumococcal conjugate vaccine (PCV7) or nirsevimab. Payment-related barriers—including long delays in integrating new vaccines into payer systems, and uncertainty about when or whether providers will be paid—were among the most frequently cited challenges in interviews and can delay or limit access in both traditional and nontraditional settings.

Health Care Provider Education and Administrative Burden

Compressed timelines and high administrative burden can reduce readiness for new vaccine implementation. Immunization programs and health systems need lead time to enroll new provider sites and train staff on product-specific benefits and storage/handling. Vaccine information must be integrated into workflows, such as EHR point-of-care prompts and standing orders. Providers also face substantial operational and administrative demands (including VFC program documentation and reporting requirements, coordination with multiple IT and billing systems, and competing clinical priorities) that can delay or crowd out activities focused on education and onboarding for new vaccines. When implementation timelines are compressed and administrative workload is high, these internal processes may be delayed or skipped, reducing provider readiness and confidence and making it harder for clinicians to answer patient questions about new products.

Public Education

Limited time for public education can delay readiness, misalign expectations, and create time for misinformation to spread. Creating effective public messaging and building trust in new vaccines takes time to identify and train trusted messengers and to develop materials that are culturally relevant, translated, and adapted to local contexts. Under compressed timelines, English-speaking audiences often receive information first while materials for other language groups arrive later, and headlines about ACIP votes can be misinterpreted as signaling immediate availability, widening gaps between public expectations and operational realities.

Safety and Reporting

New immunization products can introduce safety monitoring and reporting requirements that fall outside standard workflows, increasing the need for clear advanced communication and coordination. Novel immunization products may require providers and public health staff to adjust their use of adverse event reporting pathways, such as directing some reports to MedWatch rather than the Vaccine Adverse Event Reporting System (VAERS). These changes

can add complexity, require custom workflow adjustments, and create additional staffing or training needs. When roles, expectations, and reporting channels are not communicated clearly in advance, safety monitoring can become more difficult to operationalize during rollout.

Policy

Variation in policy environments and unresolved legal and regulatory questions can create uncertainty in how new vaccine recommendations are implemented across jurisdictions. The environmental scan notes outstanding questions about the legal and regulatory underpinnings of vaccine implementation, including how federal and state statutes influence timelines, which were not fully explored due to limited engagement with legal and policy experts. For example, there is widespread variation in the adoption and implementation of ACIP recommendations across jurisdictions. The broader legal landscape, including increasing immunization-focused state legislation, creates complex, evolving gaps that immunization programs must navigate when assessing how new recommendations will affect coverage, requirements, and operational workload.

Key Findings: Observations from the Environmental Scan

Taken together, environmental scan findings from across the seven stages reveal a set of recurring challenges and considerations that shape vaccine implementation beyond any single product or point in time. The observations below summarize the most consistent challenges and considerations seen across stages:

1. Fragmented implementation documentation limits institutional knowledge.
2. Siloed communication contributes to unclear roles and timing.
3. Limited time for programmatic, policy, and technological readiness impedes vaccine rollouts.
4. Limited time for provider and public education can delay readiness, allow misinformation to spread, and misalign expectations.
5. Barriers related to upfront cost and payment deter vaccine access.
6. Phase 2/3 clinical trial decisions have downstream implementation implications.

Conclusion

The environmental scan illustrates the complexity and interdependence of the systems that support vaccine implementation in the United States. Across stages, consistent observations included fragmented implementation documentation, siloed communication, limited time for programmatic, technological, and educational readiness, barriers related to upfront cost and payment, and the downstream implications of phase 2/3 clinical trial decision making. By serving as a consolidated record of how implementation processes have operated and by identifying and highlighting key challenges and opportunities for further consideration prior to March 2025, this scan is intended to support informed discussion, planning, and collaboration among immunization partners as new vaccines and updated recommendations continue to emerge.

Limitations

This scan reflects the U.S. immunization landscape as of March 2025 and does not capture subsequent changes. Given staffing constraints, it prioritized breadth over academic rigor and reflects the perspectives of partners available during the project timeframe, with limited engagement from some groups, including payers and legal and policy experts.

Introduction

The Vaccine Implementation Project was launched by the Association of Immunization Managers (AIM) to improve readiness for, and implementation of, new immunization products and changes to existing recommendations in the United States. For conciseness, all are referred to collectively as "new vaccine" throughout this document.

In the past two decades, the recommended immunization schedule has expanded significantly, with 11 new childhood vaccines and nine new adult vaccines added to their respective recommended schedules. There are also more than 20 novel vaccine products currently in late-stage development. Despite progress in vaccine science and policy approaches, operational delays and access challenges continue to affect uptake. These barriers and delays often stem from the longstanding fragmentation of the U.S. health care and public health systems, which can make coordination across sectors difficult even when all partners are committed to success.[1,2] By strengthening connections across the immunization ecosystem and increasing transparency around implementation processes, this project aims to support a more seamless vaccine rollout and to ensure that life-saving immunizations reach the public as equitably and efficiently as possible.

Background and Purpose

This environmental scan was initiated, developed, and completed by AIM in early 2025 to document the current understanding of the steps, partners, and timelines involved in vaccine implementation in the U.S. It focuses on routine childhood and adult vaccines, not emergency or pandemic-specific products. The purpose of the scan is to identify known trends and lessons learned—gaps, challenges, successes, and needs—to inform the next phases of the Vaccine Implementation Project and support efforts to streamline the rollout of future vaccines. It is also intended to support the development of a shared flowchart that can serve as a foundation for discussion among immunization partners and inform future work to implement new immunization technology.

This report is organized linearly, following the key phases of the vaccine implementation process. It is designed to document the most typical and routine steps followed in the U.S. for introducing new vaccines or changing recommendations, acknowledging that many variables, such as product type, target population, and current environment, can significantly influence the process. Each section begins by outlining the routine steps involved in that phase, followed by a summary of documented gaps and promising practices identified through the environmental scan. Throughout the report, the rollout of nirsevimab is used as a recent case study to illustrate the challenges associated with implementing new immunization technologies. This report uses the American Medical Association (AMA) citation style.

The Vaccine Implementation Advisory Board (Advisory Board) was assembled to provide input into the project scope, structure, meetings, and deliverables. The Advisory Board informs efforts to ensure that all partners from the vaccine ecosystem are identified and that their representatives are invited to engage in discussions that seek to improve the vaccine implementation process. Advisory Board members include AIM senior staff, liaisons from partner organizations, project sponsors, and immunization program experts.

Research Questions

1. What are the routine steps in the process of vaccine recommendation and implementation in the United States?
2. What gaps exist in the vaccine recommendation and implementation process, and what solutions have been proposed to address them?

Methodology

This environmental scan was conducted by one staff member and one consultant from AIM using both primary and secondary sources. Secondary sources included peer-reviewed literature, white papers, reports, conference materials, media articles, and documentation from immunization partners (e.g., after-action reports, developed resources, and checklists for implementation). Primary data consisted of information gleaned from 17 key informant interviews with immunization partners who were unable to share documentation directly. The project staff member and consultant reviewed and themed a separate set of materials, with findings tracked in a shared Excel database and visualized in a flowchart through Canva Whiteboard. The whiteboard format was selected after audience testing several digital tools with subject matter experts. The flowchart itself went through many iterations with input from a wide range of partners, including immunization program managers, health care professional associations, vaccine manufacturers, vaccine implementation researchers, immunization information system (IIS) experts, payment specialists, and others who support vaccine implementation. Artificial intelligence tools were used to support copyediting and formatting and as a research aid to identify publicly available citations that supported or contextualized statements made during interviews; all synthesis and analysis were performed by project staff. The geographic scope includes the U.S. and its territories and freely associated states, focusing on the time period of January 2005 – March 2025.

To address gaps identified through the environmental scan, AIM conducted interviews with six vaccine manufacturers in August 2025. The purpose of these interviews was to better understand when, how, and with whom manufacturers share information during vaccine development and launch, particularly as it relates to immunization program planning and implementation readiness. Discussions explored information-sharing practices, timing, and engagement with key partners (including federal agencies, payers, health care professional organizations, health care systems, and immunization programs) during the vaccine development and implementation process.[3]

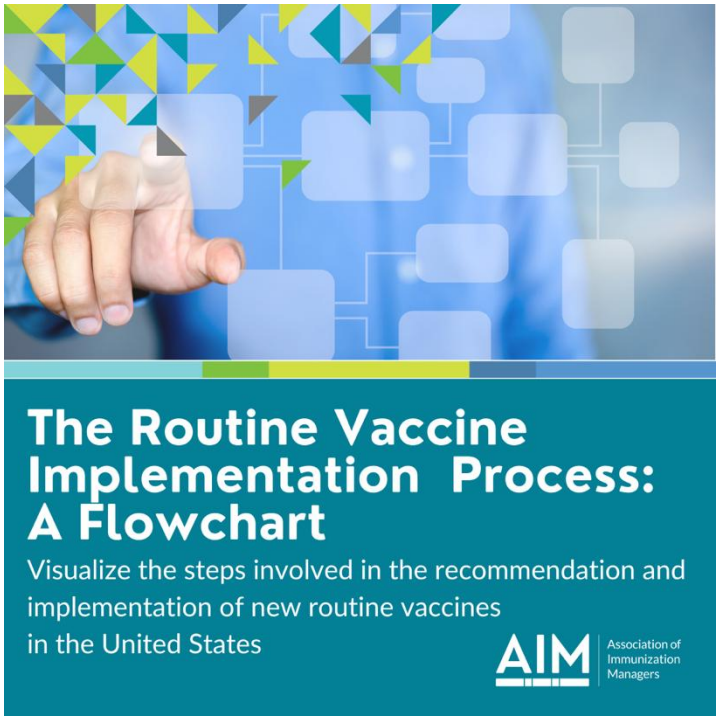
Report Limitations

Given staffing and timeline constraints, this scan prioritized breadth over academic rigor and relied on individual project staff judgement in document selection and thematic coding. Although as many partners as possible were included, findings reflect the perspectives of individuals available during the project timeframe and may not represent the full range of views across all partner types. The scan had limited engagement with payers and legal experts. Further clarification is needed to understand how health plans' internal processes and timelines vary.

While the scan focuses on the system as it existed prior to March 2025, these conditions continue to change. The scan provides a record of routine processes that may offer enduring value for future vaccine introductions, as well as a guide for considering how these processes could be strengthened and adapted.

Due to the rapidly evolving landscape during the period of this scan, many key legal and policy experts were actively responding to high-priority developments, which limited their availability for engagement. As a result, several foundational questions remain unanswered. These include uncertainties around the legal and regulatory underpinnings of vaccine implementation, such as how federal and state statutes may influence timelines, insurance compliance mechanisms, and nuances of payer regulatory processes. These questions are critical to understanding current system inefficiencies, and future project activities should seek to identify and address them. While relevant statutes and regulations may be publicly available, interpreting their implications for implementation requires the expertise of legal and policy professionals—highlighting the importance of their participation in future phases of this work.

Flowchart



AIM's draft Routine Vaccine Implementation Process: A Flowchart outlines the usual steps involved in the recommendation and implementation of new vaccines and immunization technologies in the U.S. It is intended as a tool to help visualize the most routine aspects of this process as they were in March 2025 and remains a working draft. The flowchart is expected to undergo continued iteration throughout the Vaccine Implementation Project. It reflects the most generalized steps, but we acknowledge that many variables (such as product type, target population, and current environment) can significantly influence the process. The flowchart also reflects a generalized view of immunization programs. Jurisdictions' processes vary significantly based on policies, capacity, priorities, and health department structure. This chart aims to capture common experiences while recognizing those differences.

The introduction at the top of the flowchart provides background on how to interpret it. The subsequent sections of this report expand on each section of flowchart in detail.

Report Structure

This report is organized into three main sections aligned with the flowchart: Pre-Licensure, Post-Licensure, and Post-Recommendation to Public Access. Each section is further divided into major stages (corresponding to items 1–7 on the flowchart). To clearly delineate when time periods begin, many stages are titled using regulatory milestones, such as *FDA Review & Licensure* or *CDC Adoption*; however, these stages include activities conducted by many partners during that time period, not just those conducted by regulatory bodies (see Figure 1)

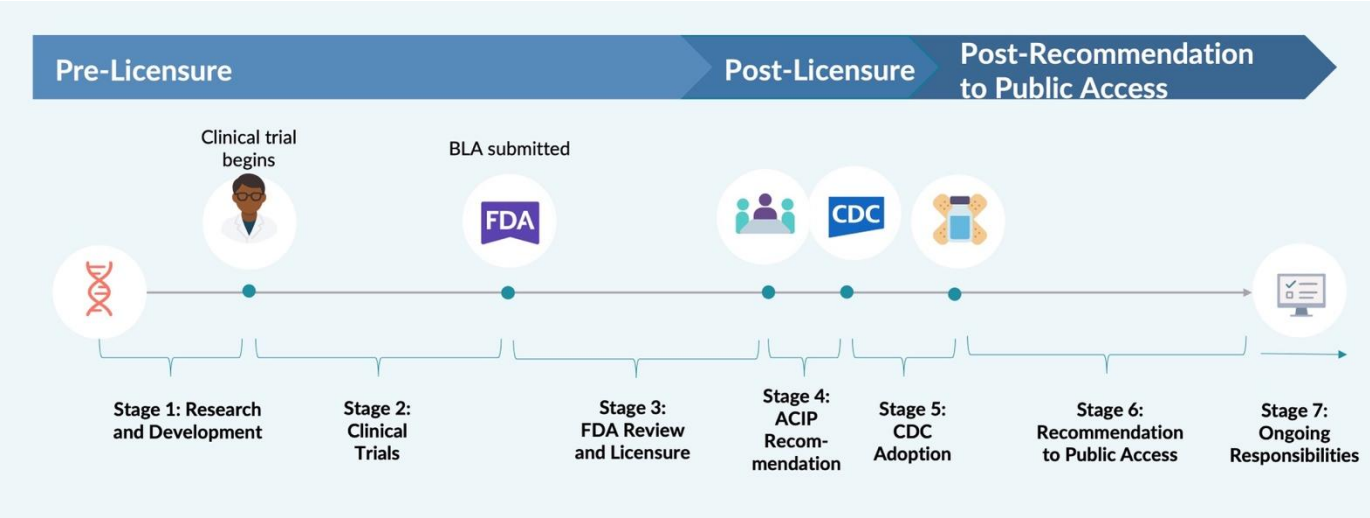


Figure 1: Environmental Scan Timeline of Vaccine Implementation

For each stage, the scan outlines the routine steps described in the source materials, followed by a section on gaps and promising practices, limited to what is documented in those sources, without additional interpretation or recommendations from the authors. Each stage includes nirsevimab as a case example.

Throughout the report, boxes labeled “Considerations” appear at the end of each stage. These callouts provide guiding questions to support discussion, planning, and coordination across immunization partners with the goal of identifying opportunities to strengthen vaccine implementation.

Routine Steps in the Vaccine Recommendation and Implementation Process

Pre-Licensure

Stage 1: Research and Development

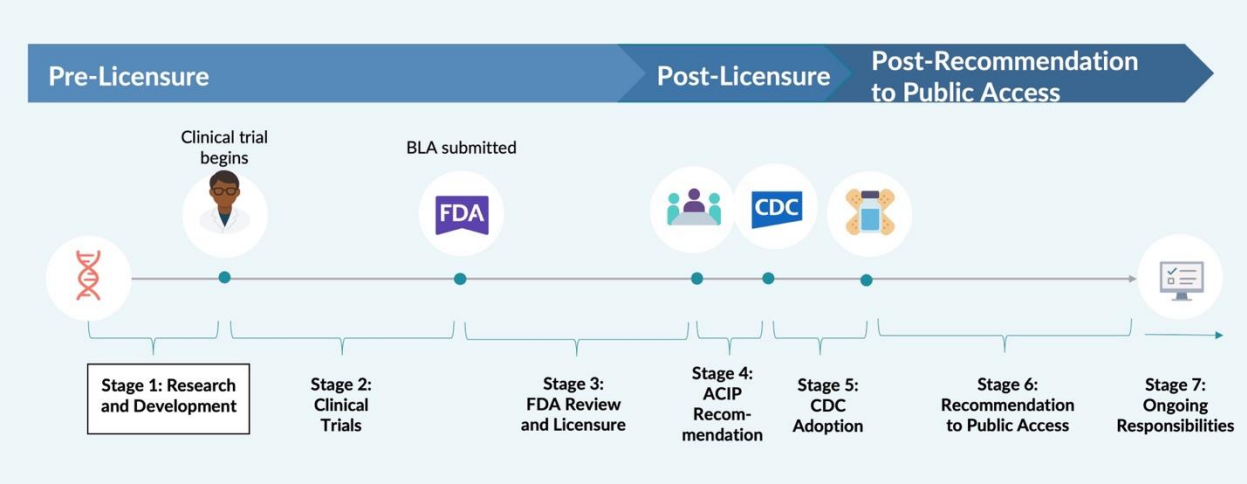


Figure 2 Environmental Scan Timeline of Vaccine Implementation - Stage 1

Note: In some cases, early research and development and clinical trial activities are conducted by academic institutions.[4] For ease and consistency, they will be listed as manufacturer steps in this report.

Routine Steps During the Research and Development Stage

The process of developing a new vaccine is a lengthy and resource-intensive process, which can span 10-15 years from early research to full licensure. This process begins with exploratory research, where scientists identify potential antigens that could stimulate an immune response against a specific pathogen.[8] The decision to develop a new vaccine is driven by a combination of scientific feasibility (not all pathogens make good vaccine candidates), public health need, and economic viability. Diseases that cause significant morbidity and/or mortality, or those with high transmission potential, are prioritized, especially if there is no effective treatment or existing immunity in the population. In the past, new vaccine targets were often chosen based on observable disease burden and the capacity to grow and attenuate the pathogen in a lab. In modern vaccinology, this decision-making is increasingly influenced by tools such as epidemiologic modeling, global burden of disease data, and genetic analysis of pathogens. For example, new vaccines are now more likely to be pursued

Case Study Timeline: Nirsevimab[5-7]

Since the 1960s, manufacturers have attempted to develop immunizations to protect children from RSV. Despite the availability of the monoclonal antibody (mAb), palivizumab, since the late 1990s for children at increased risk of severe RSV disease, RSV remains the leading cause of hospitalizations among U.S. infants, making the prevention of RSV disease a clear public health priority.

Pre-2015: While publicly available data doesn't specify an exact date, research and development for the mAb that would become nirsevimab began prior to 2015.

if they can prevent diseases with high prevalence or outbreak potential, such as human immunodeficiency viruses (HIVs), malaria, or emerging zoonotic viruses.[9] In addition to academic and manufacturer partners, the Vaccine Research Center at the National Institutes of Health (NIH) helps determine the directions of novel vaccines and biologics development through its research.[10]

Once a candidate has been identified, the manufacturer conducts target validation and candidate generation to determine which component of a virus or pathogen is required for immunity and develops potential new vaccine formulas.[11] Pre-clinical studies are conducted to evaluate the new vaccine's safety and immunogenicity using in vitro and in vivo models. During these pre-clinical studies, researchers also develop a pure and consistent vaccine manufacturing process. The manufacturer then submits an Investigational New Drug application to the Food and Drug Administration (FDA).[8,12,13] This application contains the preclinical research results and the manufacturing information, including data on the vaccine's composition, safety profile, and a proposed clinical trial plan.[13] The FDA reviews applications to ensure vaccines meet safety and regulatory standards before advancing to human clinical trials, assessing both the quality of the data and whether studies followed best practices, and works with manufacturers to design appropriate trial protocols.[8,14]

Documentation of Gaps and Promising Practices

Historically, the Institute of Medicine (IOM) played a role in prioritizing new vaccine development efforts by evaluating potential new vaccines based on public health need, anticipated impact, and cost-effectiveness. At the request of the National Institute of Allergy and Infectious Diseases of the NIH, IOM produced two reports on vaccine development in 1986 and 2000, which established frameworks for ranking vaccine candidates. The latter introduced a quantitative model to compare 26 potential vaccines based on expected health benefits and net savings.[12] In response to the 2010 National Vaccine Plan, the National Vaccine Program Office commissioned IOM to create and test prioritization methods for new vaccines to identify data gaps, promote transparency, and foster dialogue and information-sharing among decision-makers, ultimately optimizing resource use and enhancing health outcomes.[12,15,16]

This resulted in IOM introducing the Strategic Multi-Attribute Ranking Tool for Vaccines (SMART Vaccines) software in 2012—a customizable, multi-attribute decision-support tool designed to guide prioritization using user-defined criteria.[12,16] While not a decision-making tool on its own, SMART Vaccines offers a transparent, data-driven approach to support manufacturers and policymakers in aligning vaccine development with pressing public health priorities.[12] Though the tool includes limited preloaded data, gaps remain, and fully leveraging SMART Vaccines would require a robust, centralized data repository covering population demographics, disease burdens, treatment costs, and vaccine characteristics. Building a comprehensive dataset will demand coordinated effort and remains a key step toward realizing the software's full potential for strategic vaccine prioritization.[17]

In 2015, the IOM was renamed the National Academy of Medicine as part of a broader internal reorganization of the National Academies.[18] To the authors' knowledge, the National Academy of Medicine has not continued the IOM's prior role in systematically prioritizing vaccine development within the U.S. context. The National Academy of Medicine has remained active in adjacent areas, including recent work to advance pandemic and seasonal influenza vaccine preparedness and response.[7] Meanwhile, use and refinement of the SMART Vaccines tool has continued.

