AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

Recording Dose Level Eligibility
in Immunization Information Systems (IIS)

Perceptions about Benefits, Barriers and Mitigating Strategies

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AIRA AMERICAN IMMUNIZATION REGISTRY ASSOCIATION
Immunization Information Systems for a New Era

www.immregistries.org

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Executive Summary

As funding for federal programs is reduced, there is increased pressure to demonstrate that funds are being maximized and utilized for their intended purpose. The Vaccines for Children (VFC) program is designed to ensure that children whose parents or guardians could not otherwise afford to pay for immunizations can receive routine vaccinations. The VFC program has been tasked with providing justification that publicly funded vaccine is being administered only to those children that meet the required eligibility criteria.

To improve accountability for the use of VFC program funds, the Centers for Disease Control and Prevention (CDC) has begun putting increased emphasis on the use of state immunization information systems (IIS) technology to address this need. IIS are well positioned to support the goals of the VFC program by leveraging technical capabilities to record and report on vaccine doses administered from public vaccine stock and validating that public stock was administered only to VFC eligible children. Based on best practice recommendations from the Modeling of Immunization Registry Operations Workgroup (MIROW), configuring an IIS to capture dose level eligibility is one way to support VFC program objectives for improving vaccine accountability. CDC is requesting that Cooperative Agreement awardees be able to capture dose level eligibility in IIS by 2017.

As federal legislators, CDC and other federal level organizations begin making policies around dose level accountability, it is useful to consider what state immunization programs and other stakeholders like IIS and electronic health record (EHR) vendors, and national organizations like the American Immunization Registry Association (AIRA), the Association of Immunization Managers (AIM), and the Public Health Informatics Institute (PHII) perceive to be the benefits of dose level eligibility, challenges or barriers to implementation, and possible ways to overcome those barriers.

AIRA was recently awarded funds by CDC's National Centers for Immunization and Respiratory Disease (NCIRD) to coordinate a facilitated session to capture these perceptions. AIRA is a non-profit professional association that represents individuals and organizations that share and support its mission of preventing and controlling vaccine preventable disease by enhancing the capacity of IIS.

In September 2012 in St. Paul, Minnesota, immediately following the AIRA 2012 IIS Meeting, an information gathering session was conducted by a professional facilitation group. The all-day session, which was attended by invitation only, included subject matter experts (SMEs) from the IIS community representing IIS with varying levels of maturity, vaccine purchase/distribution models, IIS products, and geographic regions. The 32 selected participants included representatives with IIS, VFC, and/or Program Management expertise from grantee immunization programs of 17 states. Participants also included IIS vendors and consultants, CDC/NCIRD representatives, and staff from PHII.

During the facilitated session, participants listed 32 potential benefits of capturing dose level eligibility. Benefits were categorized as improving accountability, inventory management, and data collection, as well as supporting funding justification and standardization of systems and policies. Participants also identified a total of 68 perceived barriers to implementing dose level eligibility. For the most part, these barriers were related to technical, resource, policy or work flow issues that impacted state immunization programs, VFC providers and the IIS and/or EHR product vendors.

When asked to rank the barriers according to criticality and level of difficulty to address, the group identified 17, or 25 percent of the total list of barriers, as being both highly critical and extremely difficult to overcome. These 17 barriers were considered to be "top barriers". The group then came up with suggested strategies to overcome these issues.

In addition, there were a number of critical issues that could not be addressed during the facilitated discussion because the appropriate experts were not in attendance. Specifically participants questioned the rationale behind universally requiring implementation of dose level eligibility tracking across all grantee IIS projects when it is not a requirement of the VFC program. Other critical issues included the need for clarification on what system behavior will be considered compliant with the requirement and a need to clearly delineate the roles and responsibilities of the IIS and VFC program staff for making the system changes, implementation and enforcement of the new requirements. Impacts of the Affordable Care Act and Meaningful Use Stage 2 were also unknown and may affect how and when dose level eligibility tracking is implemented.

The results of this facilitated session contribute to a growing body of knowledge that can inform stakeholders of next steps toward successful implementation of dose level eligibility in IIS. ■

Table of Acronyms

The following table provides a guide to the acronyms used throughout this document.

AIM	Association of Immunization Managers
AIRA	American Immunization Registry Association
CDC	Centers for Disease Control and Prevention
CAT	Cost and Affordability Tool
EHR	Electronic Health Record
HL7	Health Level Seven International
IIS	Immunization Information Systems
IPOM	Immunization Program Operations Manual
MCIR	Michigan Care Improvement Registry
MIROW	Modeling of Immunization Registry Operations Work Group
NCIRD	National Centers for Immunization and Respiratory Disease
OIG	Office of Inspector General
PHII	Public Health Informatics Institute
SME	Subject Matter Expert
VFC	Vaccines for Children
VPET	Vaccine Purchase Estimator Tool
VTrckS	Vaccine Tracking System

Introduction and Background

The Vaccines for Children (VFC) program[1], a federally funded program, provides vaccine free of charge to children who might not be vaccinated otherwise due to an inability to pay. VFC eligibility is determined by immunization providers prior to the administration of vaccine. Eligible children must be 0–18 years of age and meet one or more of the following criteria: they must be Medicaid eligible, an American Indian/Alaskan Native, Uninsured and/or Underinsured (when vaccinated at a Federally Qualified Health Center). States may also offer grantee-specific vaccination programs to provide gap coverage for additionally identified populations. Individuals who are not eligible under the VFC Program or a state-funded program are considered to be ineligible and are covered through private insurance or out of pocket payment.

The VFC Operations Guide[2] states, "Vaccine accountability is a cornerstone of the VFC program and one of CDC's [Centers for Disease Control and Prevention] highest priorities." Vaccine accountability specifically refers to the ability of an immunization provider to account for how every dose of vaccine has been allocated. Vaccine accountability can also be more broadly defined as the ability to account for accurate documentation, proper funding allocation and the ability to respond to requests by the public for explanations and evidence of how public funds are spent. Better accounting for publicly funded vaccine has become increasingly important as budgets and available funding streams continue to diminish. For these reasons, immunization grantees have been asked to develop and maintain systems that ensure appropriate tracking and use of VFC vaccines at the dose level.

Capturing Dose Level Eligibility to Support Dose Level Accountability

The Modeling of Immunization Registry Operations Work Group (MIROW), a committee of AIRA, suggests that capturing VFC eligibility at the dose level in immunization information systems (IIS) is one way that states can address the need for improved dose level accountability. MIROW recommends this as a best practice in *Immunization Information System Collaboration with the Vaccines for Children Program and Immunization Grantee Programs*, Chapter 5[3] of its guidebook of recommendations for operational improvement in IIS. Dose level eligibility is defined as the ability to record VFC eligibility status at the vaccination level for each individual vaccine administered to a patient.

The capture of dose level eligibility provides increased granularity in data that supports the goal of improved vaccine accountability by ensuring that publicly funded vaccine is administered only to children that meet the eligibility criteria for each dose administered during a particular visit. The immunization provider assesses a child's eligibility and determines whether doses should be administered from publicly supplied or privately purchased vaccine inventory.

Complexities arise when a patient has varying eligibilities during a single visit. For example, a child may have private insurance that covers some of the routine childhood vaccinations but not all. In this case the child would be "ineligible" for those vaccines covered by insurance, and those doses would be administered from privately purchased vaccine stock. However, the child would be "underinsured" for the remaining vaccines, which would be given from publicly supplied VFC or state purchased inventories. By capturing eligibility at the dose level, the accountability for the use of vaccine most accurately reflects the vaccination encounter and the impact on available public and private vaccine inventory.

MIROW Best Practice Recommendations for IIS Operations

MIROW is an AIRA committee that was formed in 2005. The MIROW committee focuses on assembling groups of subject matter experts and practitioners from the immunization information system (IIS) community to identify areas for improving various aspects of IIS operations and collectively developing a set of best practice recommendations for these aspects. Each set of recommendations contributes a chapter to an operational improvement guidebook for IIS.

