Environmental Scan: Considerations for Vaccine Implementation

Executive Summary

The 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While the scan is a historical document which reflects conditions as of March 2025, it acknowledges the rapidly evolving immunization landscape and the need to adapt implementation strategies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.

View the full environmental scan.