SMART Vaccines 2.0 was developed to address the limitations of the original version, particularly in resource-constrained settings. The updated tool offers a more user-friendly interface and allows for greater flexibility by enabling users to define and weigh attributes according to local priorities. It also reduces the data burden by simplifying the types of data required, making it more accessible for use in settings with limited data availability. The tool was piloted in Uganda by the National Immunisation Technical Advisory Group to prioritize the introduction of five new vaccines, demonstrating its practical applicability and effectiveness in real-world decision-making processes. Feedback from the Uganda pilot informed further enhancements, leading to the development of PriorityVax, the next-generation platform that builds upon the strengths of SMART Vaccines 2.0 with improved usability and adaptability to various contexts.[19]

Beyond prioritizing target pathogens, the World Health Organization's Country-led Assessment for Prioritisation on Immunisation (CAPACITI) decision-support framework allows national programs and partners to integrate innovation criteria into immunization prioritization (e.g., comparing innovations, delivery strategies, and product characteristics).[20] In addition, Gavi worked with partners including UNICEF and the World Health Organization on a Vaccine Innovation Prioritisation Strategy process, which prioritized three vaccine delivery innovations as high-value areas for future investment: microarray patches, thermostability (including controlled temperature chain) improvements, and 2D barcodes on primary packaging.[21]

Although some early research, development, and clinical trial activities are conducted by academic institutions and federal agencies such as NIH, the authors of this report could not identify a formal body currently providing structured, ongoing guidance to manufacturers on which new vaccines or other immunization products are considered the highest priority for the U.S. The National Vaccine Advisory Committee (NVAC), a federal advisory board to the U.S. Department of Health and Human Services (HHS), was expected to help fill this gap through its Innovation in Immunization Subcommittee, formed in 2022. This subcommittee was tasked with drafting a report outlining a national vaccine innovation agenda and recommending priorities to guide development, to be voted on in February 2024 and updated every two years.[22] However, the report does not appear to have been published,[23] and our outreach to an NVAC committee member for participation in this project did not receive a response. At the February 2024 NVAC meeting, the Biotechnology Innovation Organization (a major trade group representing biotechnology companies, academic institutions, and related organizations) presented its own report on the state of vaccine and antibody innovation.[24] Although NVAC is expected to meet three times a year, no meetings have occurred since September 2024.

Considerations: Stage 1 Research and Development *Guiding questions to support discussion, planning, and coordination across immunization partners.*
Given there is no active mechanism for setting national vaccine development priorities, how can immunization partners best share their expertise around which vaccines and/or formulary changes should be prioritized as potential new immunization products? • How can earlier alignment between public health needs and vaccine development decisions improve preparedness, coordination, and effective use of limited immunization program resources?

Stage 2: Clinical Trials

This stage includes activities conducted by many partners that occur between the start of clinical trials and when manufacturers submit their application to the FDA for review. Please see the flowchart for a visual overview of the timing and how these steps relate to one another.

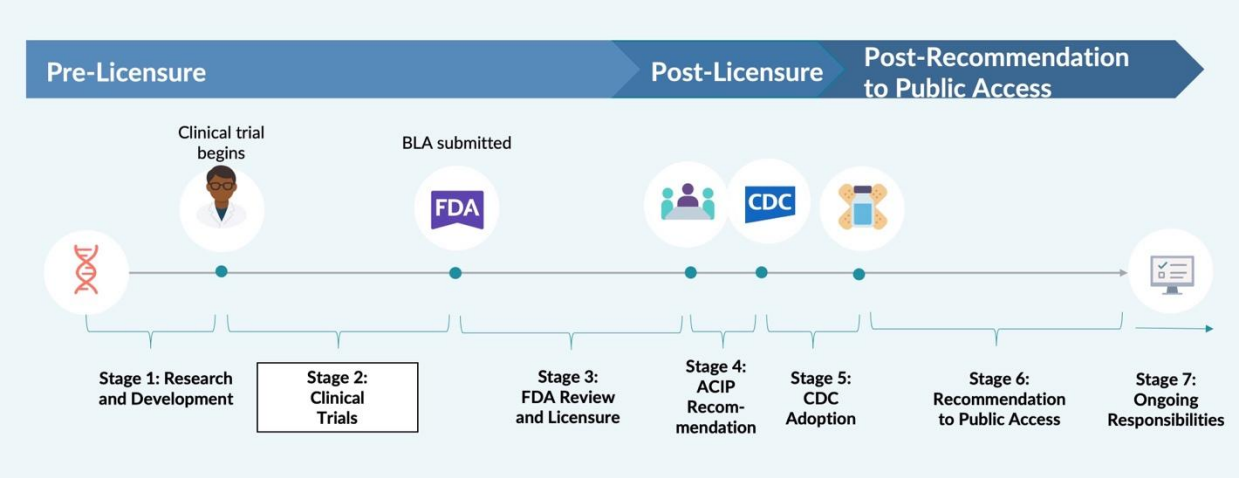


Figure 3 Environmental Scan Timeline of Vaccine Implementation - Stage 2

Routine Steps During the Clinical Trials Stage

The clinical trial process includes three phases, each increasing in size and scope.[12,30] Phase 1 trials focus on evaluating the vaccine's safety, appropriate dosage, and ability to trigger an immune response in a small number of healthy volunteers.[31] During these early-phase clinical trials, manufacturers often publicly disclose their research endeavors and initiate cost modeling to assess the financial viability of their investigational products. Manufacturers may choose to engage with the Centers for Disease Control and Prevention (CDC) at various stages of the development process, depending on their internal policies. Regular and transparent communication can support public health preparedness.[32]

If deemed safe, the vaccine progresses to Phase 2 to further evaluate safety and determine whether the vaccine is more effective than existing options.[11,31] Phase 2 trials expand to a larger group, typically several hundred participants.[31] The progression from Phase 2 to Phase 3 trials marks a notable decision point for scaling up manufacturing, including forecasting product pricing and initiating the development of new production facilities, if necessary. Around this stage, the manufacturer may also begin early market research, including testing consumer receptivity to the vaccine. However, given the rapidly evolving landscape and shifting public attitudes toward vaccination, the findings of such research are interpreted with caution.[32] Manufacturers may also convene advisory boards during clinical trials and throughout the development process to engage external partners. While practices vary by company and situation, public information on timing, participants, and decision-making is limited. The authors of this report understand, based on interviews with vaccine manufacturers, that these advisory boards can serve a range of purposes—from informing trial design and data interpretation to

Case Study Timeline: Nirsevimab6,25-29

Note: Nirsevimab was originally called MEDI8897

January 2015 – September 2016: Phase 1b/2a (MedImmune LLC) to evaluate the safety, tolerability, and pharmacokinetics (PK) of MEDI8897 in healthy preterm infants born between 32-34 weeks gestational age (GA) who are not eligible for RSV prophylaxis, using a randomized, double-blind, placebo-controlled, dose-escalation design.

November 2016 – July 2018: Phase 2 (MedImmune LLC) to evaluate the efficacy, safety, PK, and antidrug antibody (ADA) response for MEDI8897 in healthy preterm infants who are between 29-35 weeks GA and entering their first RSV season.

March 2017: Sanofi and AstraZeneca announced an agreement to develop and commercialize MEDI8897 (later named nirsevimab).

July 2019 – March 2021: Phase 3 MELODY (AstraZeneca) to evaluate the efficacy, safety, PK, and ADA response for MEDI8897 in healthy preterm infants who are between 29-35 weeks GA and entering their first RSV season.

July 2019 – May 2021: Phase 2/3 MEDLEY (AstraZeneca) to evaluate the safety and tolerability of MEDI8897 compared to palivizumab when administered to preterm infants entering their first RSV season and children with chronic lung disease (CLD) and congenital heart disease (CHD) entering their first and second RSV season.

October 2021: ACIP Respiratory Syncytial Virus Vaccines – Pediatric/Maternal Workgroup formed and began reviewing clinical trial data.

providing product-specific guidance. Guidance can include clarifying terminology for novel technologies or offering input on implementation needs, such as storage, seasonal use, or delivery logistics.[3,33]

Phase 3 trials are typically large-scale, randomized, blinded, controlled, and involving a group of hundreds to thousands of participants that is representative of the general public.[11,31] For new childhood vaccines, the trials begin with adult volunteers and move to younger groups progressively.[12,30] Since vaccines are generally administered to healthy individuals as a preventative measure, there is a very low tolerance for adverse events, even rare ones. As a result, Phase 3 vaccine trials require significantly larger sample sizes than studies of other therapeutics.[31]

During Phase 3, the manufacturer produces three or more consistency lots, which may serve as the initial supply if the vaccine receives FDA approval. The FDA conducts inspections of manufacturing facilities, although the timing of these inspections may vary.[34] Meanwhile, as part of ACIP's decision-making framework, CDC requests price estimates from the manufacturer to conduct internal cost-effectiveness analyses.[35] Academic institutions also contribute by conducting independent evaluations that support ACIP in making evidence-based recommendations.[36] After the close of Phase 3, the manufacturer creates product and packaging codes, which later form part of the vaccine's National Drug Code (NDC) used for identification and billing, and engages the American Medical Association (AMA) to request a Current Procedural Terminology (CPT) code for billing and reimbursement.[37] During this phase, CDC also begins preparing for technical implementation needs, such as Clinical Decision Support for Immunization (CDSi) planning,[35] which informs electronic health records (EHRs) and other standalone clinical decision support (CDS) engines.[38]

If Phase 3 trials demonstrate safety and efficacy, the manufacturer submits a Biologics License Application (BLA) to the FDA for review.[11,12] This process can take seven months to two years, depending on the complexity of the data and the regulatory review process.[12] The manufacturer also begins regular communication with CDC to share projected supply estimates. CDC uses this information to prepare for various supply scenarios, including potential shortages or phased rollouts.[35] At this time, manufacturers may populate pre-approval dossiers (Pre-approval Information Exchange (PIE)) to communicate relevant data to health care decision makers. The PIE Act of 2022 allows pharmaceutical and device manufacturers to optionally share select clinical and economic information with health care decision makers (payers, pharmacy benefit managers, etc.) before a product receives FDA approval, helping support earlier payer planning and informed coverage decisions. [39] Simultaneously, manufacturers may choose to begin an application for CPT codes through the AMA, if necessary (see coding section).

The Advisory Committee on Immunization Practices (ACIP) was established in 1964 to provide a standardized, science-based approach to immunization policy in the U.S. Since then, immunization schedules have evolved and are regularly updated in response to new vaccines, including those addressing emerging public health threats, as well when new epidemiologic, surveillance, safety or effectiveness data becomes available.[42]

An ACIP work group (WG) collects and analyzes data for the new vaccine and develops recommendations for consideration by the full committee.[43] WGs collaborate with federal agencies, medical societies, and other liaison organizations to ensure that their recommendations align with the latest scientific evidence.[42] WGs use the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE)[44] approach and the Evidence to Recommendations (EtR)[45] framework to evaluate data and develop recommendations. The process of developing recommendations begins with the formation of the WG.[44] Some WGs are permanent, like those tasked with adult immunization, general recommendations, child/adolescent immunization, evidence-based recommendations, and influenza, while others are developed in response to a specific need and will pause or disband once their task has been completed.[43] New ACIP WGs are established when new vaccines, new indications, or updates to existing recommendations are anticipated, or when existing recommendations are due for review (at least every seven years).[46] WGs typically begin reviewing data 12-18 months before a potential licensure decision, with timing depending on topic complexity and available evidence. For example, the ACIP workgroup on cytomegalovirus (CMV) launched early October 2024,[47] during the Phase 3 trial of mRNA-1647 (Moderna's CMV vaccine), with data anticipated in late 2025. [48]

While this environmental scan reflects the environment as of March 2025, subsequent developments through the finalization of this report at the end of March 2026 have impacted alignment between recommendations made by ACIP and other immunization partners. During this period, ACIP has issued new recommendations, but adoption has varied across jurisdictions due to concerns that the committee deviated from its standard evidence-based recommendation processes,[40] which prompted some medical associations and coalitions of states to provide differing recommendations. A federal judge granted stays in the case of AAP et.al. v. Kennedy, blocking implementation of changes to the childhood immunization schedule and invalidating related ACIP actions, citing likely violations of required legal and evidence-based processes.[41]

To develop a recommendation, the WG starts by defining the scope of the guidelines and developing its research questions using the Population, Intervention, Comparator, and Outcomes (PICO) Framework.[44,49] Next, the group either identifies a high-quality existing systematic review or conducts a new one to gather and assess the relevant evidence. The findings are synthesized quantitatively and summarized narratively. Using the GRADE methodology, the WG assesses the overall quality of the evidence and creates GRADE evidence profiles.[44] The group then completes an EtR framework to transparently evaluate seven domains: public health problem, benefits and harms of the options, values and preferences, acceptability, resource use, equity, and feasibility.[44,45] Within the feasibility domain, an assessment of implementation considerations is completed. This assessment includes questions about barriers to insurance

coverage, financial burden, integration into providers' practices, complexity of the recommendation, the range of providers who will be able to stock the vaccine, and incentivization for providers to adopt the recommendation.[36]

Through this process of collecting and analyzing data, the WG hears presentations from and asks questions of the vaccine manufacturer. The manufacturer can answer questions about clinical trial results, but both the manufacturer's representatives and ACIP WG members are governed by strict guidelines to maintain transparency and prevent inappropriate influence. WG members must report any manufacturer outreach to WG leads. All company presentations are confidential, subject to review, and approved by WG leadership prior to the ACIP session.[43] Companies must submit presentations in advance, avoid promoting products directly to WG members, clearly describe study designs and limitations, and may be restricted from discussing certain aspects of a product prior to licensure.[3] During the ACIP session, the company presents first, followed by the WG lead who presents a summary of the WG's independent interpretation of the company's data.[43] The WG then presents a summary of its work, beginning with the PICO question, followed by a review of the available data and a GRADE assessment of the quality of the available evidence and a presentation of the EtR framework with its conclusions and recommendations of the WG.[3]

Documentation of Gaps and Promising Practices

While some manufacturers engage with CDC and other public health partners early in the clinical trial process, this engagement is guided by company-specific policies and varies widely.[32,50] While manufacturers may convene advisory boards during clinical trials to engage external partners and inform product design, there is limited transparency about how these partners are selected or whether they represent the diversity of perspectives within the immunization ecosystem. This can result in feedback that does not fully reflect the operational realities across the broader implementation landscape.

Multiple manufacturers populate pre-approval dossiers (Pre-approval Information Exchange (PIE)) and share them for pre-launch coordination, but not all partners receive this information.[51] The audience for PIE presentations varies by manufacturer: most include payers, some extend to other partners such as large immunization programs or health care systems, and a few may not provide PIE presentations at all. Legal team comfort and staff capacity may also influence how widely PIE information is offered.[3] The differing access that partners have to PIE presentations can lead to missed opportunities for planning and coordination, particularly during the period between Phase 2 and 3 trials, when key manufacturing decisions are made that directly influence implementation, such as dosing schedules, packaging configurations, and product pricing.[32] Strengthening coordination and communication during this period could allow public health partners to better anticipate operational needs, inform provider education strategies, and align infrastructure planning with real-world delivery requirements.[49,51–54] Many of the detailed implementation challenges described later in this report stem from decisions made during this Phase 2 to Phase 3 window, highlighting it as a critical opportunity for collaboration.

For example, a subject matter expert (SME) on vaccine interoperability and clinical CDS shared this opportunity for improvement: National Drug Codes (NDCs) for vaccines are published in the DailyMed—a database managed by the National Library of Medicine which lists labeling submitted to the FDA and feeds source systems such as the CDC's vocabulary system and First DataBank. These source systems are used by EHRs, pharmacies, IIS, and other health IT systems. At present, the NDCs are not published to these source systems until after FDA licensure.[38,55] Without published NDCs in these systems, health IT readiness activities, including configuration and testing, cannot begin. While manufacturers cannot share NDCs for commercial or promotional purposes before licensure, they may share them as part of PIE presentations. Most do not, however, in part because NDCs may still change during label negotiations despite being known by manufacturers during later-stage FDA review. A second SME clarified that private drug pricing compendia (propriety databases, such as Medi-Span and First Databank, that publish standardized drug pricing benchmarks used by payers)[48] could in theory allow for earlier listing, with one (Red Book) allowing pre-FDA approval listing. However, current compendia policies also restrict listing until after FDA approval due to pricing, investor, and competitive intelligence considerations.[56] Taken together, these perspectives suggest that earlier publication of NDCs in these source systems could provide critical lead time for health IT vendors and public health systems to prepare.[38] This insight may warrant further exploration with additional experts.

Packaging decisions made during this time period also affect implementation. It is well understood that the format of a manufactured vaccine, whether single- or multi-dose vials, affects vaccine wastage, storage requirements, and cost per vaccination. An economic computational model found that multi-dose vials can lead to significant vaccine wastage due to expiration, particularly in rural settings with low patient volume. While single-dose vials reduce wastage and contamination risk, they are more expensive per dose and require more storage space. The computational study emphasized that the choice between single- and multi-dose vial formats ought to be guided by programmatic needs, and balance cost, storage capacity, and patient volume.[57] Although this review is focused on routine vaccines, lessons from the COVID-19 rollout on large minimum order sizes and multi-dose vials created difficulties for providers, particularly in smaller or rural settings, about vaccine wastage and inventory management.[58]

In addition to challenges with pre-licensure product information, gaps also exist in how clinical trial immunizations are recorded in IIS. IIS are confidential, population-based, digital databases that record immunization doses given by participating providers to individuals living within a defined geographic region.[59] In addition to providing vaccination records for individuals, IIS play a critical role within immunization programs as systems that manage vaccine ordering and inventory, demographic coverage estimates, patient follow-up, and evaluation or forecasting. IIS exchange data with other medical and public health information systems such as EHRs and health information exchanges (HIEs).[1] During Phase 3 trials, some clinical trial sites submit investigational vaccine data to IIS, typically through automated data exchanges. However, clinical trial vaccination data are often excluded from IIS due to blinding protocols, technical barriers, and unclear consent processes. Challenges with clinical trial IIS reporting became visible during the COVID-19 pandemic. While not the case at all trial sites, many individuals who participated

in clinical trials were blinded from knowing if they received a vaccine or placebo but needed proof of vaccination to meet work or jurisdictional vaccination requirements. Even when trial vaccines are reported to IIS, they may lack standard data elements, such as lot numbers and expiration dates, which limits the usefulness of these records for clinical care and public health decision-making. Some IIS may also be unprepared to accept data from trial sites due to jurisdictional variability in policies, infrastructure, or staffing. Vaccines which are used as reference products in clinical trials are sometimes entered into IIS without proper labeling, making it difficult to distinguish them from licensed products, while placebo data are usually omitted.[60] As a result, immunization records can become unclear or inaccurate, creating downstream challenges for vaccine administration and an inability to obtain documentation that may be needed to attend childcare or school.

Considerations: Stage 2 Clinical Trials *Guiding questions to support discussion, planning, and coordination across immunization partners.*
How might improved communication across manufacturers, federal partners, payers, and public health agencies during clinical development ultimately help immunization programs plan more effectively during later implementation phases? a) Is there potential to build on existing communication mechanisms, such as implementers' feedback during manufacturer advisory board meetings and dissemination of PIEs? b) Are there opportunities to better align the timing of select planning activities with the clinical and regulatory milestones that typically occur between Phase 2 and Phase 3 trials?

Stage 3: FDA Review and Licensure

This stage includes activities conducted by many partners that occur between the FDA's review of a BLA application and FDA licensure of a vaccine, not just activities conducted by the FDA itself. For clarity, this section has been broken into FDA Activities and Coding; however, many of these steps occur simultaneously. Please see the flowchart for a visual overview of the timing and how these steps relate to one another.