Chapter 5 of this guidebook, Immunization Information System Collaboration with the Vaccines for Children Program and Immunization Grantee Programs recommends the use of dose level eligibility to assure dose level accountability for the VFC program.

For more information about MIROW and its best practice recommendations, visit the MIROW section of the AIRA web site or the Centers for Disease Control and Prevention (CDC) web site.

Resources:
www.immregistries.org/resources/aira-mirow
www.cdc.gov/vaccines/programs/iis/activities/mirow.html

1. http://www.cdc.gov/vaccines/programs/vfc/index.html
2. http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/12-module-8.pdf
3. http://www.immregistries.org/AIRA-MIROW_IIS-VFC_Best_Practice_Guide_04-14-2011.pdf

Current Approaches to Dose Level Eligibility

State immunization programs currently have several options for meeting the need for VFC eligibility screening in an IIS. Some states screen and record eligibility at the patient level, while others may capture at the visit level, dose level, or some combination of the three. These levels can be illustrated as follows:

- **Patient level:** eligibility is stored at the patient level and is updated only when eligibility status for the patient changes. Users are not prompted to update the field at each visit[4].

- **Visit level:** eligibility is recorded according to the date of the vaccination encounter. Users are prompted to update the field every time a series of vaccinations is added or edited. The eligibility information is then stored with vaccinations administered on that date, or it updates the patient demographics depending on system vendor/configuration.

- **Dose level:** eligibility is recorded for every dose administered. Users are prompted to select the eligibility status on the vaccination detail screen, typically as a required field. The eligibility information is then stored with the record detail for each individual vaccine.

Immunization programs may also use patient and/or visit level to derive eligibility at the lower levels of visit and dose level, respectively. Approaches vary widely based on IIS system capabilities, historical practices, and the state vaccine purchase model used (VFC, VFC-select, universal purchase, etc.) or a combination of these three factors.

Because capturing dose level eligibility is seen as a good means of improving dose level accountability and in an attempt to standardize how this data is captured and reported, the CDC National Centers for Immunization and Respiratory Disease (NCIRD) has included a requirement in the 2013–2017 Cooperative Agreement[5] that state immunization programs must implement IIS infrastructure to support the VFC program goals and objectives, specifically to:

> *Incorporate dose level accountability into IIS functionality so that information can be received and stored. (Dose level accountability includes assigning a provider-determined program eligibility category for a patient to each administered dose of vaccine.)*

In order to better evaluate how this may be accomplished and what issues/barriers states may face in meeting this objective, the CDC/NCIRD worked with the American Immunization Registry Association (AIRA) and Association of Immunization Managers (AIM) to facilitate discussions with stakeholders and present findings. AIRA was tasked with conducting a facilitated, face-to-face meeting with state immunization program managers, state IIS and VFC staff, IIS vendors and other national experts. In parallel, AIM was tasked with conducting a telephone survey of state immunization programs to collect information on IIS and VFC eligibility, plus VFC accountability and general information on IIS capabilities related to vaccine ordering and shipping. The information collected by the AIRA and AIM initiatives would then be summarized and used to inform CDC and policy makers about what state immunization programs see as the benefits of using dose level eligibility tracking, but also the barriers to implementation and possible mitigations to those barriers.

This paper specifically focuses on summarizing the results of the AIRA session. The paper concludes by suggesting possible next steps that various stakeholders, including CDC, state immunization programs, national organizations like AIRA and AIM, and electronic health record (EHR) and IIS vendors can take to further the implementation of dose level eligibility tracking. ■

Practical Experiences of Implementing Dose Level Eligibility in Michigan

In 2010, Michigan's IIS, the Michigan Care Improvement Registry (MCIR), implemented dose level accountability. They did this for a variety of reasons, including changes in VFC program requirements and to improve vaccine management processes. MCIR also understood that patient eligibility did not equal dose level eligibility—especially in cases where some patients had dual eligibilities. They wanted a way to better capture what patients were receiving public doses. Perhaps most importantly, they realized that dose level eligibility would help them to determine if their vaccine programs were sustainable.

The primary benefit of using dose level accountability was that they could verify that their 317 immunization program was adequately funded to meet vaccine needs. This was especially important because funding for this program had been steadily declining each year, with a 53 percent reduction from 2010 to 2013. Yet each year, every dose of public vaccine stock was used.

Michigan first realized the benefit of tracking dose level eligibility in 2011, when the Michigan 317 program budget was $6.5 million. An initial cost analysis showed that they needed $8.5 million to meet their calculated projections. However, dose level eligibility allowed them to use the IIS to report on actual doses used in 2010. This showed that they only spent $6.2 million on vaccinating underinsured children, which meant they could avoid making program cuts. The following year, with further cuts to the 317 budget, the MCIR once again showed that no program cuts were required because the number of 317 doses used had dropped.

For the Michigan immunization program, the ability to accurately track doses with dollars spent from 317 and state funding helped them determine that the program was sustainable. As an added benefit, it also let them more tightly monitor providers for possible fraud and abuse. Michigan intends to continue using dose level eligibility given the better, more accurate reporting and transparency it enables for the use of all public vaccine stock, including VFC stock.

4. Note: A new revision of the VFC Operations Guide was released in November 2012. In this revision, patient level screening has been replaced with a visit level screening requirement. The Guide states, "Screening to determine a child's eligibility and documenting the current eligibility status to receive vaccines through the VFC Program must take place with each immunization visit". IIS may need to make system modifications to support this new VFC requirement. http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/06-module-2.pdf
5. http://www.grants.gov - Funding Opportunity Number: CDC-RFA-IP13-1301

A Facilitated Session to Determine Current Perceptions on Dose Level Eligibility

Following the conclusion of the AIRA IIS Meeting in St. Paul, Minnesota, in September 2012, a group of attendees remained to participate in an all-day facilitated session. To ensure broad representation in the session, select subject matter experts (SMEs) were invited to participate representing IIS with varying levels of maturity, vaccine purchase/distribution models, IIS products/vendors, and regional distribution. The 32 selected participants included representatives with IIS, VFC and/or Program Management expertise from grantee immunization programs of 17 states. Participants also included IIS vendors and consultants, CDC/NCIRD representatives, and staff from the Public Health Informatics Institute (PHII). A complete list of meeting participants and contact information can be found in Appendix A.

Session Goals

The session, facilitated by Advanced Strategies, Inc., was designed to determine current perceptions that state IIS had about capturing dose level eligibility. Specifically, the goals of the session were to:

- Identify possible benefits of capturing dose level eligibility in IIS
- Identify and rank barriers to capturing dose level eligibility in IIS
- Suggest candidate strategies to address the identified barriers

Although eligibility status can be captured at the patient, visit or vaccine dose level, participants were asked to focus their discussions around IIS capacity to capture and record eligibility at the dose level.

Preliminary Online Survey about State Immunization Program Perceptions

In preparation for the session, AIRA distributed a preliminary online survey to the selected SMEs. The survey was designed to get a general sense of perceptions about dose level eligibility as well as how many immunization programs had implemented or had plans to implement capturing of dose level eligibility in their IIS within the next three years. Sixteen SMEs responded to the survey on behalf of the state immunization program teams and/or IIS vendors. The session facilitators used the survey results to help frame the questions asked during the facilitated session.

Capturing the Potential Benefits of Dose Level Eligibility

During the session, facilitators asked participants to provide a list of potential benefits to capturing dose level eligibility. To do this, each participant wrote down what he or she viewed as a perceived benefit and reported this verbally. The facilitator then recorded the benefit in a document projected for all SMEs to view. The result was a single list of reported benefits.

Capturing Perceived Barriers to Implementing Dose Level Eligibility

Similarly, the facilitators gave each participant the opportunity to write down and report on what each individual viewed as perceived barriers to capturing dose level eligibility in IIS. This information was also projected and captured to produce a single, comprehensive list.

Ranking the Barriers

Next, participants were asked to rank each barrier by assigning two values: one reflected how serious they perceived the barrier to be, the other reflected how difficult they perceived the barrier would be to address or overcome. A barrier that was considered to be most serious was described as one that had to be addressed in order for dose level eligibility to be implemented. A barrier that was considered the hardest to overcome was one that required unavailable funding or resources, required political will, was highly complex, or was a combination of these issues. The resulting list with assigned values was then sorted to see the barriers that were both the most serious and hardest to overcome.

Capturing Candidate Solutions for Barriers

Finally, participants were divided into smaller groups to brainstorm possible solutions to overcome the noted barriers. These "candidate mitigations" were described as potential ways to address the identified barriers to implementation of dose level eligibility. The list of barriers was divided equally between the groups of participants, and participants brainstormed and recorded possible solutions to each issue. These possible mitigations were then collected and added to the larger document in association with the respective barriers.

Documenting the Session Results

The resulting document included all findings captured by the facilitators during the session, with a table that included the ranked barriers, the seriousness of the barrier and difficulty of overcoming the barrier, and possible mitigations for addressing the barrier.

Post-meeting Additions and Modifications to the Session Document

Advanced Strategies presented the findings of the session to AIRA in a summary document. A representative from AIRA then modified the benefits list and barrier table by associating categories to each item to help identify possible trends.

The benefits list was modified by associating each identified benefit with one of the following categories:

- **Accountability** – documents how each individual dose of vaccine was used and/or disposed of. This includes vaccine administered, wasted, spoiled, expired, transferred, borrowed or unaccounted for.
- **Data Collection** – improves current and future data collection capabilities, data quality, and/or system reporting capabilities.
- **Funding** – provides justification for budget appropriations and population needs assessment

- **Inventory Management** – improves functionality for tracking provider inventory levels and projecting vaccine needs
- **Standardization** – establishes a consistent protocol across all states for capturing and reporting data needed to support public vaccination programs

The barrier table was also modified by adding three additional columns: Category, Impacted Stakeholder and Mitigation Driver Stakeholder. The Category column associated one or more of the categories "Technical," "Policy," "Flow" or "Resource" with each barrier to help organize them into related groups. If a barrier did not logically fit in one of these categories, then a designation of not-applicable (N/A) was assigned.

Categories were defined in this way:

- **Policy** – The issue requires a new policy, policy clarification or project prioritization at either the federal or state level
- **Technical** – The barrier is related to limitations of the existing IIS and/or EHR systems
- **Resource** – The issue is affected by limited resources such as available staff, funding and/or time
- **Flow** – The barrier is related to a business process flow issue at either the state or provider level

The Impacted Stakeholder column represented the group that is most impacted by the barrier. The Mitigating Stakeholder column represented the group that would be able to take the necessary actions to resolve the issue. Groups in these columns included:

- **Provider** (private and public immunization providers)
- **State**
- **Federal**
- **Vendor** (may reference IIS vendor, EHR vendor or both)
- **National** (organizations like AIRA, AIM, HL7 [Health Level Seven International] standards group)

Results of the Facilitated Session

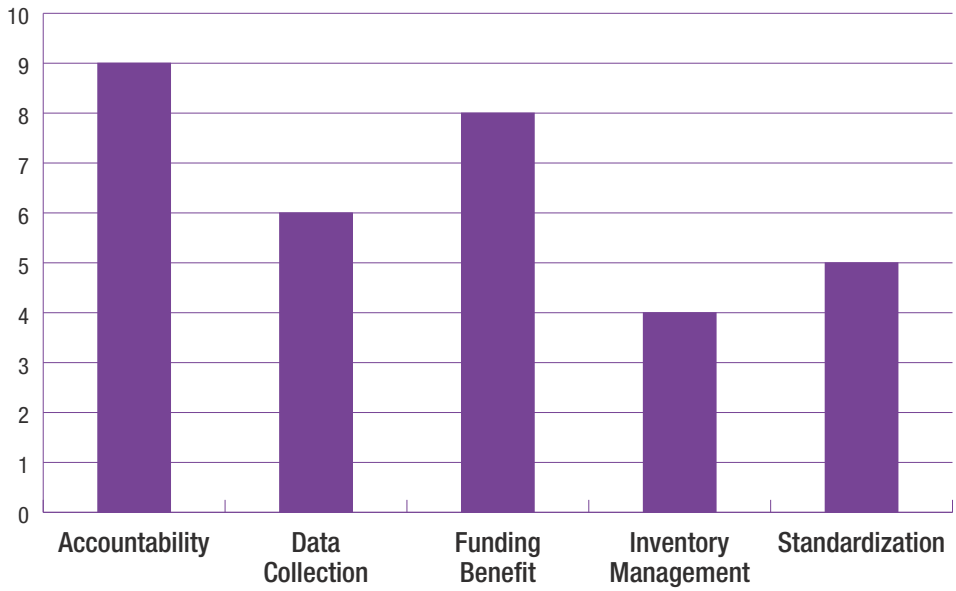
The session results provide insight into what IIS see as the most significant barriers—the "showstoppers"—for implementing dose level eligibility. This is balanced by the benefits that may be achieved through implementation; however, in order to achieve the identified benefits, a number of the critical barriers must be addressed in order to successfully move forward. Participants suggested a number of strategies to address identified barriers, and when viewed by impacted stakeholder and stakeholder that can drive the mitigation, a roadmap emerges to guide progress towards implementation of dose level eligibility.

Potential Benefits of Capturing Dose Level Eligibility

Together, participants identified 32 potential benefits of implementing dose level eligibility. These benefits included improved accountability, data collection and inventory management, along with better funding justification and standardized approaches among all IIS projects. The complete list of benefits can be found in Appendix B.

For the purposes of narration, the benefits have been loosely categorized. Figure 1 provides a visual display of how many benefits were identified in each category. Accountability (9) and Funding (8) presented the largest number of potential benefits. This was followed closely by benefits related to Data Collection (6), Standardization (5) and Inventory Management (4).

Figure 1. Top benefits of implementing dose level eligibility by benefit category.



Accountability Benefits

Accountability benefits were defined as those benefits that improve documentation for how each individual dose of vaccine was used and/or disposed of, including vaccine administered, wasted, spoiled, expired, transferred, borrowed or unaccounted for. Participants felt that dose level eligibility would improve provider awareness and may help to identify opportunities for additional education at the provider level. It may also provide valuable data to identify and address fraud, abuse and waste of publicly supplied vaccine. Generally, capture of dose level eligibility would support a greater level of accountability for patients that have eligibility in more than one category and increase awareness to ensure that publicly supplied vaccine is being administered only to children that meet the appropriate criteria. Participants also believed that it could provide better visibility and data related to a state's underinsured population.

Funding Benefits

Funding benefits were those items that help states provide justification for budget appropriations and population determinations. Participants suggested that capturing dose level eligibility provides valuable data to share with state legislatures when seeking annual appropriations, requests for gap funding or reprogramming of funds. Improved tracking and reporting will demonstrate good stewardship of public funds and may also save money at all stakeholder levels (federal, state and provider). Finally, capturing eligibility at the dose level may lead to a decreased need for or elimination of annual data requests such as the VFC population estimates, VFC practice profiles, Cost and Affordability Tool (CAT), Vaccine Purchase Estimator Tool (VPET), and spend plans.