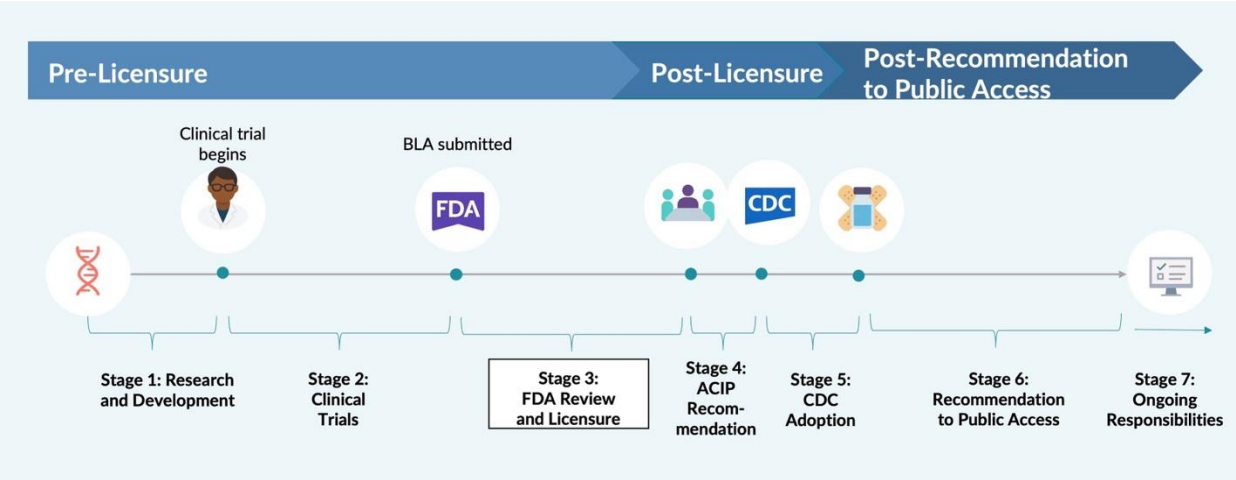


Figure 4 Environmental Scan Timeline of Vaccine Implementation - Stage 3

Case Study Timeline: Nirsevimab [61]
January 2023: FDA accepted BLA for nirsevimab and set PDUFA date for Quarter 3 of 2023. **July 17, 2023:** FDA approved the BLA for a single dose of nirsevimab for prevention of RSV-associated LRTI in infants born during or entering their first RSV season and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

Routine Steps During FDA Review and Licensure – FDA Activities

First, the FDA acknowledges the BLA submission, confirming that the submission is complete and will be reviewed. At this time, FDA sets the Prescription Drug User Fee Act (PDUFA) date, which marks the target date by which the FDA must complete its review of the BLA, typically around one year.[62] In some cases, however, the FDA designates a BLA for priority review, which accelerates the timeline by requiring completion of the review within six months from the date of acceptance. This expedited pathway is reserved for products that, if approved, would provide significant improvements in the safety, effectiveness, or diagnosis of serious conditions.[63] The FDA's Center for Biologics Evaluation and Research (CBER) conducts a comprehensive review of the BLA, which includes the review of clinical data, prescribing information, and manufacturing details, to ensure that the vaccine meets strict safety, efficacy, and quality standards.[11,12] FDA only reviews the information submitted through the BLA, and it does not make recommendations on vaccine use.[12] During this time, the previously described PIE presentations are conducted between manufacturers and health care decision makers.

Though not required, the FDA typically collects input from the Vaccines and Related Biological Products Advisory Committee, which is an external group of experts that convenes to provide scientific and medical guidance to the FDA. While not legally required to do so, FDA has historically followed the recommendations of the committee.[31] In cases involving non-traditional immunization products, such as long-acting monoclonal antibody products, the Antimicrobial

Drugs Advisory Committee may also review the application and provide recommendations.[64] If at any point in this process a vaccine does not meet safety or efficacy standards, it returns to the manufacturer for further development.[11] After all evaluations are completed, the CBER director issues final approval for the new vaccine. In rare cases, the FDA commissioner may intervene to make a final decision, particularly if there are special public health concerns or policy considerations.[12] At this time, CDC continues technical planning, such as preparing for new codes (outlined in the codes section), and begins preparing provider education and outreach materials. During FDA review, manufacturers establish product pricing (e.g., wholesale acquisition cost) and may submit pricing information to private pricing compendia in preparation for launch. Private drug pricing compendia are proprietary reference databases that collect manufacturer-submitted drug pricing information and publish standardized pricing benchmarks used by CMS and other payers to establish reimbursement rates, fee schedules, and formulary policies. The establishment of product pricing is contingent upon CPT codes being published (further explained below in the codes section). Once the FDA approves the BLA, the vaccine is officially licensed for use. As part of the approval process, the FDA officially assigns and registers the NDCs previously created by the manufacturer. Then, the FDA allows the manufacturer to update DailyMed to assign the NDC to the vaccine. This ensures accurate tracking and inventory management of the vaccine.[12,56]

Note: No documentation of gaps and promising practices were identified for this section.

Considerations: Stage 3 FDA Review and Licensure – FDA Activities *Guiding questions to support discussion, planning, and coordination across immunization partners.*
How can we ensure that immunization programs have the information and resources they need—such as anticipated dosing schedules, packaging, storage, coding, forecasting—early enough to begin preparing systems, infrastructure, and outreach strategies in advance of a recommendation? a) How can we ensure implementers have the necessary support to foster these systems changes? Are there specific implementation planning activities that immunization programs could realistically begin during the period between BLA submission and the PDUFA date? What support would be needed to help all programs initiate these steps consistently?

Routine Steps During FDA Review and Licensure – Coding

Each vaccine has several codes associated with it that allow it to be identified and ensure interoperability across immunization and health IT systems.

Table 1: Purpose and Use of Vaccine Codes

Code	Full Name	Assigned by	Assigned when	Purpose	Used by
ICD-10-CM	International Classification of Diseases, 10th edition, clinical modification — diagnoses	CDC	Released every October	Diagnostics	Health care providers, EHRs, billing systems, payers
NDC	National Drug Code	Manufac-turer and FDA	Submitted by manufacturer during research, assigned during FDA licensure	Inventory management, ordering, billing, tracking	Distributors, pharmacies, IIS, EHRs, manufactures, etc.
MVX	Manufacturer Vaccine Code	CDC	Assigned with new manufacturers or manufacturer changes	Identifies vaccine manufacturer	IIS, EHRs, public health agencies, billing systems, payers, quality measure stewards
CVX	Vaccine Administered Code	CDC	Assigned after FDA licensure	Records vaccine administration	IIS, EHRs, public health agencies, billing systems, payers, quality measure stewards
CPT	Current Procedural Terminology Code	AMA CPT Editorial Panel	Released prior to FDA approval in April, July, and October	Vaccine administration, billing and payment (and counseling in 2026)	EHRs, billing systems, payers, health care providers
G-Codes	Health care Common Procedure Coding System (HCPCS) Level II G-Codes	CMS	As needed, often prior to FDA licensure	Varies by code. Specific code set exists for billing for the administration of Medicare Part B covered vaccines	EHRs, billing systems, payers, health care providers

ICD-10-CM (International Classification of Diseases, 10th edition, Clinical Modification) is used to code and classify medical diagnoses. These codes are maintained by the CDC and updated every October.[65] Although these codes are primarily used by health care providers when diagnosing patients, ICD-10 codes are required to justify coverage and support billing codes on claim forms submitted to health plans to process payment (for example, Z23 – Encounter for immunization).[66]

National Drug Codes (NDC) are assigned by the FDA and serve as universal product identifiers for human drugs. These codes indicate the product, manufacturer or packager, and the packaging configuration (such as single-dose vials).[67] New vaccines often come in multiple presentations, so there are often multiple NDCs for a given vaccine. The NDC crosswalk table published by CDC links each NDC to other relevant codes, such as CPT/HCPCS described below. When payers update their formularies to add new vaccines, the NDC codes and crosswalk table are used to ensure pharmacy claims, and in some cases medical claims*, are processed correctly.

The Manufacturer Vaccine Code (MVX) identifies the vaccine manufacturer and is managed by the CDC Vocabulary Team.[60] The code is typically known at the time of FDA submission and is used by IIS, EHRs, public health agencies, billing systems, payers, and quality measure stewards to track and document which company produced a given vaccine.[56,67] MVX codes are regularly updated to reflect changes such as company mergers or closures.[67]

CVX codes, also known as "Vaccine Administered Codes" represent vaccine products. They capture key attributes such as vaccine formulation, concentration, and route of administration.[67] In some cases, when these attributes are consistent across products, an existing CVX code may be reused rather than creating a new one. For example, Priorix, an MMR vaccine approved by the FDA in 2022, uses the existing MMR CVX code.[68] These CVX codes are used by IIS, EHRs, public health systems, billing systems, payers, and quality measure stewards to document vaccination events, process claims, and support inclusion in immunization value sets for quality reporting. [56]

The Current Procedural Terminology (CPT) codes, developed and maintained by the American Medical Association (AMA), are used to report medical procedures and services[67], including vaccine product and administration for some payers. Each five-digit numeric code is linked to descriptive terms corresponding to a single procedure or service.[68] Starting in 2026, additional CPT codes will also be used to support payment for vaccine counseling services.[69] However, the existence of a CPT code does not guarantee payment to providers for the associated service.[66]

The process for establishing a new CPT code begins with a code change application submitted through the AMA's CPT Smart App. While anyone can submit an application, they are typically submitted by manufacturers, health care providers, medical specialties, or other professional societies. To meet the application criteria for a new CPT code, the submitter needs to share Phase 3 clinical trial data as part of the application process. The application(s) are reviewed by the AMA's CPT Editorial Panel, the body authorized to create, revise, and update CPT codes. Several work groups and professional committees of health care professionals advise the panel

* Historically, medical claims have primarily relied on CPT codes rather than NDCs; however, some payers require NDCs for vaccines on medical claims, making accurate crosswalks important to avoid claim errors.

to create the codes and associated clinical guidance. The CPT Editorial Panel meets three times a year, in February, May, and September. There are two types of CPT codes relevant to immunizations: product codes that identify the specific vaccine or immunization product and procedure (administration) codes that report the administration of the product and when applicable, whether counseling was provided.

In 2006, the AMA CPT Editorial Panel agreed that new immunization product codes should be published "early release," meaning they are published ahead of FDA licensure to better facilitate immunization reporting and implementation.[70] This process was further refined in 2024, following the release of nirsevimab, to formalize triannual publication cycles in April, July, and October.[70] These CPT product codes typically become effective six months after their release date. However, if the panel determines a vaccine is urgently needed, the AMA may expedite this schedule. In those cases, the code will have an additional publication date (outside of the April, July, and October schedule) and use a shorter implementation window, three months or less, with partner agreement based on the urgency of the situation. Once a CPT code is published through this process and the NDC is known, the CVX code is eligible for publication by CDC. Following these releases, the manufacturer can update private drug pricing compendium.

Once a new CPT procedure (e.g., vaccine administration) code is created, the AMA's Resource-Based Relative Value Scale Update Committee (RUC) assigns a value in Relative Value Units (RVUs). These recommendations are submitted to the Centers for Medicare and Medicaid Services (CMS), which determines whether to accept them. If the CPT codes and RVUs are accepted, [72] CMS incorporates the RVUs into the Medicare Physician Fee Schedule, which defines payment rates for providers. CMS publishes proposed changes to the physician fee schedule annually in July, followed by a final rule in November. CMS is responsible for payer oversight, including private insurers, Medicaid, and Medicare Advantage.[73]

Case Study Timeline: Nirsevimab [70,71]

May 2023: AMA CPT Editorial Panel approved nirsevimab CPT product codes

June 2023: AMA released CPT product codes

July 2023: FDA licensure

August 2023: ACIP recommendation

September 2023: AMA CPT Editorial Panel approved nirsevimab CPT administration codes

October 2023: RSV season begins, AMA released nirsevimab CPT administration codes

CMS standardizes and provides oversight of coding systems, called Healthcare Common Procedure Coding System (HCPCS), so payers can process claims consistently. There are two levels of HCPCS codes. Level I codes are comprised of CPT codes and maintained by AMA. HCPCS Level II codes are maintained by CMS and are used to identify products, supplies, and services not included in the CPT codes.[74] These codes are often used when a CPT code has not yet been established or when CMS requires a temporary coding solution; however, in practice, some HCPCS Level II codes may remain in use on a long-term basis.[56] A special type of HCPCS Level II code, called G-codes, are used to identify health or medical services that could otherwise be a CPT code, but for which CMS has determined that a Level II code should be issued.[75] HCPCS Level II G-codes are used

only in specific scenarios when it comes to vaccines, such as to bill Medicare Part B for the administration of certain vaccines like influenza, separate from billing for the vaccine product.[76] If relevant, CMS also determines whether the vaccine is covered under Medicare Part B or Part D, guided by statutory language.

Following FDA licensure, manufacturers are required to notify CMS that a new product has entered the market.[77] Pricing benchmarks published by private drug pricing compendia (e.g., average wholesale price) can then be used by CMS, Medicaid, and other payers to establish pricing files and fee schedules. CDC publishes the vaccine administered code set (CVX) and, if needed, manufacturer code (MVX), and updates the NDC crosswalk table, which is a reference tool that maps NDCs to other coding systems used in health care billing, reimbursement, and data analysis.[32,54,56] Once the relevant codes and drug pricing compendia are publicly available, payers may begin preparing their systems and reviewing and configuring coding logic.[66]

Together, these coding systems (NDC, MVX, CVX, CPT, G-codes, and ICD-10-CM) support a comprehensive infrastructure for vaccine data and payment. They enable accurate documentation of vaccine administration, streamline inventory management and billing workflows, and support flexible data exchange and documentation across the immunization ecosystem.[67]

Documentation of Gaps and Promising Practices – Coding

Despite the existence of a robust coding infrastructure for vaccines, including NDC, MVX, CVX, CPT, and HCPCS G-codes, gaps and delays in coding and billing processes can create downstream issues that impact vaccine access for patients and payment for providers. Variation across Medicaid programs compounds these challenges. State Medicaid programs differ in their coding and billing requirements for Vaccines for Children (VFC) program vaccines. For example, payers sometimes require the use of additional codes, or "modifiers[†]," when providers submit bills for vaccine administration. However, providers may care for patients from a number of states, and the use of modifiers often differs between payers. Additionally, some payers require billing only the VFC program vaccine product code, others only the administration code, and some both.[78] Another gap lies in misalignment of the timelines for vaccine approval, recommendation, and coding. For example, CPT codes may be finalized but not updated in payer systems, so providers may need to submit claims multiple times before payment is issued, discouraging early adoption of new vaccines and creating financial strain for providers who administer vaccines without guaranteed payment.[53]

[†] A modifier is a two-character code appended to a CPT/HCPCS code that provides additional detail about how or why a service was provided.[202]

Updating payer billing systems requires more than just adding a new code. Payers must align multiple overlapping code sets: CPT/G-codes for the vaccine product and administration and ICD-10 for the diagnoses that justify coverage. Payers also need to apply NDC crosswalk tables to link NDCs to CPT/G-codes. Ensuring that claims logic accepts the correct combination of codes may be time consuming as payers' clinical teams must review all possible codes that could be billed and narrow them to those most likely to be used. This includes anticipating and preparing for inexact matches to diagnosis (ICD-10) codes. If there are mismatches between CPT/G-codes and ICD-10 codes, claims may be denied. Only some health plans have systems that allow for testing of these code alignments to identify issues prior to the launch of a new vaccine. As there are new updates to ICD-10 codes every October, these challenges may be exasperated depending on when in the year a new vaccine is recommended.[66]

In practice, this coding misalignment often appears mismatched between vaccine product codes, administration codes, and required diagnosis codes, even when each individual code is valid. For example, during the initial rollout of nirsevimab, existing immunization administration codes included "vaccine"-specific language that did not apply to the monoclonal antibody. While a new administration code was eventually created to address this nuance, payments for claims submitted before the new code became effective may have been delayed. In addition, ICD-10 guidance specified that administration of nirsevimab should not be reported using code Z23 (encounter for immunization), but rather Z29.11 (encounter for prophylactic immunotherapy for RSV), creating another potential point of mismatch. When payer systems are not configured to recognize these combinations in advance, and when providers and their coding and billing staff are not provided guidance around new codes, claims may be denied or require manual review, contributing to implementation delays.[56]

Similar outcomes from coding misalignment may occur for new or reformulated products. Sometimes the descriptor for a billing code, such as a CPT code, does not match the new product.[66] One recent example of coding misalignment occurred during the 2024-25 influenza (flu) season, when flu vaccines changed from a quadrivalent to a trivalent formulation. This transition required providers to use CPT codes for trivalent flu vaccines, some of which had not been used in eight years. At the start of the season, many health plans had not yet updated payment rates or fee schedules for these codes, leading to denied claims and underpayments. The issue affected both private payers and Medicare, whose systems did not update until September 30, 2024. These billing and coding issues resulted in delayed payments to providers, and manufacturer and payer communications were necessary to encourage timely system updates and prevent further disruption.[79] This issue is discussed more broadly during the payment section.

Although the AMA has accelerated publication of CPT immunization product codes to allow time for health IT systems implementation, subject matter experts note that novel products can still face timing delays when new administration codes are needed, whether CPT (HCPCS Level I) or G-codes (HCPCS Level II).[80] For example, in the case of nirsevimab, the CPT administration codes became effective on October 6, 2023, after the RSV season had begun and the product was

being administered.[71] However, recent efforts to prevent these delays are promising. Multiple manufacturers are expected to apply for FDA licensure of COVID-19 influenza combination vaccines,[81] and CMS recently approved a specific CPT code to support billing for their administration.[82] If not resolved well prior to the launch of other types of future products, a lack of a code could create implementation challenges.

Considerations: Stage 3 FDA Review and Licensure – Coding *Guiding questions to support discussion, planning, and coordination across immunization partners.*
Are there opportunities to improve alignment of vaccine coding timelines and strengthen communication across manufacturers, EHR vendors, and public health systems to ensure codes are available and usable in advance of administration? Given the technical nature of the topic, is there a need for a group to advise on coding and billing issues and help address critical payment challenges for the implementation playbook?

Post-Licensure

Stage 4: ACIP Review and Recommendation

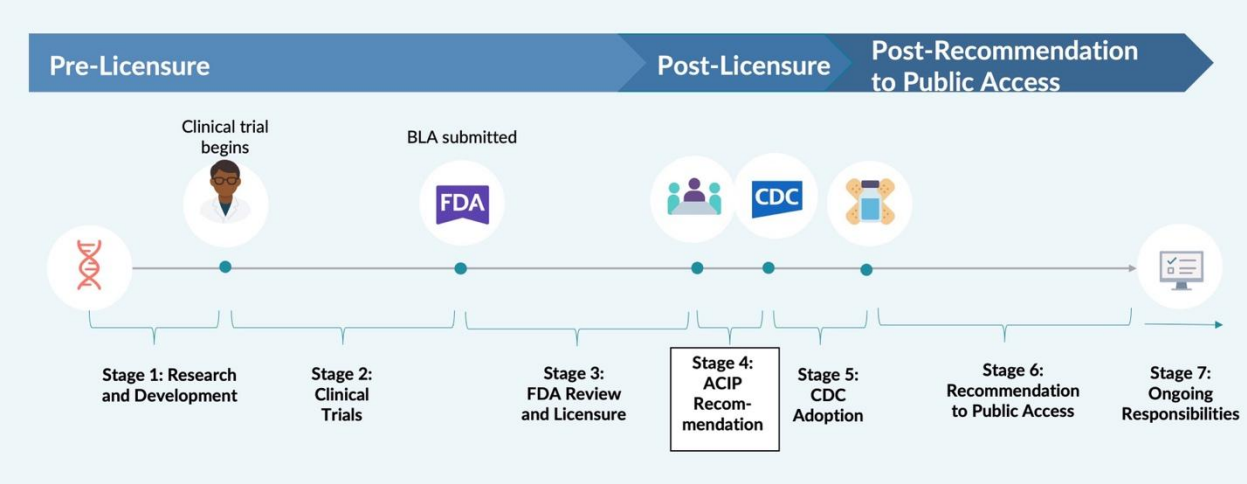


Figure 5 Environmental Scan Timeline of Vaccine Implementation - Stage 4

Routine Steps During ACIP Review and Recommendation

Following FDA licensure, ACIP (see first mention for definition and background) votes to determine if and how the new vaccine should be included in the U.S. immunization schedule. ACIP typically meets three times per year, and 60 days prior to a meeting, the information is published in the Federal Register. In exceptional circumstances, the CDC director may call an emergency meeting without prior notice, or with less than the usual 60-day notice in the Federal Register.[46] ACIP WG leads submit proposals for the ACIP agenda approximately three months before an upcoming meeting and provide justification for including the topic, proposed presentations, and other pertinent information on the meeting agenda. After receiving and

reviewing all agenda proposals, the ACIP Steering Committee meets to finalize the meeting agenda.[43] In preparation for the meeting, a briefing book is prepared and provided to the CDC director approximately three weeks prior to the ACIP meeting.[43,46] In addition, background materials may be provided to ACIP members ahead of the meeting, especially for issues that will be voted on during that meeting.[46]

ACIP is expected to review a new vaccine at the next scheduled meeting following FDA licensure. If a recommendation isn't made at that time, the committee must provide a status update.[46] The WG typically presents information at several meetings before ACIP votes on the final recommendation.[83] WG presentations to ACIP are an important step in the process, as these presentations are the mechanism through which the WG communicates its review of evidence, proposed recommendations, and key considerations to the full ACIP. These presentations help to frame the scientific and policy significance of the recommendation, which provides important context for decision-makers and implementers. A formal ACIP vote is required when there are no prior recommendations for the new vaccine, or if the new vaccine includes a novel adjuvant, targets new strains, or introduces a new age group, dose schedule, or population.[46]

As ACIP convenes and votes, immunization programs monitor developments,[84] engage in ongoing collaboration with partners and providers, and may begin developing messaging applicable to the new vaccine.[49,52] While awaiting or immediately following CDC adoption of new ACIP recommendations, immunization programs may take several preparatory steps, including preparing communications about the recommendations to providers and the public, updating factsheets and websites, and reviewing Section 317 vaccine eligibility. Immunization programs can also prepare to add new vaccines to their monthly vaccine planning documents and IIS ordering once they are available on the federal contract, incorporate new vaccines into IIS using updated CVX, MVX, NDC, and CPT codes, and update forecasting functionalities within IIS.[85] Depending on when these codes are published and available, immunization programs may incorporate the new vaccines into their IIS prior to this stage.

The VFC program is a federal program established in 1994, which pays for vaccines routinely recommended for children through 18 years of age who are Medicaid-eligible, uninsured, or underinsured, are vaccinated at a Federally Qualified Health Center or Rural Health Clinic, or are American Indian or Alaska Native.[86] After a favorable ACIP vote for a new or updated childhood or adolescent vaccine, the CDC provides a VFC program resolution that reflects the recommendation.[87] VFC program resolutions are developed by CDC through a separate process from general ACIP recommendations, based on statutory authority granted by the Omnibus Budget Reconciliation Act of 1993 (42 U.S.C. §1396s).[46] This law gives ACIP the authority to determine which vaccines, schedules, and doses are included in the VFC program.[46] This resolution defines the eligible population(s) (e.g., age groups, risk groups), the covered vaccine(s) and dose schedule, the effective date, and any special considerations (e.g., catch-up dosing, high-risk indications).[87] While alignment between ACIP recommendations and VFC program resolutions is prioritized, VFC program guidance may sometimes be broader to support

implementation[‡]. The resolution to include the vaccine in the VFC program is reviewed and voted on by ACIP members, and approved resolutions are shared with VFC program providers through state immunization programs.[46]

[‡] Not all ACIP-recommended vaccines are included in the VFC program. For example, rabies and certain travel vaccines are excluded. In some cases, immunization programs may receive limited Section 317 funds to cover related products (such as immune globulins), which are considered part of VFC eligibility but are not supplied through CDC contracts.

Documentation of Gaps and Promising Practices

Historically, differences in guidance between ACIP, state health departments, and national medical associations affected how quickly providers adopted new vaccine recommendations and may have created confusion.[88] It was not until 1995 that the child/adolescent immunization schedule was harmonized between ACIP, the American Academy of Family Physicians (AAFP), and the American Academy of Pediatrics (AAP).[89] For example, prior to 1989, ACIP recommended a single measles dose at the preschool visit. After a measles outbreak, including cases among previously vaccinated college students, New York officials planned to implement a second dose, despite national guidance. ACIP soon followed with a recommendation for a second dose at ages 4-6, while the AAP recommended it at ages 11-12 to quickly protect older children. These conflicting guidelines led to confusion among providers until a harmonized schedule was developed jointly by ACIP and the AAP.[88] This example illustrates a gap that existed prior to the adoption of harmonized schedules, when conflicting guidance from national organizations contributed to confusion at the provider level. At the time of this scan, ACIP considers implementation challenges as a factor in developing the harmonized vaccine schedule.[42] The EtR contains a checklist of considerations for the assessment of the feasibility of implementing proposed vaccine recommendations, which includes criteria related to financial barriers, simplicity, integration, and access.[36]

While this environmental scan reflects the environment as of March 2025, subsequent developments through the finalization of this report in the end of March 2026 have impacted alignment between recommendations made by ACIP and other immunization partners. During this period, ACIP has issued new recommendations, but adoption has varied across jurisdictions due to concerns that the committee deviated from its standard evidence-based recommendation processes,[40] which prompted some medical associations and coalitions of states to provide differing recommendations. A federal judge granted stays in the case of AAP et.al. v. Kennedy, blocking implementation of changes to the childhood immunization schedule and invalidating related ACIP actions, citing likely violations of required legal and evidence-based processes.[41]

Historically, a subset of immunization program managers who are more engaged with ACIP workgroups or activities have had greater awareness of information and a clearer understanding of the preparatory steps needed for implementation. However, this is not consistent across all programs, highlighting an opportunity to improve how information and actionable supports are disseminated to ensure broader readiness.

ACIP issues several types of vaccine recommendations, including universal (for all persons in an age group), risk-based (for persons with specific health or exposure risks), travel, and shared clinical decision-making (SCDM) (where vaccination is dependent on individualized discussions between providers and patients or guardians). Public health partners may consider the effect of

different recommendation types on vaccine uptake. For example, one study on human papillomavirus (HPV) in adults ages 27-45 found that provider application of SCDM may be inconsistent, and lead to increased disparities as only people in health care have access to SCDM and associated recommended vaccines.[90] A 2020 survey of primary care physicians (n=617) found approximately one-third do not know how to implement SCDM for adult vaccinations, and only 40% said SCDM recommendations display in their EHR as recommended for patients, while only 42% knew that most health insurance covers vaccines recommended for SCDM by ACIP.[91] A 2024 study on the regional disparities of the availability of meningococcal vaccines theorized the SCDM recommendation for meningitis b (MenB) vaccines may also contribute to lower vaccine stocking levels in health care offices as providers may be less likely to stock a vaccine with less predictable demand and potential financial risk compared to meningitis ACWY (MenACWY) vaccines.[92] Additionally, while CDC has defined who is eligible to conduct SCDM, providers are still confused regarding who can and how to implement SCDM.

Considerations: Stage 4 ACIP Review and Recommendation *Guiding questions to support discussion, planning, and coordination across immunization partners.*
What systems or partnerships could be strengthened to promote consistent messaging when vaccine schedules or guidance differ across jurisdictions?

Stage 5: CDC Adoption

This stage includes activities conducted by many partners that occur during the time period between CDC adoption and rollout of the vaccine, not just activities conducted by the CDC itself. Many of these steps are happening simultaneously. Please see the flowchart for a clearer picture of the timing and how the steps interrelate.

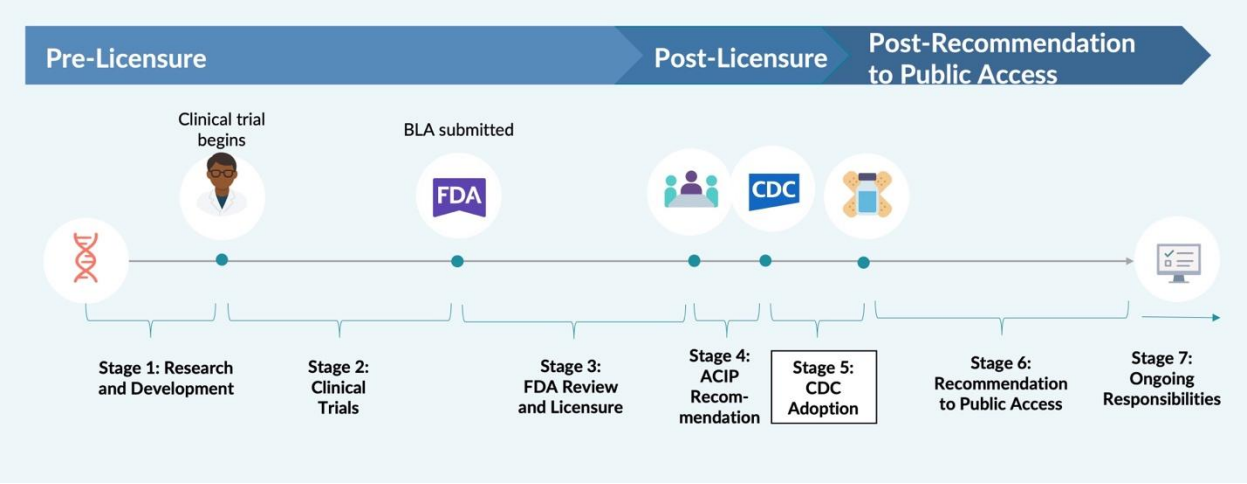


Figure 6 Environmental Scan Timeline of Vaccine Implementation - Stage 5

Routine Steps During CDC Adoption

Once ACIP recommendations are adopted by the CDC director, they become official CDC policy and are published in the Morbidity and Mortality Weekly Report (MMWR) and commonly as Policy Notes, which include both the ACIP-voted recommendations and CDC's usage guidance.[43,46,83] The ACIP WG lead oversees drafting the Policy Note and the more detailed "Recommendations and Reports," coordinating with CDC offices and ensuring input from eligible ACIP members.[43] Drafts are prepared ahead of the ACIP vote, and sections related to the specific vaccine product are shared with the manufacturer before publication to correct factual errors if needed.[43]

Case Study Timeline: Nirsevimab[29,93]
August 3, 2023: ACIP recommends use and CDC director adopts the recommendation **August 25, 2023:** MMWR published **September 25, 2023**: VIS released

If applicable, ACIP's vote to approve the VFC program resolution allows CDC to procure and distribute the vaccine through the VFC program. Once the CDC director signs off, the VFC program resolution becomes official CDC policy for the VFC program.[87] The CDC then negotiates prices with the vaccine manufacturer and finalizes the federal contract.[54]

Medicare vaccine coverage is provided by Part B or Part D, depending on the purpose and type of vaccine. Medicare Part B covers vaccine products and their administration for influenza, pneumococcal disease, hepatitis B, COVID-19, and certain vaccines needed to treat injury or exposure. In contrast, Medicare Part D covers all other commercially available vaccines needed to prevent illness, and patients pay nothing for ACIP-recommended adult vaccines under this benefit. However, newly approved vaccines are not always added to Part D formularies right away. If a vaccine is not yet listed, enrollees or their providers may request coverage through the formulary exception process. Additionally, Part D plans may pay providers using either a single administration fee or multiple fees based on factors such as the vaccine's complexity, the provider's type, and how the vaccine is administered.[94] Following the new recommendation, CMS ensures that state Medicaid policies align with the VFC program, when applicable, and that Medicaid provides payment for vaccine administration. Under the Inflation Reduction Act, effective October 2023, all ACIP-recommended adult vaccines and their administration must be covered by Medicare, Medicaid, and the Children's Health Insurance Program without cost-sharing.[95] State Medicaid programs must follow CMS guidelines at a minimum, and they add CPT codes to their vaccine tables and guidance to insurers. If they have not done so already, payers then update their billing systems to enable claims processing and payment. This process requires coordination across multiple internal teams and may take several months to complete. Depending on the health plan's procedures and when codes become available, these activities may occur at different stages in the vaccine implementation process. Typically, clinical teams decide on the appropriate diagnostic codes: IT teams build rules to support workflows (such as adding NDCs and crosswalk tables to databases and ensuring claims logic accepts all valid CPT/G-code and ICD-10 combinations), compliance teams verify regulatory alignment, actuarial teams assess cost impacts, and education teams prepare patient and provider communication

materials.[66] Due to limited engagement with payers during this environmental scan, further clarification is needed to understand how these internal processes and timelines vary.

Following MMWR publication, CDC drafts the Vaccine Information Statement through the federal rulemaking process, as required by law.[96] Interim Vaccine Information Statements (which allow for more timely updates between full revisions), multi-vaccine Vaccine Information Statements (which reduce the number of documents patients must review), and CDC supplemental materials (which provide additional context) support clear and accessible vaccine communication while continuing to meet legal and ethical standards for informed vaccine consent.[96]

CDC then updates its systems and resources to support implementation. CDC uses a web-based management application called the Vaccine Tracking System (VTrckS) to oversee the logistics of the publicly funded vaccine supply chain (see more information in distribution and administration section). Health IT systems, such as VTrckS, use code sets to ensure vaccine data are consistently identified and interpreted across systems. Code sets are standardized systems used to classify and encode information, particularly in health care, to facilitate communication, billing, and standardization. CDC adds the new vaccines to VTrckS, using updated code sets to allow for vaccine ordering from the federal contract through the VFC program.[35] CDC also finalizes updates to the CDC Clinical Decision Support for Immunization (CDSi) Project, which uses the new ACIP recommendations to develop clinical decision aids for the newly recommended product. These decision aids make it easier for health information systems to give healthcare providers the tools to automatically determine if and when a patient is due for the newly recommended immunization. These systems include HIEs, IIS, and EHRs.[97] However, these updates are not immediate. Once the CDSi guidance is finalized, IIS must adapt their programming and EHR vendors must update their systems, which can take additional time before providers see the changes in practice.[3] Additionally, the vaccine is added to distributor contracts and the CDC's Epidemiology and Prevention of Vaccine-Preventable Diseases manual, commonly known as the Pink Book.

In the U.S. there are 61 IIS[§], which include all states, territories, freely associated states, and several large cities (e.g., New York City, Philadelphia).[98] IIS vendors begin preparing for administration of the newly recommended immunization product by updating system coding, displays, and outputs (such as NDCs, MVX codes, CVX codes, allergy risk codes, and crosswalk tables) to support accurate data capture and reporting. Vendors also add the new vaccine and its

[§] As of July 2025, the number of federally funded immunization programs increased from 64 to 66.

related code sets to the list of vaccines jurisdictions can incorporate into their IIS platforms. In parallel, IIS vendors update CDS or other forecasting tools to reflect the new recommendation.[99]

EHR vendors similarly update their systems to include the new vaccine, ensure accurate forecasting, and integrate all relevant code sets, enabling proper documentation of vaccine administration in patient records and accurate reporting to IIS, payers, Vaccine Adverse Event Reporting System (VAERS), and other entities. As of 2025, at least 97% of IIS allow for bidirectional exchange of information between IIS and EHR systems,[100] allowing health care providers to submit immunization records directly from the EHR to the IIS, and to receive immunization records from the IIS into the EHR for their patients.[101] Following the ACIP recommendation, and the publication of CDSi Logic Specification and Supporting Data,[97] EHR vendors update their system's code sets to ensure the new vaccine is included in bidirectional messaging. In circumstances where there is a new immunization technology which an EHR may technically define as a drug and not a vaccine, such as nirsevimab, additional testing may be required to ensure the IIS can accept messages from the EHR.[82] Following ACIP approval, professional medical associations typically begin preparing resources for their members to support them in incorporating the new vaccine into practice. These resources may include visual or written reference guides to help providers understand a host of issues, such as the nuances of ACIP recommendations, dosing, administration, product ordering and inventory management, eligibility, coding, payment, recall for subsequent doses, documentation, and patient education.[102–106] Each professional medical association operates differently, with many having work groups or advisory groups that meet regularly to discuss the development of clinical guidance and/or documents related to immunizations and infectious diseases. Other associations meet on an ad-hoc basis as ACIP and CDC issue new recommendations and guidance or update routine immunization schedules.[107,108]

Documentation of Gaps and Promising Practices

The translation from ACIP recommendation to routine use of a new vaccine requires complex technological processes coordinated across multiple systems, including IIS and EHRs, as well as anticipation of logistical and operational challenges.[58]

IIS play a critical role in vaccine ordering, documentation, and forecasting, yet some systems are unable to fully support new products at the time of CDC adoption. For example, at the time of ACIP recommendation, only 52% of jurisdictions reported that their IIS could document nirsevimab, and just 68% could use their systems for ordering nirsevimab in the VFC program. These barriers were largely attributed to funding limitations and vendor constraints.[109] Shortly after CDC adoption, in September 2023, ACIP recommended Pfizer's RSVpreF vaccine (Abrysvo) for pregnant persons as a one-time dose for individuals at 32-36 weeks gestation between September and January (and therefore likely to deliver during RSV season). ACIP clarified that either maternal vaccination during pregnancy or nirsevimab administration to the infant is recommended, but both are not needed in most cases.[84] This created additional complications for IIS and some EHRs, which did not have the ability to link maternal and infant records, making

it difficult to determine whether infants had already received RSV protection via maternal vaccination or needed to receive nirsevimab after birth.[110]

Concerns were also raised about the lack of integration between EHRs and IIS, which impairs accurate tracking and reporting. Nirsevimab presented new challenges in that it was classified by FDA as a "drug" and not a "vaccine," as it is a product that provides passive immunization. EHRs are not programed to identify "drugs" that are administered and to send those records to the IIS, which meant there was a need to create pathways that could ensure this data exchange. This circumstance required additional testing to ensure that the IIS could accept administration messages from EHRs. This was an issue that had not been previously encountered. In addition to these issues, immunization programs had not received guidance regarding cost, distribution, packaging, or storage. A 19% average reduction in IIS funding further limited immunization programs' ability to effectively incorporate new immunization products like nirsevimab.[109] Beyond technical capabilities, IIS policies vary widely across jurisdictions, contributing to fragmented data. Differences in mandatory reporting laws, consent requirements, and data sharing protocols result in inconsistent vaccine documentation and gaps in measuring vaccination rates. [111]

Additionally, CDS may not adequately handle complex or risk-based recommendations, which can result in incorrect forecasting. For example, nirsevimab dosing is weight-based (50 mg for infants weighing <5 kg and 100 mg for those ≥5 kg), and ACIP further recommends a 200 mg dose (two 100 mg injections) for children ages 8-19 months at increased risk entering their second RSV season. These nuances can create documentation and forecasting errors, such as valid second-season doses being flagged as duplicates. These errors can undermine provider trust and hinder uptake. Likewise, IIS are good at recommending vaccines based upon the data entered into the system, such as age-based recommendations, but they are not currently configured to assess and recommend all risk-based recommendations (e.g., health care worker, immunocompromised, traveler, pregnancy), which can result in failure to recommend some vaccines. To expand IIS capabilities, additional resources are needed to support standardization and adoption of these standards.

While CDC's CDSi provides standardized forecasting logic that can be consistently implemented across IIS and EHRs, point-of-care reminders are implemented at the EHR or health system level and vary widely based on local configuration, workflow design, data availability, and vendor-specific functionality. Although both aim to support timely vaccination, point-of-care reminders depend on how individual EHRs operationalize clinical decision support standards and are therefore less uniform than IIS-based forecasting. While studies have shown EHR point-of-care reminders can improve delivery of vaccination, EHR systems are not always updated in a standardized manner following new recommendations. EHR order sets can also help differentiate between specific vaccines recommended for certain special populations. A recent study used the example of the 2022 changes to the ACIP recommendation for hepatitis B vaccine (HBV) in adults (to include all adults 19-59 years without prior vaccination or past/current infection) and provided detailed guidance on how to implement vaccine screening logic into EHRs. For multi-dose vaccines, scheduling follow-up visits and orders needs to be integrated into the clinical

workflow. The publication highlights the importance of ensuring EHR prompts reach beyond clinicians and include all staff with the authority to vaccinate, such as pharmacists, medical assistants, and nurses.[112]

The point at which health systems begin planning for the rollout of new immunization technology varies widely. A few health systems prepared extensively to integrate nirsevimab, offering potential promising approaches. For example, while many birthing hospitals have yet to begin administering nirsevimab in the hospital because of a mix of financial and operational concerns, the Pediatric Infectious Disease team at Stanford Hospital in California began planning in the summer of 2023 for the anticipated FDA approval of nirsevimab. Preparation included forming a multidisciplinary team that handled forecasting dose needs, developing EHR orders with appropriate defaults, integrating the immunization into existing workflows and order sets with minimally disruptive clinical decision support, creating educational materials for staff and caregivers, and adapting to the ongoing supply challenges. Due to its extensive operational preparations, Stanford was ready to offer nirsevimab to all eligible inpatient newborns, regardless of insurance status, just a few weeks after the 2023 RSV season began.[113]

The time to implement vaccine recommendations in the health care setting can be very lengthy. One health system's integration of HPV vaccine support illustrates how implementation can be a multi-year, evolving process, especially for vaccines with changing recommendations over time. Although ACIP recommended the HPV vaccine in 2006, it took six years for the health system to add it to health maintenance reminders, a significant delay between national guidance and clinical integration. Subsequent updates in 2016 and 2020 were made to reflect evolving risk-based criteria and an "early start" approach, which required updating EHR decision support tools to align with the new recommendations. By 2023, the health system further enhanced access by allowing self-scheduled vaccinations through MyChart.[114] This example underscores the inefficiencies present in the implementation of vaccine recommendations into clinical work flows, which can result in missed opportunities for vaccination and ultimately leave patients at risk for vaccine-preventable diseases.

Although some immunization programs and public health partners have been known to offer EHR guidance for the implementation of new vaccines, as with the example of California offering EHR guidance for infant VFC program eligibility and nirsevimab screening for Oracle and Epic,[115] such efforts appear to be ad hoc rather than systematic.