Data Collection Benefits

Data collection benefits focused on improving current and future data collection capabilities, data quality, and/or system reporting capabilities. Working with EHR vendors early to define what data should be collected and transmitted would help ensure provider participation once dose level eligibility is fully implemented. As many provider offices move towards becoming paperless practices, the EHR becomes the central hub for all patient information and provider business processes. Proper data collection and transmission to the IIS ensures that providers are able to comply with vaccine accountability requirements. States initiating billing projects believed that better tracking of eligibility criteria would be particularly beneficial for ensuring that vaccine doses get billed out correctly and appropriately to Medicaid, Medicare and the various private insurance entities. Capturing data at a more detailed level also prepares IIS for future data requests that may not be anticipated today and provides opportunities for evaluating data quality at a deeper level.

Inventory Management Benefits

Inventory management benefits focus on improved functionality for tracking provider inventory levels and vaccine needs. Particularly, capturing dose level eligibility allows state immunization programs to better forecast provider vaccine inventory needs, evaluate provider order requests, and determine inventory replacement for states using the replenishment model. Additionally, provider inventory reporting should be easier and more accurate as suggested by participants.

Standardization Benefits

Standardization establishes a consistent protocol across all states for capturing and reporting data needed to support public vaccination programs. Some of the primary benefits included opportunities to openly discuss policy among stakeholders and development of best practice guidelines to ensure a consistent implementation by all states. It also establishes a uniform method to report and derive data for information sharing among all stakeholder levels – federal, state and provider. Finally, it provides national EHR vendors with a consistent standard for implementing the necessary changes within their systems to support the capture and transmission of required vaccine information.

Barriers to Implementation of Dose Level Eligibility

Collectively, session participants identified 68 barriers to implementing dose level eligibility. After sorting the barriers by their rankings, 17 of these barriers were believed by participants to be both most serious and most difficult to overcome. Table 2 has been adapted from the session documents and describes the predominant barriers, along with the designated Category, Impacted Stakeholder, Mitigating Stakeholder and Proposed Solutions. The complete table of barriers can be found in Appendix B.

Table 2. Top barriers to implementing dose level eligibility, stakeholders and candidate mitigations (sorted by barrier category).

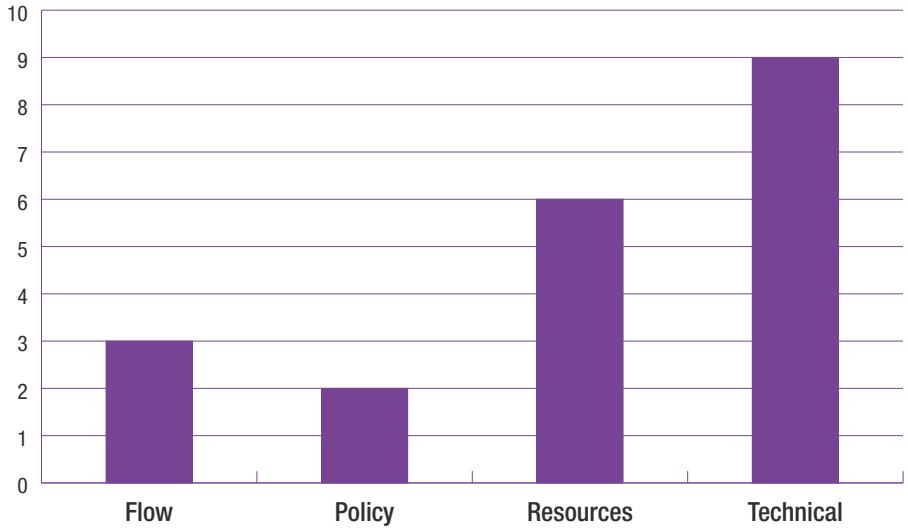
Category	Barrier Description	Impacted Stakeholder	Mitigating Stakeholder	Proposed Solutions
Policy	Inaccurate or incomplete data may lead to inappropriate changes to program funding or reduced eligibility.	Federal	State	• Reassurance from CDC that inaccurate data isn't used for policy decisions • Standardize data collection policy (methods, IIS, no IIS, paper, etc.) • Standardize application of policies • Clear policy and documentation on use of data by CDC
Policy	Questions about what CDC is going to do with this information and concern that states may be held accountable for the accuracy of data that may be of questionable quality	State	Federal	• CDC communicates their intent for how the data will be used • CDC conducts change management transition process
Resource	State immunization programs have too many simultaneous mandates from CDC and the State with limited staff and funding to complete all of this in the specified timeframe.	State	Federal, State	• Increased funding • Extend implementation timelines • Leverage national partner organizations • Implement pilot projects before nationwide mandate
Resource	There are too many unfunded mandates being put upon programs from both the federal and state levels that require time and resources to accomplish.	State, Providers	Federal, State	• Increased funding • More flexibility for how and when grantees meet the mandated requirements
Resource	Development and implementation of technical solutions (IIS and EHRs) can be expensive.	State	Federal, State	• Increased funding • Better prioritization of CDC program requirements that require system enhancements
Resource	Competing priorities and siloed program mandates. Someone at the Federal level should think about the priorities, especially in light of the Office of Inspector General (OIG)[6,7] priorities.	State	Federal	• Consensus of priorities and requirements by CDC leadership across all branches • Standardize requirements for easier implementation • Address disproportionate ratio of funding to required/expected work load
Resource	Extensive training that is required of the providers, the IIS, and state and local VFC trainer staff—especially for inventory reconciliation.	State	State	Cooperative agreement with PHII or AIRA for training materials that can be adapted by each state.
Resource, Flow	Data quality concerns and where the burden for data quality assurance will fall.	State	State	Include as part of routine business process review and start planning for it now.
Technical	The lack of interoperability between provider systems. Either we are going to need incredibly intelligent provider staff or we are going to have to ensure that CDC's Vaccine Tracking System (VTrckS), EHR and Billing systems work together for a complete Inventory Data System.	Provider or Vendor	State	• Develop comprehensive training programs • Apply thoughtful system design that supports the business process • Design enhancements in a way that is intuitive and friendly to the end user • Leverage common knowledge and best practices from the IIS community
Technical	Not all IIS have inventory reporting capabilities to support reconciliation at the dose level.	State	State	• Increased funding • Standardized requirements
Technical	Some EHRs don't track eligibility at any level, let alone at the dose level.	Vendor	National	• Develop best practices and guidelines at the National level • Provide consistent communication to EHRs from the National level
Technical	Not all EHRs have the ability to send the required data and may not be using the most current version of HL7. Systems must be able to send both the eligibility and the funding source.	Vendor	Vendor	• Leverage national best practices and develop standardized requirements for implementation • After EHRs enhance systems, verify proper data transmission through testing
Technical	EHR vendors are not getting consistent guidance from the IIS and VFC community as a group about what they should be tracking. They need specific recommendations/best practices.	Vendor	National	Develop best practices and guidelines at the National level
Technical	Electronic Data Exchange is causing problems (not collecting in a standardized fashion, transmitting incorrectly, poor data quality, etc.).	Vendor	State	Develop best practices and guidelines at the National level
Technical	The variety of ways that eligibility is documented and transmitted by the EHR systems. Not documenting in a place that we pull from or not documenting accurately.	Vendor	National, State	• Leverage national best practices and develop standardized requirements • Providers should use state specific codes • Work on national code set.
Technical, Flow	As states implement dose level eligibility, it is unknown what may be encountered in systems and processes.	State	State	Establish pilot efforts to identify best practices and share troubleshooting with other states
Technical, Flow	Limitations of systems (EHR and IIS) and business processes (end users).	Vendor, Provider	State	Leverage national best practices and develop standardized requirements.

6. https://oig.hhs.gov/oei/reports/oei-04-10-00430.pdf
7. http://www.cdc.gov/vaccines/programs/vfc/index.html

Top Barrier Categories

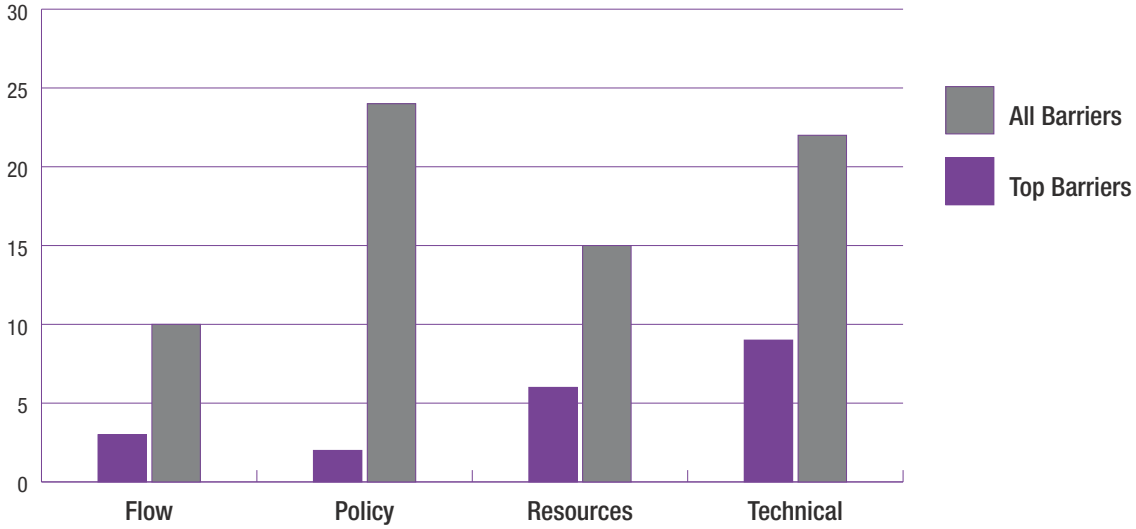
As displayed in Figure 2, participants indicated that Technical barriers made up the largest number of critical barriers (9). This was followed by barriers related to Resources (6), Flow (3) and Policy (2).

Figure 2. Top barriers to implementing dose level eligibility by barrier category.



When compared to the list of all identified barriers (Figure 3), those associated with Policy (24) presented the greatest number of barriers, followed by Technical (22), Resource (15) and Flow (10). This analysis suggests that Technical and Resource barriers may be the most difficult to overcome, but policy issues are plentiful and will need to be addressed in order to successfully implement dose level eligibility.

Figure 3. Top barriers by category compared to all barriers by category.



Top Technical Barriers

Technical barriers were related to limitations of the existing IIS and/or EHR systems. These barriers ranged widely but generally revolved around inadequate system capabilities to capture and/or exchange data elements. Participants believed that a lack of interoperability between IIS and CDC's Vaccine Tracking System (VTrckS[8]), provider EHRs, and billing systems, would either require provider staff to be very technically savvy or require IIS to carry the burden for initiating and/or maintaining this interoperability.

In addition, EHRs receive inconsistent guidance about what they should be tracking and reporting when it comes to eligibility and accountability because universal guidelines and specifications have not yet been created. Without clear, consistent guidance that includes recommendations and best practices, they may be hesitant to make changes.

8. http://www.cdc.gov/vaccines/programs/vtrcks/about.html

Participants also expressed concern that a lack of key capabilities in EHRs and IIS would make it difficult to effectively implement dose level eligibility tracking. For example, some IIS lack critical reporting or vaccine reconciliation capabilities, and some EHRs aren't capturing VFC eligibility at any level. Plus, participants expressed a feeling of uncertainty and discomfort about what might happen when they do implement dose level eligibility; they don't know what system or process difficulties they may encounter as they implement.

Data exchange was another top barrier. EHRs may not be using the most current version of HL7, which causes issues with the ability of the EHR to send messages containing both the eligibility status and funding source to the IIS.

Top Resource Barriers

Barriers related to limited resources—whether the staffing, funding or time required to properly and successfully implement dose level eligibility—accounted for a third of the top barriers that participants identified. For the most part, these barriers concerned a lack of funding for mandates, too many simultaneous mandates from CDC and states, competing priorities for funding and staff resources, and significantly numerous and complex requirements for gaining funding to develop and implement this IIS capability.

Other issues around resources included the extensive training that would be required of providers, IIS, and state and local VFC staff, especially around inventory reconciliation. In addition, data quality could present an additional demand on resources. It also creates the question of who will be responsible for the process of ensuring data quality and how that will fit into the business flow.

Top Policy and Flow Barriers

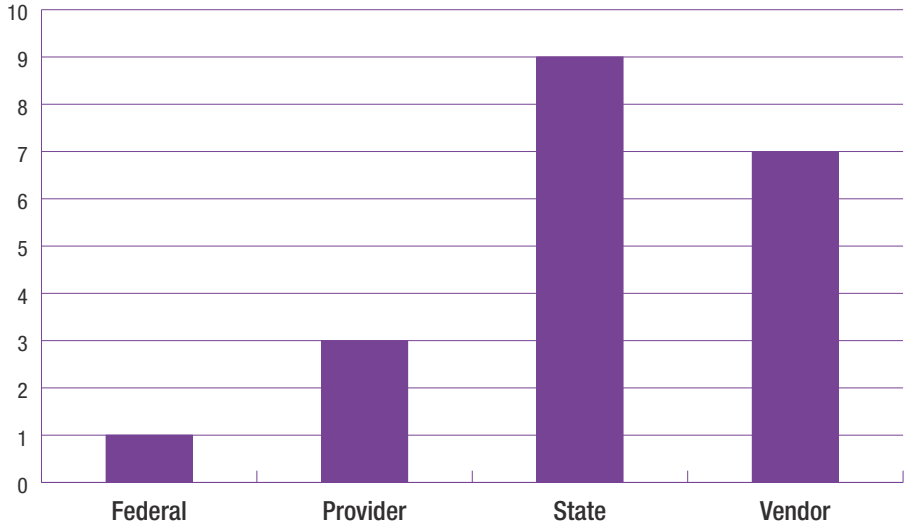
Combined, the Policy and Flow categories accounted for just under a third of the perceived top barriers. Work flow barriers related to a business process flow issue at either the state or provider level and were intertwined with a resource or a technical barrier. Barriers that related to both business flow and technical issues revolved around uncertainties about the types of business process issues and system issues that might arise as an IIS develops and implements dose level eligibility tracking and how that may factor into end user clinic flows. An additional barrier relating to both business flow and resources was targeted at who would be responsible for data quality assurance and how that would factor into the data monitoring process.

Policy barriers were issues that require a new policy, policy clarification or project prioritization at either the federal or state level. A primary policy barrier stemmed from questions about CDC's rationale for universally requiring collection of eligibility at the dose level in an IIS when it is not a requirement of the VFC program. Participants also expressed concerns about how CDC will use dose level eligibility data to make decisions regarding program funding and allocation. In particular, programs expressed concern that decisions about programs might be made based on inaccurate or low quality data over which IIS have little or no control.