Looking across recent implementation efforts, several documented strategies and process improvements offer insight into how public health agencies and health care providers have approached similar challenges in the past. For example, numerous quality improvement projects have been published on increasing hepatitis B birth dose administration, which could have been used in advance to prepare materials for hospitals for the launch of nirsevimab. Examples included standardizing the vaccination process through admissions documentation, clearly defined administration timing, scripted nurse communication with parents, and targeted education and engagement of obstetricians and pediatricians.[116–118]

Considerations: Stage 5 CDC Adoption *Guiding questions to support discussion, planning, and coordination across immunization partners.*
What strategies could help ensure that infrastructure (e.g., IIS and EHR systems) is ready in time to support implementation once CDC adopts a new routine vaccine? What mechanisms could ensure integration of new vaccine recommendations across delivery settings, including non-clinical settings such as pharmacies and settings that have not traditionally participated in the VFC program (e.g., birthing hospitals)?

Post-Recommendation to Public Access

Stage 6: Post-Recommendation to Public Access

This stage includes activities conducted by many partners that occur during this time period and has been broken into three main sections: Supply, Distribution and Administration (which is further organized by partner), and Ongoing Safety Monitoring and Liability. However, many of these steps are happening simultaneously. Please see the flowchart to understand timing on how they interrelate.

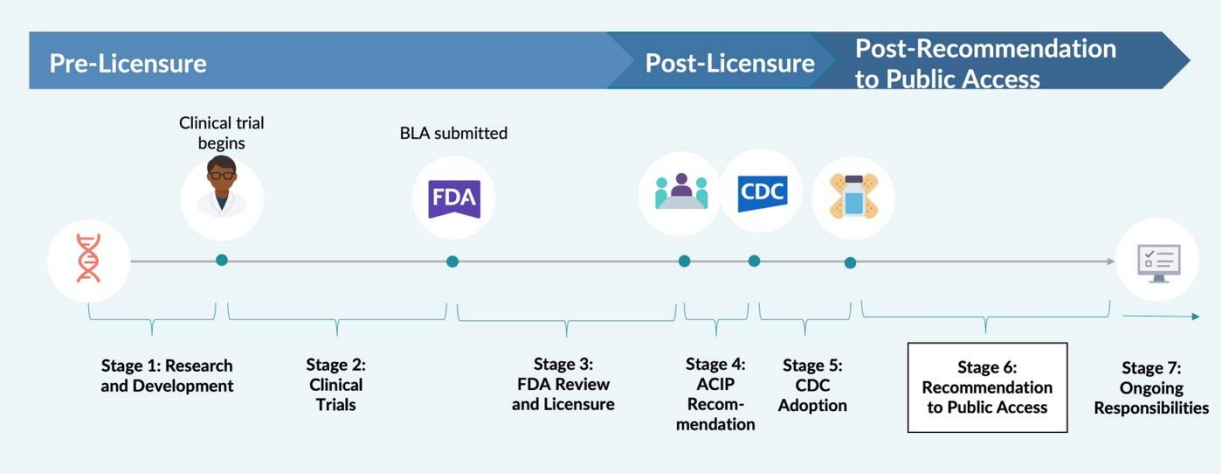


Figure 7 Environmental Scan Timeline of Vaccine Implementation - Stage 6

Case Study Timeline: Nirsevimab
August 3, 2023 - AHIP publishes support for timely coverage of new RSV mAb immunization product across payers. **Early September 2023** - Immunization programs detail nirsevimab ordering plans in monthly vaccine planning documents. **September 29, 2023** - Nirsevimab ordering opens for the VFC program. CDC publishes a nirsevimab addendum outlining modifications to routine VFC program requirements, including permission for jurisdictions to conduct virtual enrollment visits for birthing facilities. CDC also issues updated provider VFC documents clarifying that adverse events following nirsevimab-only administration must be reported to MedWatch, instead of VAERS, as the mAb is classified as a drug and not a vaccine. **October 20, 2023** - CDC pauses VFC ordering due to limited product supply to ensure immunization programs that had not ordered could equitably receive doses. **October 23, 2023** - CDC releases a Health Alert Network notification in response to limited supply of nirsevimab. CDC recommends prioritizing available nirsevimab 100 mg doses for infants at the highest risk of severe RSV disease. **October 27, 2023** - CDC releases updated VFC borrowing* guidance following limited supply of nirsevimab. **November 11, 2023** - Several (6+) jurisdictions have either already redistributed nirsevimab doses among VFC providers, or are planning to do so, in order to more equitably distribute limited allocations of doses. **By January 2024** – Demand has decreased, and additional supply is available, allowing a return to original recommendations. **Borrowing occurs when privately purchased vaccine is given to a VFC-eligible child, or VFC vaccine is given to a privately insured child. Borrowed doses are later returned, and borrowing is regulated both by CDC and the jurisdiction.*

Routine Steps Managing Vaccine Supply

Near the end of the regulatory process, manufacturers will scale up vaccine production, due to the large financial investment that is needed.[30] The exact timing of manufacturing depends on many factors: whether a new facility type needs to be built, how long the product takes to make, and the financial risk a manufacturer is willing to make depending on anticipated product demand.[32]

With increased production, manufacturers may identify a projected shortage due to production issues or unexpectedly high demand. CDC plans for several different supply situations.[54] If publicly funded supply is projected to be inadequate, CDC may establish jurisdiction-specific ordering allocations (fixed amounts of vaccine doses per jurisdiction) or thresholds (ordering caps that replenish between ordering periods); however, we did not find evidence that this is common prior to initial rollout. For example, during the 2023 rollout of nirsevimab, the CDC paused VFC program ordering and then issued a Health Alert Network Health Advisory on the shortage after VFC ordering opened, recommending providers prioritize 100 mg doses for the highest-risk infants.[119]

If CDC does not set allocation or threshold limits on the ordering of VFC program vaccines for jurisdictions, immunization programs may determine a VFC program allocation strategy to ensure equitable access based on parameters such as geography or priority populations. For example, with nirsevimab, some immunization programs initially allowed open ordering, while others implemented ordering caps. Depending on the recommendation, immunization programs may use provider ordering history for other vaccines for a comparable population to help predict provider demand, such as using rotavirus vaccine ordering as a predictor of the need for nirsevimab doses.[120]

After rollout, CDC may also set ordering limits if supply becomes an issue, and ACIP may even temporarily update schedules or recommendations to account for these supply problems. For example, due to a manufacturing shortage in the late 1990s, the tetanus and diphtheria (Td) vaccine distribution schedule was changed to defer routine boosters. Td vaccine was distributed only to select providers, including hospitals and emergency departments. The routine Td vaccine schedule resumed in 2002 once supply stabilized.[121] In 2002 the ACIP recommended that all providers delay administration of the routine childhood varicella vaccine dose typically administered at age 12-18 months until age 18-24 months.[122] Similarly in 2004, the CDC modified pneumococcal conjugate vaccine recommendations to temporarily suspend the routine administration of the third and fourth doses for low-risk children.[123]

In 1982, the CDC established a stockpile of vaccines equal to a six-month supply of routine childhood vaccines (except influenza), 126,129-130 as required by law.[126] Prior to 2002, the National Pediatric Vaccine Stockpile only contained vaccines for which there was a single manufacturer but it was later expanded in response to supply shortages.[121] Today, CDC purchases a six-month supply for the stockpile, while manufacturers are responsible for storing

and maintaining this six-month reserve of their products.[**35] However, during the early rollout of a new vaccine, manufacturers are already producing at peak capacity and may be unable to set aside sufficient doses for the national stockpile.[121]

Documentation of Gaps and Promising Practices - Supply

During periods of unstable vaccine supply, jurisdictions reported to AIM that they would benefit from transparency around the number of doses they can expect earlier in the rollout process so they can plan and forecast provider allocations appropriately.[127] Strengthened communication and planning between public health agencies and manufacturers has improved the overall vaccine supply since the historically large shortages in the early 2000s, but there are opportunities for improvement. Beginning in 2001, vaccine availability was compromised for approximately five years. Six routine childhood vaccines (covering nine diseases) faced supply shortages. These shortages were caused by 1) business decisions to leave the market, 2) production problems, 3) adherence to manufacturing requirements, and 4) changes in formulation to remove thimerosal.[121] However, in recent rollouts, challenges have centered around unexpectedly high demand for new products, such as with the 2023 rollout of nirsevimab.[119] This issue is not new. Similar challenges with high demand were seen with the heptavalent pneumococcal conjugate vaccine (PCV7) rollout in October 2000.[124]

When nirsevimab was introduced, the immunization community was not broadly aware of the impending supply shortage. As a result, only some immunization programs implemented an initial cap on provider orders, leading to disparities in distribution that favored programs that placed VFC program orders quickly or in large quantities. This necessitated course corrections and, in some cases, the redistribution of doses.[127] By the time CDC paused VFC program ordering of nirsevimab in response to the shortage, allocations were unequal across jurisdictions. In circumstances where demand outpaces supply, public health and manufacturers should work together as early as possible to communicate timely updates and reprioritize available doses, as appropriate. In 2004, the first year of the universal recommendation of influenza vaccine for children ages 6-23 months, an unanticipated suspension of an overseas manufacturer led the ACIP to revise the influenza vaccination recommendations to focus on high-risk individuals. Although the federal government had no legal authority to oversee distribution, the remaining manufacturer, Sanofi Pasteur, voluntarily changed its distribution plans to follow ACIP

[**] Unfortunately, authors could not find newer resources on the National Pediatric Vaccine Stockpile, and the vast majority of interviewees and SME partners did not know it existed and assumed it was part of the strategic national stockpile.

recommendations. State health departments also cooperated in redistributing vaccine across state lines.[124]

Considerations: Stage 6 Post-Recommendation to Public Access – Supply *Guiding questions to support discussion, planning, and coordination across immunization partners.*
What steps could be taken by partners in the immunization community to anticipate and plan for demand-supply mismatches?

Routine Steps During Vaccine Distribution and Administration

Many of the steps during vaccine distribution and administration are happening simultaneously. For ease of reading, this section is divided into Steps by Partners, Access, and Payment.

Steps by Partners

Manufacturer and initial communications

Although details vary by product and manufacturer, manufacturers typically begin adverting the new product and shipping doses directly to health care providers or third-party distributors following CDC adoption. This occurs for both publicly and privately funded vaccines.[32]

CDC

Once the CDC director adopts the ACIP recommendation for a new vaccine, the agency oversees the logistics of the publicly funded vaccine supply chain (including ordering, inventory, shipping, and tracking) via VTrckS, a web-based management application. Since 2013, all federally funded immunization programs have used VTrckS to manage public vaccine inventory, monthly vaccine planning documents, and provider orders. Health care providers submit and track vaccine orders either through their state IIS, which connects to VTrcks, or directly within VTrckS.[128] When new vaccines are implemented under supply constraints, immunization programs use VTrckS to manage orders for priority groups and ensure equitable distribution across geographies, demographics, and provider types. CDC also publishes the preliminary Vaccine Information Statement, a federally required document which is provided to patients or caregivers at the time of vaccination and that outlines the risks and benefits of vaccine.[96]

Immunization programs

Following CDC adoption, immunization program activities vary across jurisdictions due to differences in operational structures, policies, and legal regulations.[85] In some jurisdictions, immunization programs must acquire and adopt formal vaccine recommendations from jurisdiction-specific committees or advisory boards, as required by their state law. AIM's 2022 Annual Survey (n=53 of 64 jurisdictions) found that at least 24 U.S. states and territories had established immunization advisory committees to support vaccine-related decision-making. These committees typically include physicians, public health professionals, nurses, public

advocates, and members of the general public. Committee reporting structures vary. About half report to immunization program leadership, while others report to state health departments or legislative bodies. Their responsibilities often include implementing ACIP recommendations, determining school and childcare vaccine requirements, advising on vaccine supply and safety, selecting vaccines for purchase, and supporting IIS operations. Some states maintain multiple advisory bodies to separately address clinical and policy issues. Overall, these committees provide helpful guidance for implementing new vaccines and strengthening immunization program infrastructure.[129]

Immunization programs also determine how the vaccine will be covered across funding streams, such as the VFC program and Section 317 program, to support equitable access.[130] The Section 317 program is a federal grant program administered by the CDC that provides limited funding to jurisdictions to purchase vaccines for uninsured and underinsured adults or for outbreak response. This funding helps ensure equitable access to recommended vaccines and vaccines needed for post-exposure prophylaxis or catch-up immunization in the case of an outbreak of a vaccine-preventable disease. In most cases, Section 317 funding is also the sole funding source available to support immunization program infrastructure.[131] In "universal purchase" states where the immunization program supplies all or select ACIP-recommended vaccines to all children (regardless of insurance status), immunization programs must ensure adequate funding for the purchase of new vaccines using a combination of the VFC program, Section 317, state,[87] and/or health plan funds.[132,133] Some jurisdictions also operate adult universal purchase programs,[134] which may require additional steps to secure funding, depending on the program's structure.

Immunization programs notify the state Medicaid and the Children's Health Insurance Program (CHIP) about the inclusion of the new vaccine into the state VFC program. [130] CHIP, jointly funded through the federal government and states,[135] provides health coverage to eligible children either through Medicaid expansion or as a stand-alone CHIP program, depending on the jurisdiction. CHIP-eligible children have family incomes that are too high to meet eligibility criteria for Medicaid but too low to afford private insurance coverage.[136] States with stand-alone CHIP programs must purchase vaccines for enrolled children using CHIP funds, not VFC program funds.[137]

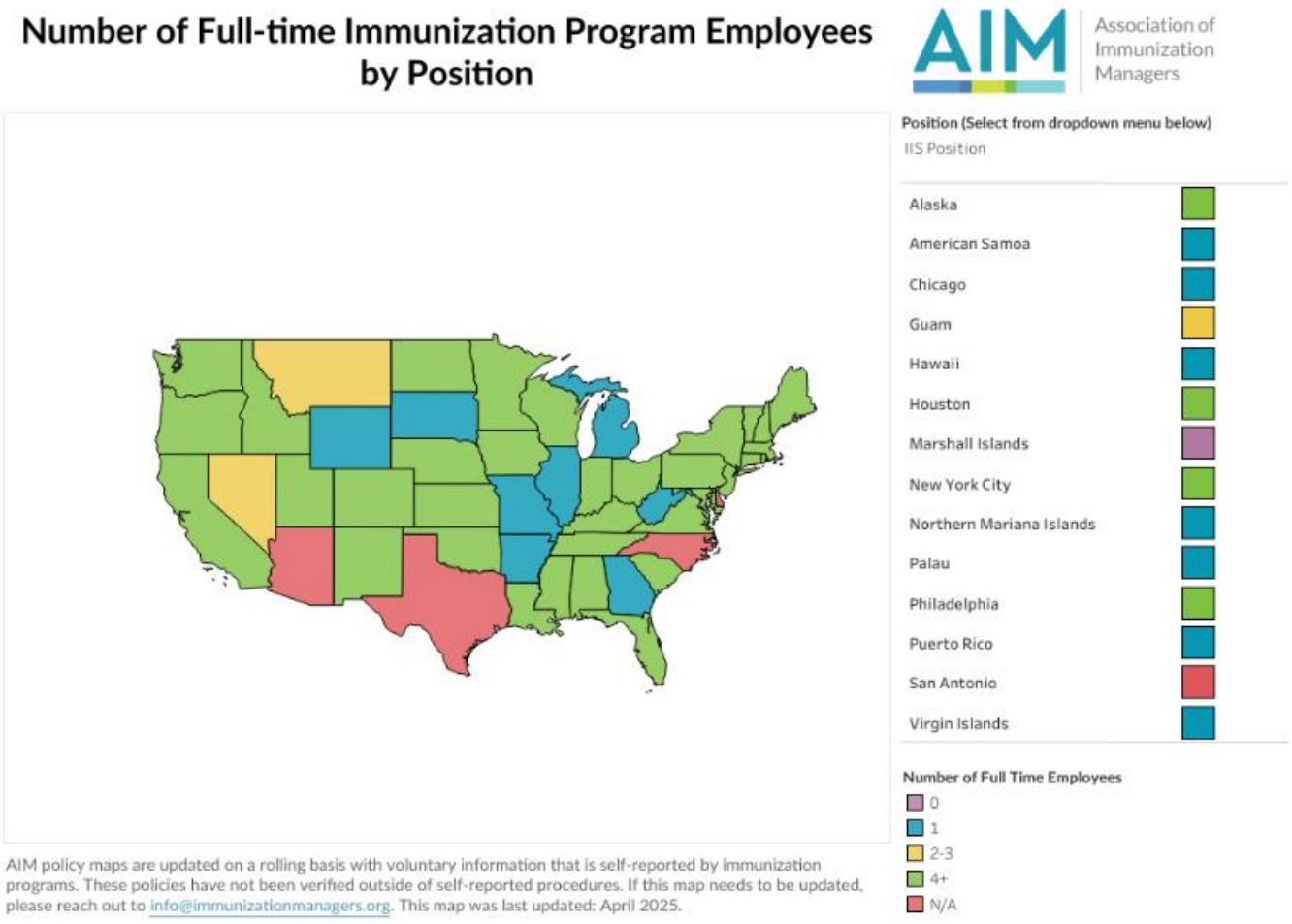
Immunization programs adjust internal systems to manage ordering, inventory, and distribution and to monitor provider compliance with the requirements of the VFC program. This may include, but is not limited to, updating vaccine planning documents (VFC program/Section 317 program eligibility charts, billing code tables, and health plan documentation), modifying public and private vaccine order options, monitoring provider ordering and reporting, and overseeing VFC program accountability. [130]

Although interviews indicated that many immunization programs and partners begin preparing for implementation before formal ACIP recommendation or state-level advisory committee approval, the timing and nature of these steps vary.[138] For example, one statewide immunization coalition collaborates early with partners to develop consistent messaging, collect necessary codes, and monitor insurance coverage updates.[138] It also conducts disease and vaccine

education sessions for providers.[138] A few interviewees suggested that timing and level of involvement may depend on the immunization program manager's experience.[49,52] AIM's 2024 Annual Survey highlights significant variability in full-time employee staffing across jurisdictions, which can affect each program's capacity during new vaccine implementation. An interactive map is available to explore jurisdiction-specific differences in staffing levels by position (Figure 8).[134,139] The pace of immunization program activities also rely heavily on the timing of federal action and communications. For example, although the ACIP workgroup publicly supported administering nirsevimab at birth for infants born during RSV season as early as February 2023,[140] key operational materials were not shared with awardees until closer to the start of the RSV season in October. CDC distributed the VFC Program Operations Addendum for nirsevimab and the updated VFC Program Provider Agreement on September 29, 2023, the same day VFC program ordering opened and just two days before RSV season began. As a result, immunization programs had limited time to recruit and enroll birthing facilities in the VFC program, which is critical to ensuring access to nirsevimab at the earliest opportunity.

Immunization programs may also develop public and provider education campaigns to support uptake, though this varies widely by jurisdiction.[49,52] Depending on the vaccine and available

Figure 8 Snapshot of AIM Interactive Policy Maps Number of Full Time IP Employees by Position



funding, CDC may develop education materials, but according to former CDC employees interviewed, there are rarely resources for formal social marketing or mass media campaigns at this stage.[54]

However, it is important to recognize that immunization programs operate within complex state and federal frameworks, taking policy direction from governors or state health officers while relying on federal funding streams, such as CDC grants, for implementation. In addition to these federal processes, many operational activities and priorities vary by state, reflecting differences in governance structures, public health capacity, and local needs. In this context, program capacity is shaped by available staffing and funding, so not all new or expanded tasks are immediately feasible. Distinguishing essential functions from aspirational ones is critical to realistic planning and execution.

Health Care Providers and Organizations

Following CDC adoption, health care provider organizations and professional associations may issue their own formal recommendations for new immunization products, as appropriate.[53]

These organizations often convene advisory or working groups on an ad hoc basis to review new ACIP recommendations and sign off on immunization schedule changes.[107,108] For instance, the AAFP endorsed RSV antibody for use in infants and young children on August 10 2023, one week after the ACIP recommendation, following a formal review from the AAFP's Commission on Health of the Public and Science.[141] These associations also disseminate prepared resources to their members and promote guidance from state, local, and territorial immunization programs, as appropriate.[53]

Health care providers must also complete a range of operational and logistical activities to prepare for administering a new vaccine. This includes ordering vaccines either through their jurisdiction's immunization program or via private purchase, updating billing systems that are not integrated into the EHR, and training staff on product-specific storage, handling, and administration requirements. Providers must ensure that their current supplies and workflows meet cold chain requirements and that their EHR systems are configured to document vaccine administration and transmit records to the IIS in accordance with local regulations. In addition, providers are responsible for billing insurers appropriately for both vaccine administration (for public and commercial payers) and the vaccine product itself (for commercial payers only). They must also be prepared to report any adverse events following immunization to the appropriate vaccine safety monitoring systems. In non-traditional settings, such as birthing hospitals, providers may need to enroll in the VFC program and establish processes for verifying patient eligibility, obtaining consent, and documenting administration, an approach that was used during the rollout of nirsevimab. [53,142]

Payment

Since passage of the Affordable Care Act in 2010, insurance plans offered on the Health Insurance Marketplace®, along with nearly all other commercial insurance plans, must cover

routinely recommended vaccines without charging a copayment or coinsurance when provided by an in-network provider. Commercial health insurance plans are required to cover newly recommended vaccines starting with the plan year that begins on or after one year from the date the recommendation is issued, although some may choose to cover them without delay during the same plan year as when the vaccine is newly recommended.[143,144]

Access

Access to new vaccines depends on how each jurisdiction structures and coordinates its vaccination delivery systems. Each jurisdiction's availability and configuration of provider networks, mobile clinics, school-located vaccination initiatives, Federally Qualified Health Centers, and rural health centers varies, shaping how residents can access vaccinations.[80,145] These differences influence the logistics of distribution, provider enrollment, and the populations that are reached during different phases of a new vaccine rollout. Decisions about where and how vaccines are offered are shaped by supply and availability across these settings. When supply is limited, jurisdictions may prioritize certain settings (e.g., birthing hospitals, pediatric offices, or community health centers) to promote equitable access.[146] At the state and local level, standing order policies, where permitted by state law, can further support access by authorizing vaccine administration under approved protocols across multiple provider types and settings, enabling more rapid and consistent implementation during rollout.[147] These access decisions are closely linked to supply management processes discussed in more detail in the Supply section.