Top Barriers by Impacted Stakeholder

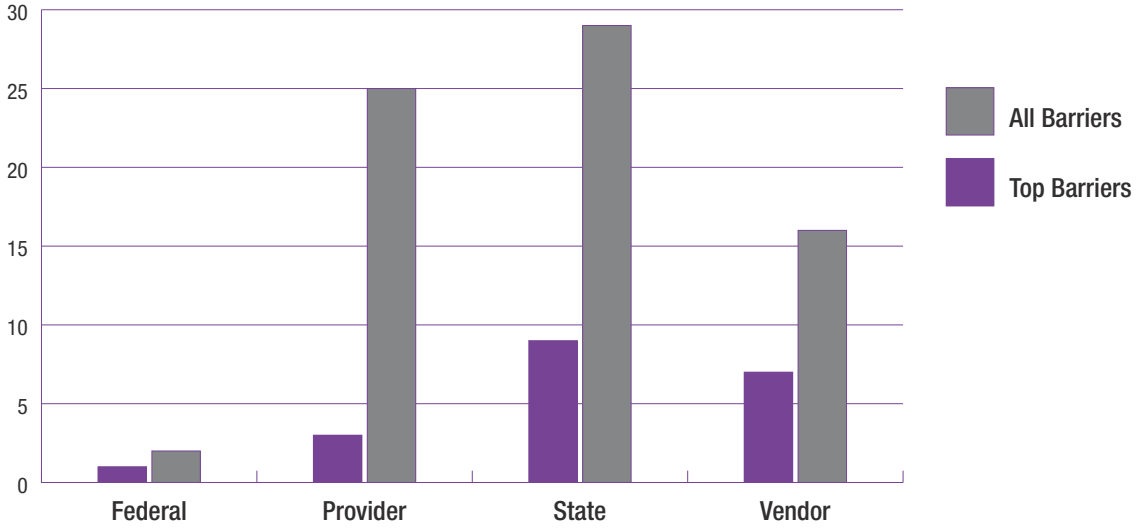
A secondary sort of the top barriers by impacted stakeholder was conducted to analyze which stakeholders are most affected by the new requirement to capture dose level eligibility. Figure 4 reveals that the stakeholders most impacted by the top barriers were the State Immunization Programs (9) and the IIS and EHR Vendors (7), who collectively represent those stakeholders with the greatest responsibility for developing and implementing the new functionality. Providers (3) and Federal stakeholders (1) were impacted by far fewer barriers.

Figure 4. Top barriers to implementing dose level eligibility by stakeholder impacted.



When compared to the list of all identified barriers (Figure 5), State Immunization Programs (29) were still the most impacted stakeholder, followed by Providers (25), Vendors (16) and Federal stakeholders (2). This analysis suggests that Providers will also be greatly impacted and play a significant role in the successful implementation of dose level eligibility.

Figure 5. Top barriers by stakeholder impacted compared to all barriers by stakeholder impacted.



Highlights from "Immunization Grantees Perspectives on Dose Level Accountability in IIS"

The Association of Immunization Managers (AIM) worked with the Child Health Evaluation and Research Unit of the University of Michigan to survey immunization grantee staff about their perceptions of dose level eligibility. This study was conducted just before the facilitated session in Saint Paul, and findings of the study were presented as an introduction to the session. Following is a description of this study, along with some of the high-level findings:

Structure of the Study

- **Method:** Phone Interviews with the program managers, VFC staff, and/or IIS staff of state immunization grantee programs.
- **Goal:** To determine capabilities of the IIS and current practices the immunization program had in place to ensure VFC accountability.
- **Number of Participants:** 46 (44 states and 2 cities)

Current Capabilities

Of those surveyed, 32 indicated that they already have some way of capturing or generating dose level information. Of those 32, 30 said that they capture dose level information for at least some children, while 21 said that dose level eligibility information is required for some IIS users.

Highlighted Perceptions

Many of the findings of this study echoed those of the AIRA facilitated session. Participants expressed:

- **Concern over technical issues,** such as interoperability issues with other systems like inventory, and a lack of standards for transmitting dose level eligibility information to IIS from EHRs.
- **A need for greater guidance;** for example, respondents wanted to understand if it was better to capture dose level eligibility alone or dose level eligibility plus funding source.
- **An issue of competing priorities** that require IIS to make tradeoffs such as capturing information like lot number, expiration date, and vaccine, but not eligibility. Plus, dose level accountability may not currently be a high priority compared to other mandates.
- **A need for greater flexibility for such mandates;** for example, IIS may wish to delay implementation of dose level eligibility until they see how EHRs and VTrckS work together around vaccine inventory.
- **Numerous concerns related to providers,** including the impact of frequent staff turnover, the fact that vaccinations are a just a fraction of what providers do, worries about keeping providers participating in the program, and concerns that documentation tasks may be too burdensome for providers.
- **Worries about data quality** that might occur because a vendor can simply copy visit level data into the dose level field to meet state requirements for VFC providers to capture dose level eligibility.

Proposed Solutions

Candidate solutions followed a few central themes. These included involvement by CDC, addressing inadequate funding and resource availability, standardizing approaches by developing and applying guidelines and policies to address issues with inconsistencies, and support from national organizations like AIRA and PHII to provide best practices and guidance.

Guidance, Clarification and Support from CDC

Participants consider CDC to be a central player in helping them overcome a number of the top barriers. For example, participants suggested that CDC could provide a more detailed explanation on why collection of dose level eligibility is being required for all states and provide reassurance that inaccurate data would not be used in making policy and funding decisions about programs. Clear policies on the use of data by CDC could help alleviate this barrier. They also thought it would be helpful for CDC to smooth the transition to requiring dose level eligibility by implementing a transition management process and use of pilot models.

Participants said that requiring dose level eligibility is one more mandate amongst many existing ones that state IIS must juggle. They believed that CDC could help minimize the impact of competing priorities by gaining consensus both within and across branches of CDC on prioritizing mandates. In addition, to address the barrier of unfunded mandates or mandates with inadequate funding and resources, participants suggested that CDC could provide additional funding.

Funding and Resources

With shrinking budgets across most government organizations, the request to do more with less is not unusual; however, many states feel that to implement mandates like dose level eligibility, additional funding will be required. Participants believed that the barriers of competing priorities and siloed initiatives could be addressed by allocating funds amongst programs differently or by reorganizing how work is done to achieve greater efficiencies.

Participants also thought that the requirements for funding were often too complex and difficult to meet, so suggested that CDC could grant some flexibility around meeting those requirements. Along the lines of flexibility, they also suggested that state IIS be given more flexibility in how they meet unfunded mandates.

Standardization and Development of Guidelines and Policies

A significant number of candidate mitigations stressed the need for the development of standards and policies. For example, to address the barrier of inconsistencies in how EHRs document and transmit eligibility to the IIS, participants suggested that state IIS could work with providers to ensure they use standardized code sets. This would require the development of a national code set that builds on those standardized codes already articulated in the HL7 Implementation Guide[9] — an effort that might be done in partnership with CDC and a national organization like AIRA, AIM or PHII.

To address concerns over inaccurate data being used by CDC to make program decisions, participants believed that a universal data collection policy would need to be developed to address how states can reconcile data coming in through various reporting methods: captured and reported through direct interface with the IIS, use of an EHR and transmission of data to the IIS, and use of paper-based recording/reporting methods. These collection and reporting policies would then need to be applied in a standard way across all states.

Best Practices and Recommendations from National Organizations

Many state IIS have come to rely on national organizations like AIRA, AIM and PHII to develop and manage collaborative projects that address issues or requirements common to state IIS. They believed that the issue of competing priorities could be addressed through a national initiative managed by one of these organizations. They also thought that these national groups could ease the barrier of the training that will be required of providers, IIS, and state and local VFC staff through a cooperative agreement that would help them develop a base set of training materials that could then be adapted for each state.

One area that participants thought national organizations could be of great assistance was EHR communications capabilities. They believed that these organizations could provide guidelines and best practices to EHR vendors. Such guidelines would help vendors develop capabilities to track dose level eligibility and offer guidance on using HL7 to transmit accurate eligibility data to the IIS. This mitigation strategy could also help address the barrier of vendors getting inconsistent guidance from the IIS and VFC community about what they should be tracking.

Finally, participants believed that pilot projects and development of best practices and guidelines could help reduce the uncertainty of what may happen from a system or business process standpoint when implementing dose level eligibility. Such projects could also identify ways to overcome limitations of EHRs and IIS as well as business process issues that may be encountered during implementation.

Along with the strategies proposed in this section, participants also identified possible next steps that the various stakeholders can take to begin addressing the documented barriers. ■

9. http://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html

Possible Next Steps

At the conclusion of the session, the group compiled a list of possible next steps and action items to further the implementation of dose level eligibility. The majority of these items focused on engaging all affected stakeholders to inform them about the requirement, address implementation barriers and begin establishing a roadmap for a full transition by 2017.

Suggested strategies included:

- Sharing the results of the facilitated meeting with CDC (particularly VFC program leadership and policy managers at CDC), state immunization program representatives, IIS vendors, and any other relevant parties.
- Creating a clear plan for the transition to dose level eligibility and establishing an appropriate timeline. This may require leadership from national organizations and the establishment of standards to guide the process.
- Communicating with EHR vendors about what capabilities are needed in EHRs to enable dose level eligibility tracking and taking advantage of windows of opportunity and discussions in the EHR community to leverage other planning and development efforts already under way.
- Updating appropriate program documents like the Immunization Program Operations Manual (IPOM[10]) and VFC Operations Guide to address the evolving requirements of the VFC program.

A number of discussion items that the group felt were critical to address could not be addressed during the facilitated discussion because the appropriate experts were not present. Many expressed the opinion that dose level eligibility should not be universally applied until these issues were addressed because they may impact when, if and how dose level eligibility is implemented.

The following list presents these critical issues:

- What is the rationale behind the CDC/NCIRD directive to implement dose level eligibility tracking in IIS? Specifically, participants wanted to know the costs and benefits of implementing dose level eligibility tracking, how many states need or want this level of tracking, and how many patients does this apply to (it was suggested by one state during the session that this may affect less than 5% of the target population)?
- What methods of capturing dose level eligibility will be considered compliant with the Cooperative Agreement requirement? IIS programs need definitive guidance on what constitutes an acceptable approach for recording dose level eligibility (e.g., is it acceptable to derive dose level from visit level, can the IIS leverage default values for eligibility at the dose level and user can edit if needed, where should the data be stored in the patient/vaccination record?).
- What are the roles and responsibilities of the IIS as compared to the VFC program? IIS can ultimately implement whatever functionality is needed to support the needs of the VFC program, but implementation and enforcement predominantly fall to the VFC program staff.
- How will the Affordable Care Act[11] factor into this effort and the overall impact on VFC eligibility in general?
- How will Meaningful Use Stage 2[12] impact EHR vendors and system capabilities for transmitting data like dose level eligibility? What do those implementation timelines look like? ■

10. http://www.cdc.gov/vaccines/vac-gen/policies/ipom/default.htm
11. http://en.wikipedia.org/wiki/Patient_Protection_and_Affordable_Care_Act
12. http://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2

Conclusion: Overcoming the Barriers to Implementing Dose Level Eligibility

The findings of the facilitated session, as well as those of the preliminary survey, the University of Michigan study, and the practical experiences of the Michigan Care Improvement Registry (MCIR) all support the belief that capturing dose level eligibility in IIS provides many valuable benefits. However, the large number of barriers to implementing dose level eligibility captured in the one day session indicates that all stakeholders have numerous issues to overcome —especially the state immunization programs, IIS and EHR vendors, and VFC providers.

Further, 25 percent of the identified barriers are perceived to be critical and extremely difficult to overcome. The majority of these top barriers impact state immunization programs, who expressed concern over a lack of staffing, time and funding to implement such mandates. These top barriers also impact IIS and EHR vendors, who must meet technical challenges to enable accurate capture and exchange of this data while also designing systems that are easy to use by providers.

Addressing the documented barriers will take time and commitment from stakeholders. These include federal stakeholders like CDC, professional organizations like AIRA and AIM, national informatics groups like PHII, standards-developing entities like HL7 International, immunization providers, state immunization programs, and IIS and EHR vendors. As the list of proposed solutions and next steps indicate, active participation by stakeholders can eliminate perceived barriers and promote successful implementation of dose level eligibility. Ultimately, advanced eligibility tracking will lead to improved accountability, data collection and inventory management while supporting a standardized application of policy and more accurate justification for funding allocations. ■

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Appendice B — Barriers and Benefits Tables

Patient Dose-Level Eligibility Barriers

The list of patient dose-level eligibility barriers is the primary deliverable from the session. The initial list of barriers was developed by the group via structured brainstorming, in which some time was allowed to push on and clean up the description. After the initial list was identified the participants, working in sub-groups, ranked each barrier and identified candidate mitigation strategies for the barrier.

Column Descriptions:

- **Category –** Added after the session in order to organize the barriers into related groups. Categories include:
  - > Policy – Issue requires a new policy, policy clarification or project prioritization at either the federal or state level
  - > Technical – Barrier is related to limitations of the existing IIS and/or EHR systems
  - > Resource – Issue is affected by limited resources such as available staff, funding and/or time
  - > Flow – Barrier is related to a business process flow issue at either the state or provider level

- **Stakeholder** (Impacted by Barrier or Drives Mitigation) – Added after the session in order to organize the barriers and mitigations into related groupings. Stakeholder groups used in describing those impacted and those driving mitigation include:
  - > Provider (includes private and public immunization providers)
  - > State
  - > Federal
  - > Vendor (may reference IIS vendor, EHR vendor or both)
  - > National (e.g. AIRA, AIM, HL7 spec organization)

- **Barrier Description** – Description of the barrier, obstacle, issue that exists in trying to implement patient dose-level eligibility

- **Rank** – The relative seriousness of the barrier and the difficulty of implementing given the barrier
  - > Seriousness: How serious a problem is it? How big a deal?
    A – Could not implement without this being addressed
    C – Would cause trouble if not addressed
  - > Ease: How difficult would it be to address the barrier?
    A – Requires unavailable funding of resources, political will and/or is highly complex
    C – Would distract resources or take time from other efforts

- **Candidate Mitigations** – Potential items which should be considered when developing strategies to mitigate the barriers to implementation

- **Orig. ID** – The ID which was used during the session. This represents the order in which the barrier was identified. After the session the list was sorted to raise more serious barriers and easier to implement barriers to the top.

Barriers List:

Note: The list has been sorted to raise more serious barriers and harder to implement barriers to the top. In addition, two items which were not barriers were removed from the list.

ID	Category	Barrier Description	Rank		Stakeholder		Candidate Mitigations
			Serious	Difficulty	Impacted	Drives Mitigation	
1	Technical	Not all EHR tracks eligibility at any level; let alone dose level	A	A	Vendor	National	• Best practices, guidelines (National level) • Consistent communication (National level)
2	Resource	The requirements for funding of development and implementation for registries.	A	A	State	Federal, State	• Money • Priorities
3	Technical	The EHR ability to send the data; and which HL7 are they able to send; can they send both the eligibility and the funding source. Depends on which HL7 version they are using.	A	A	Vendor	Vendor	• EHR works and then the message • National best practices
4	Technical	EHR are not getting consistent guidance from the IIS and VFC community as a group about what they should be tracking. They need specific recommendations and best practices.	A	A	Vendor	National	• EHR works and then the message • National best practices
5	Technical	The lack of interoperability between provider systems. Either we are going to have incredibly intelligent provider staff or we are going to have to ensure that the VTrckS and EHR/EMR and Billing work together; Inventory Systems Data, …	A	A	Provider or Vendor	State	• Solid training • User friendly system • Thoughtful design (business process) • Common knowledge
6	n/a	Some states are paper based and don't have the systems to support the operations.	A	A	State	State	
7	Resource	Too many mandates from CDC and the State at the same time and we have limited staff and funding to complete all of this in the time frame.	A	A	State	Federal, State	• Funding • National initiative • Timeline • True pilots prior to implementation
8	Resource	Unfunded mandates.	A	A	State, Providers	Federal, State	• More money • More flexibility for grantees
9	Resource	Competing priorities. Someone at Federal level should think about the priorities, especially in light of the OIG priorities. Silo'ed work priorities.	A	A	State	Federal	• Consensus at CDC level at a high level, not just within a branch, but across branches • Standardization of requirement • Disproportionate funding for work load – attention to divisions of work or funding
10	Policy	What is the CDC going to do with this information? We may be held accountable for something we cannot be sure of the accuracy of.	A	A	State	Federal	• CDC tells us • CDC conducts change management transition process
11	Policy	It could happen that inaccurate data forces you to change your program inappropriately, e.g. reduce eligibility for a program.	A	A	Federal	State	• Reassurance from CDC that inaccurate data isn't used for policy decision • Standardize data collection policy (methods, IIS, no IIS, paper, etc.) • Standardize application of policies • Clear policy and documentation on use of data by CDC
12	Resource	Extensive training that is required of the providers and the IIS & state and local VFC trainer staff. Especially for inventory reconciliation.	A	A	State	State	• Cooperative agreement with PHII or AIRA for training materials that can be adapted per state.
13	Technical, Flow	Limitations of systems (EHR and IIS) and business processes capabilities (end users).	A	A	Vendor, Provider	State	• Best practice guidelines
14	Technical	Electronic Data Exchange is causing problems.	A	A	Vendor	State	• Refer to other barriers (too vague)
15	Technical, Flow	As you implement you don't know what you might encounter in our systems or processes.	A	A	State	State	• Establish pilot efforts to identify best practices and share troubleshooting with other states
16	Technical	Not all IIS have inventory reporting capabilities to support the reconciliation at the dose level.	A	A	State	State	• Require resources