Documentation of Gaps and Promising Practices – Distribution and Administration

Payment

Payment-related barriers consistently emerged as a major concern in the key informant interviews conducted for this scan, often ranking as the first or second most frequently discussed issue in the process of vaccine implementation.[35,50,53,148] In particular, partners highlighted the challenges posed by the upfront cost of vaccines and delays in timely payment for vaccine products and administration by payers. Even after a vaccine is recommended, it can take months for both public and private payers to integrate new vaccines into their payment systems.[138] Larger health plans that work across numerous states and with many pharmacy and provider partners may take even longer to build out their payment workflows.[66] This uncertainty creates hesitancy among providers who take on financial risk when providing newly approved vaccines without guaranteed payment. Ultimately, patients miss out on the opportunity to receive a new vaccine, leaving them at risk for preventable disease.[35,53,110,148]

Additionally, changes in vaccine indication, such as expansion to a new age or risk cohort, can exacerbate these delays. Payers and third-party systems may have rigid claim adjudication logic that rejects claims falling outside predefined parameters, creating real-time denials and contributing to the perception that the vaccine is not covered.[80] On the payers' side, this claim adjudication logic is dependent on matching diagnostic (ICD-10) and billing codes (CPT/HCPCS

G-codes) with ACIP recommendations. When no precise code set exists to match an ACIP recommendation, multiple health plan teams (clinicians, pharmacists, IT, and compliance) must review all possible options, test claims logic, and determine which codes are both covered and most likely to be used. For example, ACIP might recommend vaccination for "all adults over 60," but CPT/HCPCS and ICD-10 do not contain a single, precise code that matches that population or description. Instead, health plans must decide whether to accept a general preventive code, an age-based code, or a set of risk-based codes. This time-consuming process can lead to payment delays which cause provider hesitancy and claim denials.[66]

The substantial upfront cost of vaccines remains a significant barrier to the implementation of new immunization products. For example, during the nirsevimab rollout, many pediatricians faced challenges in stocking commercially acquired doses due to the upfront cost of $495 per dose[146] and uncertainty about when they would receive insurance payment. As a result, some pediatric practices only offered nirsevimab to VFC program-eligible patients, while others opted not to stock nirsevimab at all, citing a lack of equal access for both commercially and publicly insured patients. [53] Similarly, the introduction of PCV7 in 2000, one of the most expensive vaccines at that time ($121 per dose in 2025 dollars[149]), led to both public and private clinics in many states developing a two-tiered system where only VFC program-eligible children could receive a PCV7 vaccine. In five states with universal purchase policies, all recommended childhood vaccines were provided to private providers, except for PCV7.[124]

The upfront cost of nirsevimab and uncertainty about payment also limits its administration at birth, despite the CDC's recommendation for infants to receive nirsevimab during the first week of life, ideally during the hospital stay. While nearly 50% of U.S. births are eligible to receive vaccines through the VFC program, only 10% of birthing hospitals participated in VFC program at the start of the 2023 RSV season, rising to 36% at the beginning of the 2025 RSV season.[150] Most birthing hospitals negotiate payment for a "bundle" of services, meaning payers provide a fixed payment for all services surrounding prenatal care, labor, delivery, and post-partum care. Since the cost of nirsevimab has still not been factored into most of those negotiated payments,[146] hospitals have no ability to recoup the cost of nirsevimab from commercial payers through the bundled payment mechanism. Since most hospitals are not enrolled in the VFC program, and many providers find the VFC program's administrative process burdensome,[146,151] neither publicly nor privately insured infants can access nirsevimab in the majority of birthing hospitals.[110] Even in jurisdictions with relatively high hospital participation in the VFC program, timely administration of nirsevimab remains challenging. A New York City study found that only about half of the nearly 14,000 doses administered to infants born shortly before or during their first RSV season[152] were given within the first week of life.

Other payment issues have also emerged in the literature. Although enrolled health care providers receive free vaccines for children covered by the VFC program, the low payment rate for vaccine administration often does not cover the costs associated with administering vaccines. State Medicaid administration payment rates are limited by federal regulation, which has not been updated since 2012, and are historically lower than those under Medicare or private

insurance.[153] A 2023 assessment of facilitators and barriers to VFC program participation in one state confirmed that low payment rates for vaccines made participation financially unsustainable for some practices.[154]

A 2023 report from a state-level "Vaccine Congress" found that payment-related issues contributed to challenges in childhood vaccine delivery. Families often face confusion about vaccine eligibility and are afraid of high costs, among other non-payment concerns. Barriers to vaccine delivery at the provider level include the administrative and regulatory burdens of participating in the VFC program, which can be especially challenging for smaller practices. This particular Vaccine Congress found that many providers choose not to stock all recommended vaccines due to high upfront costs, strict storage requirements, and concerns about wastage. The report identified enhancing provider payment models as an opportunity for improvement to encourage provider participation.[151]

Available literature identified several other opportunities for improvement. A 2023 qualitative study examining payer opportunities to improve HPV vaccine uptake in safety-net settings identified several themes that may be applicable to other new vaccines, particularly those with lower-than-desired demand.[155] One identified opportunity was the inclusion of vaccines in payer quality improvement initiatives, such as pay-for-performance (P4P) programs for providers[156] and Healthcare Effectiveness Data and Information Set (HEDIS) measures for systems (e.g., HEDIS Combination 2 for adolescent immunization). In this study, some payers suggested that higher administration fees or value-based payment programs could be used to incentivize vaccine delivery.[155] Another theme emphasized the importance of including vaccine coverage into all potentially applicable state programs. For instance, California's Family Planning, Access, Care, and Treatment Program included cervical cancer screening but did not cover HPV vaccination at the time of the study. The study's findings underscored the importance of public health building partnerships with payers who juggle many competing priorities and may not be motivated to prioritize vaccination.[155] Although the findings were specific to HPV and safety-net settings, they may highlight broader opportunities for immunization programs to collaborate with public health and community organizations, and to work with payers to ensure vaccines are promoted and available within existing service settings.

Payment challenges are not limited to traditional health care provider offices, they also extend to public health agencies. Historically, state and local health departments have faced substantial barriers to billing public and private insurance plans for immunization services. These barriers include challenges related to funding, staffing, software, insurance verification, and third-party payer relationships. In response, the CDC implemented the Billables Project (2009-2016), which provided funding and technical assistance to build billing capacity in 38 jurisdictions. Despite this support, many departments continued to struggle with the upfront costs of maintaining separate private vaccine inventories and navigating complex and inconsistent payment processes. Project recommendations for improving the payment process included using supplemental funding sources to cover startup costs, developing standardized training materials, subcontracting when staff is limited, and establishing strong relationships with payers to improve communication.[157]

These financial challenges affect providers' willingness and ability to offer newly recommended vaccines. However, payment alone does not ensure access.

Access

Geographic and Socioeconomic Barriers

A key to the successful implementation of new vaccines is addressing geographic variability, particularly across rural areas and U.S. territories and freely associated states (TFAS). TFAS may face infrastructure limitations, limited vaccine allocations, shipment delays, and cold chain management issues, often due to remote outer islands with limited infrastructure or the effects of natural disasters such as hurricanes.[158] Similarly, rural areas in both TFAS and the continental U.S. struggle with lower health care provider density, which complicates vaccine delivery and access.[145,158]

During the COVID-19 pandemic, TFAS communities were able to overcome many of these challenges through innovative delivery strategies and multilevel coordination with federal, local, and regional partners.[158] Jurisdictions and partners outside of TFAS may consider whether these lessons can be applied to other resource-constrained settings and for other new vaccines. Additionally, differences in seasonality and climate may affect recommendations in TFAS or other U.S. regions, requiring tailored vaccine access, communication, and public health strategies for new immunization products.[146] For example, while administration of nirsevimab is recommended between October 1 and March 31 throughout most of the continental U.S., certain jurisdictions with tropical climates, such as Hawai'i, Guam, and the U.S. Virgin Islands, are encouraged to provide nirsevimab all year due to differences in the seasonality of the RSV virus in those locations.[159]

In rural counties, health care provider availability further complicates vaccine access. A 2024 study showed that rural counties with fewer primary care providers had lower stock levels of the MenB vaccine compared to MenACWY, whereas counties with more primary care providers had significantly more doses of both meningococcal vaccines.[92] Younger children in rural areas are especially impacted by vaccine access issues. As of 2025, 24 states did not allow pharmacists to administer vaccines to children younger than 7 years of age,[160] making access to pediatric primary care providers even more important.[146,161] Access challenges may be exacerbated in situations where new ACIP recommendations require catch-up for older children. Vaccines focused on adolescents may also face greater barriers as adolescents have fewer interactions with health care providers and some vaccines may require multiple doses over several visits.[162]

Many families face logistical barriers, such as lack of reliable transportation, childcare, internet access, or inflexible appointment times, which can hinder access for working families and those in rural communities.[151]

While local health departments have historically served as critical access points for routine immunizations, their capacity and role have shifted in recent years, particularly since the COVID-19 pandemic. Many departments are now understaffed, face workforce attrition, or are limited

by local ordinances that restrict the types of vaccines they can administer.[163,164] Past experiences demonstrate how resource and policy constraints can strain these systems. For example, when Missouri implemented a seventh-grade hepatitis B vaccine requirement in 1999, state funding covered vaccine purchase but not the operational costs of delivery. As a result, many health departments, particularly those in rural areas, experienced sudden surges in patient volume and struggled to meet demand without alternative delivery mechanisms such as school-based clinics.[165] Without sufficient funding and planning to support local infrastructure, new vaccine initiatives risk overburdening health departments that no longer have the resources to function as the front-line access point they once were.

From the immunization program perspective, a 2008 AIM study found that HPV vaccine adoption timelines varied widely across states, often reflecting geographic and socioeconomic differences in available funding sources (e.g., Section 317, state, and local funds). Programs with limited or unstable funding faced particular challenges in ensuring equitable access for underinsured and underserved populations, exacerbating existing disparities between regions. Additional barriers, such as the need for provider education, IIS updates, policy approvals, and inconsistent engagement from hospitals and private providers, further influenced implementation capacity across communities. Key enablers of successful implementation included timely vaccine stock availability and the publication of ACIP recommendations in the MMWR. These findings highlight how geographic and socioeconomic variation in resources, infrastructure, and provider engagement can shape the pace and equity of vaccine implementation, emphasizing the importance of coordinated planning and sustained funding to reduce disparities.[166]

Priority Populations

The introduction of new immunization products may come with additional recommendations for high-priority populations, complicating the process of ensuring equitable access. For example, nirsevimab is recommended for children aged 8-19 months who are at increased risk for severe RSV illness, including American Indian and Alaska Native children.[167] For priority populations, vaccine rollout should consider potential limitations to clinical access, health literacy, and other social determinants of health that vary depending on the populations of focus. Effectively engaging leaders within these prioritized populations is vital to ensuring access, tailored messaging, and trust in new vaccines.[150,155]

Community-based efforts are essential to overcoming these barriers and ensuring equitable access to new vaccines. For example, the COVID-19 vaccine rollout by the San Carlos Apache Tribe and San Carlos Apache Healthcare Corporation, in collaboration with the Indian Health Service, highlighted the importance of proactive planning and culturally tailored outreach in vaccine implementation. Planning began months before vaccine approval, which included acquiring an ultra-cold freezer, developing a vaccine administration playbook, identifying high-risk individuals, and launching educational campaigns in English and Apache. This groundwork allowed the San Carlos Apache Tribe and San Carlos Apache Healthcare Corporation to begin vaccinations the day after doses arrived and focus operational energy on emerging challenges.

Community outreach featured live videos of Tribal leaders receiving vaccines, radio messaging, and personal storytelling to improve vaccine confidence. The program expanded to include drive-through, pop-up, and door-to-door vaccination events. While these efforts were labor-intensive, they ensured vaccine access for this population. Cross-trained staff and federal support were important factors in making these efforts feasible. Although these strategies occurred during a pandemic, they emphasize the importance of community-based, culturally sensitive approaches for achieving equitable vaccine access and uptake, especially in communities with historical trauma from medical institutions.[168]

As an essential partner in reaching historically marginalized and medically underserved communities, independent community pharmacies are well-positioned to support equitable vaccine access.[169,170] During the COVID-19 pandemic response, the Federal Retail Pharmacy Program administered nearly half of all doses of COVID-19 vaccines through June 2023, but required independent pharmacies to build connections with seven different data systems and organizations with their own requirements. This set up created inefficiencies, inconsistent messaging, and offered no direct funding support. The fragmented infrastructure placed significant operational burdens on pharmacies and highlighted the need for streamlined systems, consistent communication, and defined roles. To ensure efficient rollout of new vaccines, public health agencies have established long-term agreements with independent pharmacy networks that clarify expectations, support centralized data exchange, and provide funding for training, outreach, and logistical coordination. The Independent Community Pharmacy Readiness and Response Consortium, an initiative of the National Community Pharmacists Association, offers a structure for this type of streamlined engagement. To maintain readiness, it is important to reinforce partnerships between independent pharmacies, community organizations, and government agencies, establishing a foundation for more equitable and efficient implementation of future vaccines.[169]

Many creative and well-documented approaches exist for improving vaccine access across the lifespan, particularly for priority populations. Strategies such as using mobile clinics, hosting vaccination events in non-traditional settings (e.g., places of worship), or co-locating vaccine services with other needed community resources (e.g., food banks) have long been used, but expanded substantially during the COVID-19 pandemic.[171] Pediatric providers have also contributed by offering adult caregivers vaccines during pediatric appointments, helping extend vaccine access to adults who are willing to be vaccinated.[172] These community-based delivery models demonstrate how adaptable, locally driven approaches can bridge access gaps.

Providers and the VFC Program

At the provider level, barriers such as administrative and regulatory burdens related to the VFC program create significant challenges, particularly for smaller practices.[151,154] Providers perceive the VFC program regulations as overly rigid, requiring manual data entry, frequent reporting, and complicated inventory processes.[151]

A state's 2023 assessment of VFC program participation identified several specific operational challenges that deterred provider engagement, such as the requirement for dose-for-dose restitution when VFC program vaccines are mistakenly administered to non-eligible patients, delays in ordering, requirements to keep manual temperature logs, and the complexity of reconciling inventory with IIS. Integration issues between EHRs and IIS further hinder data reporting and program compliance. Collectively, these barriers contribute to provider attrition and reluctance to enroll in their jurisdiction's VFC program.[154]

One state's Vaccine Congress identified several opportunities for improvement, including streamlining VFC program requirements and enhancing payment for vaccine administration to ease provider participation. The Vaccine Congress brings together immunization partners to assess policies and system changes that impact the vaccine delivery system and to help partners define, plan, and prioritize improvement strategies.[151] According to Vaccine Congress participants, investing in dedicated vaccine coordinators and support staff can improve clinic efficiency, while stronger interoperability between EHRs and immunization information systems can reduce administrative burden. Additionally, the Vaccine Congress emphasized that aligning vaccine regulations and funding across jurisdictions would help create a more consistent and equitable immunization infrastructure.[151]

Even when vaccines are accessible and payment structures are in place, successful implementation also depends on operational readiness, provider capacity, and public trust, each of which may pose additional challenges during distribution and administration.

Considerations: Stage 6 Post-Recommendation to Public Access - Vaccine Distribution and Administration

Guiding questions to support discussion, planning, and coordination across immunization partners.

Payment

- How might earlier, or more consistent, communication with payers improve provider confidence in payment timelines and reduce vaccine implementation delays?
- What supplemental funding mechanisms could help support provider practices with high upfront costs or limited resources?
- What allowable strategies could CDC and immunization programs adopt to reduce administrative burden and improve VFC program participation?

Access

- How could we help mitigate geographic challenges in rural and territorial communities prior to rollout?
- Given funding constraints, how could we support immunization programs in planning early with trusted community messengers for smoother rollouts in priority populations?

Education for the public, providers, and partners

- What sections should be included in a playbook for immunization programs to support program managers with varying experience levels in preparing for newly recommended vaccines?
- What can partners do to better coordinate existing efforts on messaging, partner alignment, public and provider education?

Routine Steps Related to Ongoing Safety Monitoring and Liability

Vaccine pharmacovigilance refers to the process of trying to detect uncommon adverse events following vaccination and determining whether there is a causal relationship to immunization between the event and vaccination. Vaccine pharmacovigilance includes passive and active surveillance, clinical investigation and associated special studies, and causality assessments.[147] Rigorous and ongoing post-licensure vaccine safety monitoring is a vital piece of the vaccine implementation process. Vaccines are continuously monitored for safety though a variety of systems designed to rapidly detect both common and uncommon adverse events. The U.S. has several safety systems responsible for vaccine pharmacovigilance, most of which are led by CDC and FDA. The table below explains the roles of each of the major systems,[173–178] and subsection 6 of AIM's implementation flowchart shows how they fit together (see Figure 9). Due to the scope of this paper, we provide only a high-level summary of these complex and rigorous systems. For more detailed descriptions, please refer to each system's website and frequently asked question pages.

Table 2: Vaccine Safety Systems in the U.S. 182,185,187-191

Acronym	Full Name	Type	Agencies Involved	What is Being Studied
VAERS	Vaccine Adverse Event Reporting System	Passive surveillance	CDC, FDA	Reports of adverse events following vaccination from providers, patients, manufacturers. Early vaccine warning system.
VSD	Vaccine Safety Datalink	Active surveillance	CDC, 11 integrated health care organizations	Mines EHR data to assess vaccine safety and detect adverse events in near-real time
CISA	Clinical Immunization Safety Assessment Project	Clinical consultation/ research	CDC, academic medical centers	Provides expert clinical consultation for complex adverse events and conducts in-depth clinical research to evaluate and improve vaccine safety

PRISM	Post-Licensure Rapid Immunization Safety Monitoring Program	Active surveillance	FDA	Subset of the FDA Sentinel System which monitors vaccine safety using large-scale health insurance claims databases
BEST	CBER Biologics Effectiveness and Safety System	Active surveillance	FDA (via Sentinel Initiative), CMS, DoD	Uses EHR and large-scale claims data to evaluate the safety and effectiveness of biologic products
V-safe	V-safe	Active surveillance (voluntary)	CDC	Text/email system to monitor real-time post-vaccination health status (COVID-19 or RSV only)
MedWatch	MedWatch: The FDA Safety Information and Adverse Event Reporting Program	Passive surveillance	FDA	Non-vaccine immunization products (e.g., mAbs) are reported in MedWatch when administered alone, but to VAERS if co-administered with vaccines
DMSS	Defense Medical Surveillance System	Active surveillance	DoD	Tracks vaccine safety and health events among military personnel using comprehensive medical and administrative data. Used for research and to investigate vaccine adverse events
I-STAR	Indian Health Service Safety Tracking and Response	Passive plus incident-based reporting	Indian Health Service (IHS)	Monitors and investigates vaccine-related and other adverse events within IHS facilities. Includes requirements to report to other systems, like VAERS and MedWatch

Additionally, smaller population-specific passive systems exist, such as the Department of Veterans Affairs Adverse Drug Event Reporting System;[181] however health care providers are required to report to VAERS by law.[176,182]

Each of these systems is closely monitored by the requisite agency. In the case of VAERS, both FDA and CDC review the data. Based on VAERS data and/or reports in the other safety systems,

|FDA determines subsequent regulatory actions. This could include changes to vaccine labeling, fact sheets, requiring the manufacturer conduct additional studies, or removal of licensure, among other actions.[183]

In addition to the federal agencies, the ACIP routinely reviews post-licensure safety monitoring data collected by these systems. These reviews often include VAERS data on the number of reports received, seriousness of adverse events, identified safety signals, and any data from other relevant safety systems. For example, in the months following the recommendation that adults aged ≥60 receive an RSV vaccine under shared clinical decision making, ACIP reviewed data from V-safe, VAERS, VSD, and CISA.[184] ACIP continued closely monitoring the adult RSV vaccines for safety signals over subsequent meetings, particularly as they relate to Guillain-Barré syndrome, and assessing whether the benefits of the vaccines outweigh their risks. After multiple meetings to review safety data, as of March 2025, ACIP recommended universal RSV vaccination for adults ≥75 years, and for adults aged 60-74 at increased risk for severe RSV disease.[184,185]

In addition to close reviews of safety data by federal agencies and ACIP, the FDA routinely inspects vaccine manufacturing facilities following licensure and recommendation. FDA also requires the manufacturer perform specific tests on each vaccine lot prior to distribution, as specified under the vaccine's licensure. Manufacturers are also required to submit samples of each vaccine lot and the results of the testing to the FDA. A lot cannot be distributed until the FDA approves it, which is a process called lot release.[186]

In the U.S., the National Vaccine Injury Compensation Program (VICP) governs vaccine liability. VICP was designed as a no-fault alternative to the traditional tort system by providing compensation to people who file a petition and are found to be injured by certain vaccines. The program helps to limit manufacturer and provider liability, helping to stabilize the vaccine supply and related costs, while also providing compensation to families without the need to engage in a lengthy and costly lawsuit against the manufacturer.[187] The VICP is funded by a $0.75 excise tax on each vaccine-preventable disease (antigen) contained in a covered vaccine recommended for routine administration to children. Not all vaccines are covered by the program. For a new vaccine to be covered in VICP, several steps must be followed:

- The CDC must recommend the vaccine for routine administration to children or pregnant people.
- Congress must approve an excise tax on the vaccine, which funds the administration of the VICP.
- The HHS secretary must amend the vaccine injury table through regulation.[188,189]

The vaccine injury table lists specific injuries associated with VICP-covered vaccines and defines time periods for these injuries. Changes to the table are made after a recommendation from the Advisory Commission on Childhood Vaccines to the HHS secretary, followed by a federal rule-making process with a public comment period. [188,189]

The VICP does not cover vaccines issued under the Public Readiness and Emergency

Preparedness Act, such as COVID-19 or smallpox vaccines. These are covered under the Countermeasures Injury Compensation Program, administered by the Health Resources and Services Administration and funded through annual congressional appropriations. The Countermeasures Injury Compensation Program compensates individuals for injuries that may be related to vaccines, medications, or other items used in response to public health emergencies or security threats. [188,189]

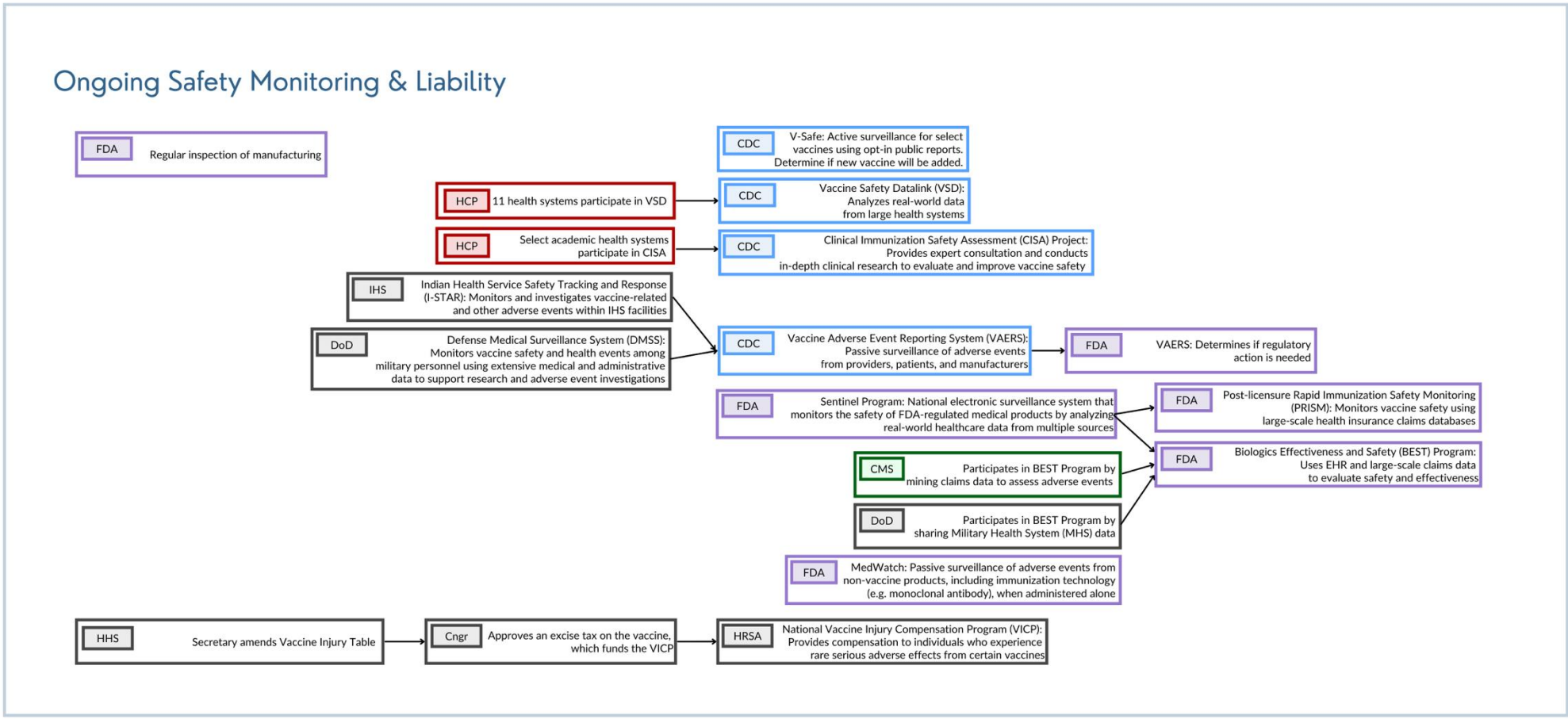


Figure 9 Snapshot of AIM's Vaccine Implementation Flowchart on Ongoing Safety Monitoring & Liability, Section 6

Documentation of Gaps and Promising Practices – Ongoing Safety Monitoring and Liability

Research from scientists in the vaccine community identifies opportunities to improve the U.S. vaccine safety systems.[190,191] A 2024 paper highlighted opportunities for strengthening U.S. vaccine safety programs using lessons learned from vaccine safety and monitoring system during the rollouts of COVID-19, H1N1, and routine vaccines. Although many of the specific recommendations (such as restructuring to adopt a consistent cross-agency system for assessing and reporting on vaccine safety and expanding mechanisms to evaluate vaccine effectiveness alongside safety) are beyond the scope of this paper, the authors highlighted the importance of rapidly communicating safety monitoring plans well in advance of new vaccine rollouts and publicly promoting surveillance findings to build public confidence.

In addition to the importance of communicating safety monitoring plans to the public well in advance of a new rollout, logistical challenges may also need to be addressed. For example, as new immunization products are recommended that may not be classified as vaccines, additional efforts may be needed to ensure efficient systems for reporting safety concerns. For instance, adverse events following administration of nirsevimab alone must be reported to MedWatch, whereas those following co-administration with a vaccine are reported to VAERS. This requires providers to be educated on this difference, and for clinics and hospitals to implement appropriate reporting protocols.[146,192]

Considerations: Stage 6 Post-Recommendation to Public Access - Ongoing Safety Monitoring and Liability *Guiding questions to support discussion, planning, and coordination across immunization partners.*
How can public health partners work to communicate safety monitoring plans in advance of rollout in ways that help immunization programs build public trust and support vaccine uptake? What resources or coordination mechanisms could help ensure that health care systems and providers are prepared for any changes to traditional adverse event reporting pathways, particularly with the rollout new immunization products that use novel technology?

Stage 7: Ongoing Responsibilities

This section is organized into three areas: continuing education and monitoring optimal uptake, school and childcare requirements, and other policies. However, many of these steps are happening simultaneously. Please see the flowchart to understand timing on how they are related to one another.

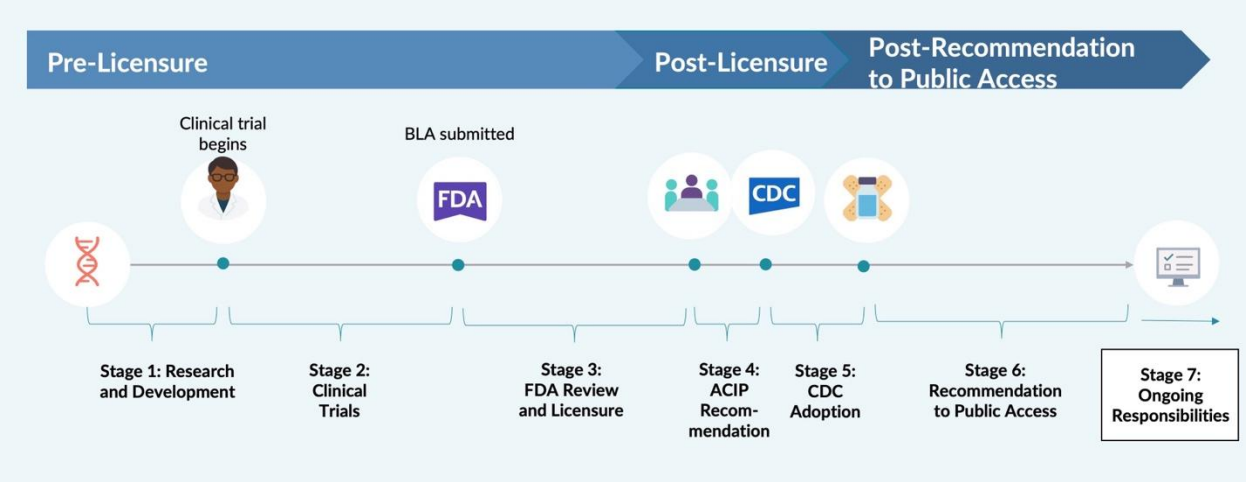


Figure 10 Environmental Scan Timeline of Vaccine Implementation - Stage 7

Routine Steps Related to Continuing Education and Monitoring Optimal Vaccine Uptake

Following the initial rollout of a new vaccine, immunization programs and partners have ongoing responsibilities to support vaccine uptake and address emerging challenges. Immunization programs continue to engage local partners, coalitions, and advisory groups, while also maintaining provider and public education efforts. They are responsible for staying current on ACIP recommendations, Vaccine Information Statements, and coding updates, and making necessary adjustments to IIS. Additionally, immunization programs play a key role in monitoring provider ordering patterns and working to ensure optimal vaccine uptake.[49,52]

At the national level, the CDC supports continued education efforts and posts updated Vaccine Information Statement materials as needed. ACIP continues to review safety and efficacy data, issuing updated recommendations as new evidence emerges. Meanwhile, health care providers, professional associations, and related organizations are tasked with identifying and responding to ongoing implementation issues, including payment challenges, standing order templates, educational needs, and clarification of clinical guidance.

Regulatory oversight and post-approval monitoring remain important ongoing responsibilities throughout the life cycle of a vaccine. If safety or, less commonly, efficacy concerns emerge after licensure, manufacturers may agree to conduct Phase 4 studies.[31] Nearly all new vaccine approvals in the past 15 years have come with post-approval commitments or requirements.[31] Additionally, manufacturers may need to conduct additional studies for expanded indications, such as approval for new age groups or high-risk populations.[12] If serious problems arise after a vaccine has been licensed and included in the CDC guidelines, ACIP may revise its recommendation, recommend the use of a different vaccine, or discontinue the recommendation.[31] For example, in August 1998, RotaShield was licensed to protect infants against rotavirus.[88] By 1999, ACIP and the AAP recommended its use in healthy infants. However, post-licensure surveillance revealed 15 cases of intussusception reported to VAERS

between September 1998 and July 1999, with 80% occurring after the first dose and within a week of vaccination. Without a comprehensive study but citing safety concerns, ACIP withdrew its recommendation in November 1999, and Wyeth voluntarily withdrew the vaccine from the market.[88]

Documentation of Gaps and Promising Practices – Continuing Education and Monitoring Optimal Vaccine Uptake

Effective vaccine implementation requires collaboration among public health agencies, health care providers, and key partners. Intervals throughout the implementation process, including waiting for FDA licensure, ACIP recommendation, and the formation of school requirements (see flowchart), can be effectively used to educate health care providers and the public, address anticipated access issues, and demonstrate safety profiles.[162]

While this environmental scan focuses on the logistical and policy steps involved in vaccine implementation, it is important to acknowledge that broader social and behavioral factors are also critical to the success of vaccine implementation efforts. Elements such as developing evidence-based, audience-tailored messaging, garnering provider and public confidence, combating misinformation, and recruiting support from nontraditional partners should be considered early in the implementation planning process, with collaboration across the immunization community to ensure these efforts are aligned.[50,193,194] Without progress in these areas, even the most refined operational vaccine implementation plans will not lead to increased vaccination rates.[88] While this report does not delve deeply into these well-researched topics, a few examples are included from past immunization efforts to highlight previous pitfalls that could inform future rollouts.

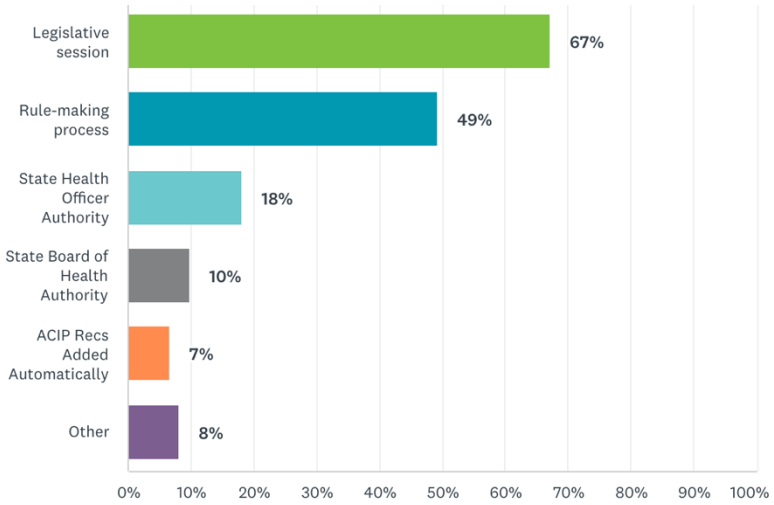
The CDC's Vaccinate with Confidence framework, developed during the COVID-19 response, offers insights that are also applicable to implementing new vaccines, particularly in diverse and historically marginalized communities. Programs that engage community leaders, faith-based organizations, and culturally aligned messengers are more effective in promoting vaccine uptake, highlighting the importance of local trust-building for any new vaccine. There is a need for multilingual and culturally sensitive messaging during the rollout of new vaccines. In the case of COVID-19 vaccines, materials were developed in over 40 languages and adapted to an array of communities. Effective outreach involves tailored messaging and integrated health communication. Phased, flexible strategies may be more effective than broad public messaging campaigns. The use of storytelling, arts-based outreach, and digital platforms, such as virtual town halls and social media, can expand the reach of vaccine education campaigns.[193]

Routine Steps Related to School and Childcare Vaccine Requirements

In the years following the initial rollout of a new routine childhood vaccine, state-level vaccine policy determines whether the vaccine is adopted under school requirements. In 1905, the U.S. Supreme Court found that a community's need to be protected from infectious diseases justifies reasonable state requirements to be vaccinated. Since then, various courts have affirmed the government's authority to establish policies that protect the health and well-being of children

and communities.[195] School and childcare vaccination laws protect the entire community, intended to protect children in high-risk settings and to promote herd immunity through increased community coverage.[195,196] These requirements can be effective in raising vaccination rates. For example, a 2022 study found that children and adolescents living in states with school or combined school and childcare entry requirements were 35-40% more likely to initiate or complete the hepatitis A vaccination series than were children in states without such requirements.[197]

Figure 11: AIM 2024 Annual Survey
What is the process for a vaccination to become required for school entry? (Check all that apply) (n=61)



Adoption of school-entry requirements is determined by administrative procedures, as well as political, cultural, and social factors that vary by state.[198] The process for a vaccination to become required for school entry depends on the jurisdiction (see Figure 11). AIM's 2024 Annual Survey (n=61 of 64 immunization programs) found that although most immunization programs require a law change through the legislative process (n=41), some programs report using more than one pathway. Rule-making processes in the executive branch (n=30) are also common. Some state requirements depend on a state health officer (n=11) or Board of Health authority (n=6). In the survey, fielded between November 2024 and March 2025, at least four programs reported that ACIP-recommended vaccines are added automatically based on existing rules or legislation.[139] How quickly states adopt the ACIP recommendations varies widely.[198] A recent legal epidemiological review of 51 jurisdictions found substantial delays between ACIP recommendations and state-level adoption of school-entry mandates for vaccines like MenACWY and tetanus, diptheria, and pertussis (Tdap), which could have impacts on herd immunity and disease prevention.[198] The average delay was 9.6 years for the first MenACWY dose, 8.2 years for the MenACWY booster, and 4.9 years for Tdap.[198] The review found that most jurisdictions used regulatory mechanisms to adopt these policies rather than legislative statutes, which allow for potentially quicker action. However, challenges with coordinating across agencies and anti-vaccine advocacy slowed the process, especially following the COVID-19 pandemic.[198]

Documentation of Gaps and Promising Practices - School and Childcare Vaccine Requirements

While ACIP issues guidance on how vaccines are to be used in clinical settings, state-level vaccine policy plays a critical role in translating national recommendations into actionable public health requirements, particularly through school and childcare entry requirements.[198]

However, according to AIM's position statement, vaccine requirements "must be used sparingly, approached cautiously, and considered only after an appropriate vaccine implementation period." This ensures the proper infrastructure is available to sustain a requirement, such as insurance coverage, adequate funding, stable supply, IIS integration, and support from providers and the public. Vaccine requirements should be approached with careful consideration of their epidemiological, economic, and ethical implications, as misapplication of such policies could jeopardize public support for immunization programs and reverse existing progress. Any efforts to establish school or childcare vaccine requirements should follow established jurisdiction processes, including consultation with the state health agency's immunization program and procedures for evaluating the addition of new vaccines to school requirements, which may include advisory committee review, public input, and thorough risk-benefit analysis.[199] Similarly, proposals to add or change exemption policies should be closely aligned with the jurisdiction's immunization goals. It is important to anticipate and adequately fund the operational components of new vaccine requirements, and whenever possible, incorporate alternative immunization strategies, such as mobile clinics and school-located vaccination events, to reduce pressure on health departments.[165]

The landscape of school vaccine requirements in the U.S. is changing, with a notable increase in legislation aimed at expanding exemptions and emphasizing individual choice. AIM's 2024/2025 Legislative Session Report found that 28% (153) of the vaccine-related bills introduced during that session had to do with vaccine requirements and exemptions (61 of which were specific to K-12 schools). Of the 153 bills related to requirements, only 11% (17) of bills sought to promote vaccination by either adding vaccine requirements or making it harder to obtain an exemption, while the majority aimed to broaden exemptions or limit mandates.[200]

Documentation of Gaps and Promising Practices – Other Policy

ACIP recommendations have far-reaching policy implications, with nearly 600 statutes and regulations referencing ACIP across 49 states, three territories, and DC. Many of these laws reference ACIP recommendations as a basis for developing or implementing vaccine policy. When new ACIP recommendations are implemented, the related state or territorial policy may automatically change as well, depending on how the law is structured. According to a 2025 assessment from the Association of State and Territorial Health Officials, references to ACIP recommendations may affect vaccine policy in areas such as school immunizations, immunization mandates for health care workers and patients, insurance coverage requirements, provider scope of practice, standing orders, protocols for vaccine administration, notifications for recommended or overdue immunizations, and vaccine purchasing determinations. For example, New Mexico law authorizes the state's vaccine purchasing fund to "be used for the purchase, storage, and

distribution of vaccines, as recommended by the Advisory Committee on Immunization Practices."[201] As ACIP recommendations change, immunization programs must be prepared to assess and respond to the broad legal and operational impacts that may affect the implementation of new or updated vaccine recommendations within their jurisdiction.

Considerations: Stage 7 Ongoing Responsibilities *Guiding questions to support discussion, planning, and coordination across immunization partners.*
How should future phases of this project engage payers and policy partners to clarify implementation processes and inform more coordinated decision-making? How can the immunization community better coordinate provider and public education strategies early in the implementation process to set public expectations of timing and availability, build confidence, address misinformation, and lay the groundwork for future policy efforts, such as school-entry requirements? What strategies or tools could help immunization programs anticipate and navigate jurisdiction-specific legal or policy changes triggered by ACIP recommendations?

Conclusions

These conclusions should be considered alongside the report's limitations, which reflect the project's broad scope, evolving landscape, and reliance on available data and expert input.

Key Findings: Overall Observations

This environmental scan identified persistent and recurring challenges that affect how quickly and equitably newly recommended vaccines are implemented. Many of the observations below reflect not just what appeared consistently in the literature and interviews, but what was notably absent or inconsistently documented across sources. To help translate these findings for future discussion and action, the considerations from earlier sections are restated here. These guiding questions are intended to support discussion, planning, and coordination across immunization partners as they consider opportunities to strengthen vaccine implementation.

1. Fragmented Documentation Limits Institutional Knowledge

Documentation of vaccine implementation processes is uneven across both time periods and topics. Some phases, such as safety monitoring and vaccine effectiveness, are well documented across all vaccines. However, operational and logistical implementation challenges (such as coding integration, EHR readiness, IIS configuration, and storage and handling requirements) are documented inconsistently. For example, AIM staff recalled that health care providers had to procure freezers during the rollout of the measles, mumps, rubella, and varicella (MMRV) in the mid-2000s, yet there is little public documentation on how immunization programs navigated those challenges or supported providers.

Some implementation periods are far better documented than others. In particular, the early 2000s, the COVID-19 pandemic, and the recent rollout of nirsevimab stand out for the volume and detail of available documentation. The early 2000s were marked by a range of implementation challenges (including manufacturer closures, product shortages, and the removal of thimerosal from most vaccines) and these events generated unusually rich records of operational barriers and policy adjustments.

Because documentation gaps are especially pronounced in the period between licensure and early rollout, this scan relied heavily on recent examples like nirsevimab that remain in the active memory of public health professionals. As of December 2025, 42% of jurisdictions had experienced program manager turnover in the past two years, meaning many current program managers may be implementing a newly recommended product for the first time with no, or limited, access to institutional knowledge of past rollout efforts. The absence of accessible, practical implementation guidance from past rollouts can leave programs without a clear roadmap during critical early steps.

Considerations: Fragmented Documentation Limits Institutional Knowledge *Guiding questions to support discussion, planning, and coordination across immunization partners.*
How can lessons from recent and future rollouts be better captured and preserved to inform future implementation planning? *Education for the public, providers, and partners* • What sections should be included in a playbook for immunization programs to support program managers with varying experience levels in preparing for newly recommended vaccines?

2. Siloed Communication Contributes to Unclear Roles and Timing

Many immunization partners and subject matter experts expressed uncertainty about the roles and responsibilities of different organizations involved in vaccine implementation, particularly regarding the timing of key actions and decisions. For example, while many participants were aware of restrictions on communication between manufacturers and the ACIP, several were unclear about what, when, and with whom CDC is permitted to communicate. According to former CDC staff interviewed for this scan, many of the perceived restrictions are actually driven by company-specific policies, rather than federal regulation. Similar uncertainty emerged around other critical steps, such as timelines for payer engagement and which agencies and organizations lead those efforts. These knowledge gaps reflect the challenges of navigating a system where information is not always shared broadly or consistently.

Communication throughout the vaccine implementation process appeared siloed and with limited established pathways for sharing information across partners. In some cases, proactive planning mechanisms may exist, but they are not always widely visible or clearly communicated to those who could benefit from them. During this scan, questions frequently emerged—such as when implementation planning typically begins, who is involved, and how information flows between agencies and organizations. These were not questions the literature could reliably answer, and they often remained unclear even in expert discussions. For example, basic details like, “Who engages payers?” lacked consistently documented explanations, pointing to a broader absence of shared reference points across the immunization community.

The scan identified few routine, transparent structures for cross-partner communication. One partial exception is the PIE process, through which manufacturers voluntarily share select information with payers and other healthcare decision-makers in advance of FDA approval. However, this information is not routinely shared with other partners involved in downstream implementation, limiting its utility for broader planning efforts.

Together, these gaps in communication and role clarity appear to contribute to missed opportunities to prepare immunization systems, healthcare providers, and partners early in the rollout process. Many of these barriers stem from the historically fragmented nature of the U.S.

healthcare and public health systems, yet there remain opportunities for partners to strengthen communication and coordination within this structure.

Considerations: Siloed Communication Contributes to Unclear Roles and Timing *Guiding questions to support discussion, planning, and coordination across immunization partners.*
What mechanisms could help clarify and communicate the roles and responsibilities of key partners across the vaccine development and implementation timeline—particularly in the absence of formal cross-partner structures? Is there potential to build upon existing mechanisms, such as Pre-approval Information Exchange (PIEs)?

3. Limited Time for Programmatic, Policy, and Technological Readiness

Logistical barriers

With the rollout of new vaccines, demand may begin immediately after CDC adoption, but immunization programs and partners often have limited time to prepare for logistical barriers, particularly for publicly funded vaccines. These barriers can include enrolling new VFC program providers, managing unique storage and handling requirements, and addressing mismatches between vaccine supply and demand. Current processes for responding to these challenges often leave immunization programs with limited time and flexibility. For example, during the rollout of nirsevimab, immunization programs had not received guidance regarding cost, distribution, packaging, or storage at the time of ACIP recommendation. The guidance needed to enroll specialty providers (e.g., birthing hospitals) in the VFC program was not shared until the day VFC program ordering opened, just two days before RSV season began. Recent implementation experiences underscore how compressed timelines can hinder provider enrollment and slow early access in key settings.

Policy readiness

Variation in policy environments and unresolved legal and regulatory questions can limit readiness and create uncertainty in how new vaccine recommendations are implemented across jurisdictions. Existing federal and state policies influence implementation timelines, coverage pathways, operational requirements, and provider participation, yet these policy considerations are not always fully clear at the time of recommendation. This scan identified outstanding questions related to the legal and regulatory underpinnings of vaccine implementation, including how federal and state statutes shape timing and adoption, though these issues were not fully explored because of limited engagement with legal and policy experts during the scan. There is also substantial variation across jurisdictions in how ACIP recommendations are adopted and operationalized. In addition, the broader legal landscape, including increasing immunization-focused state legislation, creates evolving challenges that immunization programs must navigate when assessing how new recommendations will affect coverage, requirements, and workload.

IIS/EHR Updates

Time, and often financial resources, are needed to incorporate new products into existing IT structures, such as forecasting tools, vaccine ordering and documentation systems (IIS), EHRs, payer systems, and public dashboards. Many of these systems depend on finalized code sets (CVX, MVX, NDC, and CPT codes), some of which are not always published in key source databases until after licensure, limiting the ability of health IT vendors and public health programs to begin configuration and testing in advance.

Innovation

New immunization products that involve novel platforms, delivery mechanisms, or patient populations often require even more preparation time for successful rollout. These innovations can introduce unexpected challenges across systems and workflows, many of which are historically not accounted for in planned implementation timelines.

For example, the rollout of RSV immunization products surfaced several issues that extended beyond typical readiness gaps. IIS platforms encountered deduplication problems when handling weight-based dosing of nirsevimab, and many EHRs initially classified the mAb as a drug rather than a vaccine. This required additional testing to ensure that IIS could accept incoming records from EHRs. Maternal RSV vaccination introduced further complexity, as most systems lacked the ability to link maternal and infant records, limiting the functionality of CDS systems in determining eligibility.

In addition, novel products may require adjustments be made to adverse event reporting systems. For instance, nirsevimab must be reported to MedWatch when administered alone, rather than through VAERS, introducing an additional layer of coordination for providers and public health staff. These kinds of system-wide changes fall outside of standard workflows and often require custom solutions or extra staffing, underscoring the need for extended lead time when introducing new immunization technologies.

Considerations: Limited Time for Programmatic, Policy and Technological Readiness *Guiding questions to support discussion, planning, and coordination across immunization partners.*

FDA Review
• How can we ensure that immunization programs have the information and resources they need (such as anticipated dosing schedules, packaging, storage, coding, forecasting) early enough to begin preparing systems, infrastructure, and outreach strategies in advance of a recommendation?
  ○ How can we ensure implementers have the necessary support to foster these systems changes?
  ○ Are there specific implementation planning activities that immunization programs could realistically begin during the period between BLA submission and the PDUFA date? What support would be needed to help all programs initiate these steps consistently?

Coding

- Are there opportunities to improve alignment of vaccine coding timelines and strengthen communication across manufacturers, EHR vendors, and public health systems to ensure codes are available and usable in advance of administration?

- Given the technical nature of the topic, is there a need for a group to advise on coding and billing issues and help address critical payment challenges for the implementation playbook?

CDC Adoption

- What strategies could help ensure that infrastructure (e.g., IIS and EHR systems) is ready in time to support implementation once CDC adopts a new routine vaccine?

- What mechanisms could ensure integration of new vaccine recommendations across delivery settings, including non-clinical settings such as pharmacies and settings that have not traditionally participated in the VFC program (e.g., birthing hospitals)?

Ongoing Responsibilities

- What strategies or tools could help immunization programs anticipate and navigate jurisdiction-specific legal or policy changes triggered by ACIP recommendations?

4. Limited Time for Provider and Public Education

Immunization programs require time to prepare providers and educate the public before a new vaccine becomes available, especially when system changes are required. For example, enrolling birthing hospitals into the VFC program or preparing IIS and the public for changes to a delivery platform (e.g., self-administered nasal spray vaccine). Even in routine cases, health care systems need time to train staff on product-specific storage and handling, update protocols, and prepare answers to patient questions. Without sufficient lead time, internal processes (such as developing standing orders, integrating vaccine information into admissions documentation, and readying patient education materials) may be delayed or skipped entirely. These delays can affect both internal provider readiness and patient confidence. Providers also balance multiple competing priorities, and vaccines are only one part of their broader workload, which can further constrain the time available for new vaccine preparation.

Creating effective public messaging and building public trust in new vaccines takes time. Trusted messengers need to be identified and trained. Materials should be culturally relevant, translated, and adapted to the local context. With limited time to test messages in advance or tailor them to specific populations, there is more room for misinformation to begin circulating. In compressed implementation timelines, English-speaking audiences often receive information first, while materials for other language groups arrive later, contributing to disparities in early access to reliable public health information.

Public expectations about when a new vaccine will be available often diverge from operational realities. There is typically a gap between an ACIP vote and the point at which people can receive the product. With COVID-19 vaccines, that gap was unusually short, creating ongoing unrealistic expectations of subsequent vaccine rollouts. Headlines about ACIP votes may be interpreted as signaling immediate availability, which can generate demand before systems, insurance coverage, and supply are ready. Managing these expectations while other implementation tasks are underway can add pressure for programs and providers.

The literature offered limited insight into when broad public education efforts typically begin or how they are coordinated, making it difficult to assess how consistently these strategies are implemented, with many available examples being jurisdiction specific.

Considerations: Limited Time for Provider and Public Education

Guiding questions to support discussion, planning, and coordination across immunization partners.

ACIP Review and Recommendation

- What systems or partnerships could be strengthened to promote consistent messaging when vaccine schedules or guidance differ across jurisdictions?

Access

- How could we help mitigate geographic challenges in rural and territorial communities prior to rollout?
- Given funding constraints, how could we support immunization programs in planning early with trusted community messengers for smoother rollouts in priority populations?
- What can partners do to better coordinate existing efforts around messaging, partner alignment, public and provider education?

Ongoing Safety Monitoring and Liability

- How can public health partners work to communicate safety monitoring plans in advance of rollout in ways that help immunization programs build public trust and support vaccine uptake?
- What resources or coordination mechanisms could help ensure health care systems and providers are prepared for any changes to traditional adverse event reporting pathways, particularly with the rollout of new immunization products that use novel technology?

Ongoing Responsibilities

- How can the immunization community better coordinate provider and public education strategies early in the implementation process to set public expectations of timing and availability, build confidence, address misinformation, and lay the groundwork for future policy efforts (such as school-entry requirements) when appropriate?

5. Barriers Related to Upfront Cost and Payment

Cost

The upfront cost to providers to stock new vaccines is a well-documented barrier, particularly for small practices. These financial hurdles can prevent providers from stocking a vaccine at all, delay access, or contribute to inequities in availability. For example, with the introduction of PCV7 in 2000, the cost of stocking private-pay doses led to the development of two-tiered systems in many states where only VFC program-eligible children could receive the vaccine. Similar patterns have emerged in the rollout of nirsevimab, where some smaller outpatient provider offices did not stock the product due to concerns of the upfront cost.

Payment delays and complexities

Payment-related barriers emerged as a major theme in both the literature and interviews conducted for this scan. In nearly every interview or discussion, payment was one of the most frequently cited challenges in the vaccine implementation process. It can take many months for public and commercial payers to integrate newly recommended vaccines into their payment systems, which may delay provider payment. Uncertainty about when or whether they will be paid may cause providers to delay offering a new product broadly, affecting both commercially and publicly insured patients. Recent examples, including the rollout of nirsevimab, highlight how payment gaps can delay vaccine delivery in non-traditional settings, such as birthing hospitals.

Several partners expressed uncertainty about what payers need to do in order to begin paying for a newly recommended vaccine. In some cases, partners reported having no well-established contacts with payer organizations or struggling to initiate those conversations.

Considerations: Barriers Related to Upfront Cost and Payment

Guiding questions to support discussion, planning, and coordination across immunization partners.

Ongoing Responsibilities

- How should future phases of this project engage payers and policy partners to clarify implementation processes and inform more coordinated decision-making?

Payment

- How might earlier or more consistent communication with payers improve provider confidence in payment timelines and reduce vaccine implementation delays?
- What supplemental funding mechanisms could help support provider practices with high upfront costs or limited resources?
- What allowable strategies could CDC and immunization programs adopt to reduce administrative burden and improve VFC program participation?

6. Phase 2/3 Decisions Have Downstream Implementation Implications

The period between Phase 2 and Phase 3 clinical trials may represent the first critical window where decisions are made affecting downstream implementation. Although timing and circumstances vary widely by product, our preliminary conversations with subject matter experts suggest that many pivotal decisions occur after the FDA begins reviewing Phase 2a data but before Phase 3 results are available. During this period, manufacturers may more accurately project pricing and make manufacturing decisions that directly affect implementation, such as packaging, storage, and handling requirements. ACIP workgroups may be formed and or begin reviewing Phase 2 data, and payers may initiate early cost analyses.[††] Manufacturers might also conduct market research, including consumer receptivity testing and input from advisory boards. These early activities have substantial downstream implications for implementation, including impacts on insurance coverage and payment structures, the timing and nature of questions raised by ACIP workgroups, and insights into public perception that can inform future provider and public education efforts.

Considerations: Phase 2/3 Decisions Have Downstream Implementation Implications *Guiding questions to support discussion, planning, and coordination across immunization partners.*
How might improved communication across manufacturers, federal partners, payers, and public health agencies during clinical development ultimately help immunization programs plan more effectively during later implementation phases? a) Is there potential to build upon existing communication mechanisms, such as implementers' feedback during manufacturer advisory board meetings and dissemination of PIEs? b) Are there opportunities to better align the timing of select planning activities with the clinical and regulatory milestones that typically occur between Phase 2 and Phase 3 trials?

7. Other

Considerations which do not fit into the above observations.

[††] We are still pending confirmation from payers.

Considerations: Other *Guiding questions to support discussion, planning, and coordination across immunization partners.*
Research and Development • Given there is no active mechanism for setting national vaccine development priorities, how can immunization partners best share their expertise around which vaccines and/or formulary changes should be prioritized as potential new immunization products? • How can earlier alignment between public health needs and vaccine development decisions improve preparedness, coordination, and effective use of limited immunization program resources? *Supply* • What steps could be taken by partners in the immunization community to better anticipate and plan for demand-supply mismatches?

Appendix A

Executive Summary
Vaccine Implementation Project – Manufacturer Interviews (September 2025)

Purpose
The Vaccine Implementation Project seeks to improve readiness and implementation of new immunization products. To inform this work, six vaccine manufacturers were interviewed in August 2025 to better understand when, how, and with whom they share information during vaccine development and launch, particularly as it relates to immunization program planning and implementation readiness.

Methods

- Six of seven invited manufacturers participated in structured, confidential interviews in August 2025.
- Discussions focused on information sharing practices, timing, and engagement with key partners (including CDC, CMS/Medicare, payers, health care professional organizations, health care systems, and immunization programs) throughout the vaccine development and implementation process.
- Manufacturers described their partner engagement as of March 2025.

Key Takeaways

1. **Manufacturer engagement varies widely across partners.**
    - Manufacturers interact differently with key partners and communication is often influenced by organizational policies and priorities in addition to regulatory requirements.
    - Some communication occurs pre-licensure (e.g., pipeline or PIE presentations), while most intensifies after FDA approval and ACIP recommendations.
2. **Confidentiality agreements enable early discussions**
    - Confidentiality agreements are critical for facilitating early, strategic discussions, especially with organizations like CDC and medical societies.
3. **Early disease-specific education supports pre-launch coordination**
    - Manufacturers consistently use early disease education and ongoing scientific engagement as a mechanism to build awareness and lay groundwork for later rollout; however, product-specific details are often delayed due to regulatory restrictions.
4. **Advisory boards used inconsistently for implementation planning**
    - All interviewed manufacturers use advisory boards, but timing, purpose, and participants vary widely (from clinical trial design to marketing).
    - Not all manufacturers consistently convene advisory boards to specifically focus on implementation planning; and advisory boards may be an underutilized tool for this purpose.
5. **PIE practices vary; regulatory clarity could expand early engagement**
    - Pre-Approval Information Exchange (PIE) presentations are widely used (5 of 6 manufacturers), but practices differ by company.

- Legal team preferences and staffing constraints can limit the breadth of PIE activities.
- Most manufacturers engage in PIE presentations with partners between BLA submission and FDA licensure, but timing and recipients vary, with payers being the most common recipients.
- Broader clarity on PIE regulations could strengthen pre-launch coordination. Clarifying what is permissible could enable more structured engagement, such as presentations to clinicians at AIM or groups of immunization programs as healthcare decision makers, helping implementers prepare more effectively.

6. **Conferences are key data sources and potential implementation planning opportunities**
    - Presentations at conferences like ID Week are often the first-time product-specific information becomes publicly available.
    - Future implementation efforts should consider how to better use these venues to prepare the immunization community ahead of product launch.

Limitations

Insights reflect only six manufacturers and there was variability in interviewees roles and perspectives.

- Interviewees described engagement as of March 2025, and these practices may evolve quickly given the changing public health environment.
- Interviews underscore that engagement often varies not just by company, but also by vaccine and situation.
- Qualitative data is subject to interpretation and recall bias, and perspectives may not fully represent each company's internal processes.

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Glossary

AAFP: American Academy of Family Physicians

AAP: American Academy of Pediatrics

ACIP: The Advisory Committee on Immunization Practices

AIM: Association of Immunization Managers

AMA: American Medical Association

BEST: Biologics Effectiveness and Safety System

BLA: Biologics License Application

CBER: Center for Biologics Evaluation and Research

CDC: Centers for Disease Control and Prevention

CDS: Clinical Decision Support

CDSi: Clinical Decision Support for Immunization

CHD: Congenital Heart Disease

CHIP: Children's Health Insurance Program

CISA: Clinical Immunization Safety Assessment Project

CLD: Chronic Lung Disease

CMS: Centers for Medicare and Medicaid Services

CMV: Cytomegalovirus

CPT: Current Procedural Terminology

CVX: Vaccine Administered Code

DMSS: Defense Medical Surveillance System

EHR: Electronic Health Records

EtR: Evidence to Recommendations

FDA: Food and Drug Administration

GA: Gestational Age

G-Codes: Healthcare Common Procedure Coding System Level II G-Codes

GRADE: Grading of Recommendations, Assessment, Development and Evaluation

HBV: Hepatitis B Virus

HCPCS: Healthcare Common Procedure Coding System

HEDIS: Healthcare Effectiveness Data and Information Set

HHS: U.S. Department of Health and Human Services

HIE: Health Information Exchange

HIV: Human Immunodeficiency Viruses

HPV: Human Papillomavirus

ICD-10-CM: International Classification of Diseases, 10th edition, clinical modification

IIS: Immunization Information Systems

IOM: Institute of Medicine

I-STAR: Indian Health Service Safety Tracking and Response

IT: Information Technology

MenACWY: Meningitis ACWY

MenB: Meningitis B

MMR: Measles, Mumps, and Rubella

MMRV: Measles, Mumps, Rubella, and Varicella

MMWR: Morbidity and Mortality Weekly Report

MVX: Manufacturer Vaccine Code

NDC: National Drug Code

NIH: National Institutes of Health

NVAC: National Vaccine Advisory Committee

P4P: Pay-for-performance

PCV7: Heptavalent Pneumococcal Conjugate Vaccine

PDUFA: Prescription Drug User Fee Act

PICO: Population, Intervention, Comparator, and Outcomes

PIE: Pre-Approval Information Exchange

PK: Pharmacokinetics

PRISM: Post-Licensure Rapid Immunization Safety Monitoring Program

RSV: Respiratory Syncytial Virus

RUC: Based Relative Value Scale Update Committee

SCDM: Shared Clinical Decision-Making

SMART Vaccines: Strategic Multi-Attribute Ranking Tool for Vaccines

SME: Subject Matter Expert

SNS: Strategic National Stockpile

Td: Tetanus and diphtheria

Tdap: Tetanus, diphtheria, and pertussis

TFAS: Territories and Freely Associated States

U.S.: United States

VAERS: Vaccine Adverse Event Reporting System

VFC: Vaccines for Children

VICP: National Vaccine Injury Compensation Program

VSD: Vaccine Safety Datalink

VTrckS: Vaccine Tracking System

WG: Work Group