ID	Category	Barrier Description	Rank		Stakeholder		Candidate Mitigations
			Serious	Difficulty	Impacted	Drives Mitigation	
17	Resource, Flow	Data quality issues; and where does the burden fall for data quality checking?	A	A	State	State	• Discuss as part of BR process plan for it
18	Technical	The variety of ways that eligibility is documented and transmitted by the EHR systems. Not documenting in a place that we pull from; or accurately	A	A	Vendor	National, State	• Providers should use state specific codes. • Work on national code set.
19	Policy	Lack of direction for what we should do as we move further down and if we move to only dose level, how are going to evaluate patient level when there is a variance in the dose level. E.g. if children are under-insured.	A	B	State	Federal	• We have to deal with it
20	Technical	In our current standard we don't ask for funding source (OBX) or patient level information (PV1-20); therefore may not be able to derive dose level from patient level.	A	B	Vendor	National	• Put PT back • Mapping data from each data source (e.g. EHR, flat file, direct UI) • Ask provider for funding source (public/private) • Address PT default to dose • Create/assure dose level can translate to PT • Not make providers do dose level accountability • Wait until we know outcome of ACA
21	Technical	Lack of knowing what it will take to make needed changes. E.g. What is the scope of the effort on the IIS side; what changes would need to be made to IIS, cost, etc. Does anyone who has done this have some scope of effort? A lot of factors may affect this.	A	B	State	State	• AIRA – AIM initiative to provide understanding and guidance
22	Policy	What problem is dose level accountability going to solve; I need to communicate to my provider, funders and other stakeholders to gain their support?	A	C	State	Federal	• Varies by states; hard sell – should come from the national level.
23	Flow	Disconnect between those who are screening for eligibility and those administering and entering the shot information.	A	C	Provider	Provider	• Consistent education and training
24	Policy	The providers need to understand why because they are the ones who influence the EHRs to support the requirements.	A	C	Provider	State	• CDC has to be clear about why • Clearly define risk for stakeholder • Education
25	Resource	We have to do this pretty fast and while we are changing IIS, VFC, etc.	A	C	State	State	Additional funding Overcome political barriers at jurisdiction level
26	Policy	It is unclear why we are running to get this done before we have been required to even get it started. Our agreement is to start by January 2013 and then we have five years to get this implemented. Is CDC telling us we have to get this done now? Can we wait for the other support to be in place (e.g. EMR, MIROW)? Note: it says you must work toward, not get it done. It may be more efficient if we slow down? Note: currently we have the attention of the EHR vendors that want to accommodate this. So there may be benefit in moving forward faster than required.	A	C	State	Federal	Additional funding Solve some issues/table other issues

ID	Category	Barrier Description	Rank		Stakeholder		Candidate Mitigations
			Serious	Difficulty	Impacted	Drives Mitigation	
27	Policy	We need clarification of the definition of dose level eligibility. What qualifies as dose level eligibilities?	A	C	State	Federal	• Combine CDC guidance with work product from this meeting.
28	Technical	How we define the fields in HL7 and whether it is Required or Required but can be Empty. We may not have all of the fields needed in the current spec. Approach to certifying solutions is focused on supporting IIS needs. This may require updates or clarification in the HL7 implementation guide.	A	C	Vendor	National	• Joint application development including guidelines from MIROW and system specific joint application development (e.g. WIR, STC, Envision)
29	Policy	This is not a requirement of the VFC program operational guide (pg. 7); this is a registry requirement and not something that providers had to do as a part of the VFC program	B	A	Provider	State	• Guide could be changed without changing the law
30	Resource	The financial cost to the solution providers. We have providers at various releases/stages in their development of their EHR; every change is a cost to them; the cost was a barrier.	B	A	Provider	State	• Possible financial assistance • Best practice guidance for EHR vendors
31	Resource	Staff required to roll in the changes and other staff needed to support the effort. Who accumulates the data if you are a paper based? The barrier is the amount of staff required to process paper and mixed systems with multiple data feeds	B	B	State	State	•
32	Flow	We have to manage our expectation of what the IIS can really do; putting in the data creates other issues. E.g. borrowing is very difficult to manage if the providers don't store the vaccines separately because public and private can have the same lot numbers.	B	B	State	State	•
33	Resource	There is more to implementation than just development.	B	B	State	State	•
34	Policy	We are trying to use VFC codes and use them for something they were not intended. Note: There is a lot of pressure on the $4b programs that drive the need for accountability. Subgroup: there are different funding streams, but we need one solution that supports them all.	B	B	State	Federal	• Need to make the clarifications that VFC and 317 exist, need to have solution that works for both • Use the data that has been collected and report data to justify
35	Policy	Once you look, what do you do with the findings; accountability, e.g. you are using public dose incorrectly, now what do we do with that, how far do you push it.	B	C	State	State	• Funding • Guidance/policy • Define consequences • Funding/staffing • Education • Feedback loop to providers/stakeholders
36	Policy	Some states don't have IIS mandates at all and are not in a position to require it. This would impact their approach.	C	A	State	State	• Provider training and benefit • National best practices • Pass mandates – examples are out there
37	Resource	If you have to support multiple streams of information to capture this data across the board; there is a significant workload associated with this.	C	A	State	State	• Addressing data quality and standards across system
38	Technical	Inconsistency in requirements across multiple data streams, e.g. a required field in the direct user interface and not required in the EHR	C	A	Vendor	State	• Standards
39	Technical	There is a barrier between the level of maturity between the inventory functionality from the IIS (more) and the EHR. The vendors are going to be creative in what they do and will create a mess if we don't have clear guidelines for them. Note: this may be less of an issue for pediatric vendors.	C	A	Vendor	State	•

ID	Category	Barrier Description	Rank		Stakeholder		Candidate Mitigations
			Serious	Difficulty	Impacted	Drives Mitigation	
40	Flow	We found out the hard way that people were not documenting things correctly; e.g. for the direct user interface – they relied on pre-population based on patient data. It was painful for the providers to go back and correct the data.	C	A	Provider	State	• Lessons learned document
41	Resource	The time management and resources required seems daunting.	C	A	State	State	• Additional funding (e.g. make this a funded mandate)
42	Policy	Type of providers and the structure of public service provisions; e.g. lots of private providers versus LPH or others. How much can be dictated about their operations?	C	A	Provider	State	• Identify who is who. Determine if there are really that many differences.
43	Resource	The combination of high learning curve and high staff turnover.	C	B	Provider	State	• Note: difficult because out of our control
44	Policy	Balancing facilitating the requirement with sustaining VFC participation by the providers. Keeping providers in the program.	C	C	Provider	State	• EHR standards will help
45	Policy	Balancing facilitating the requirement with sustaining VFC registry participation.	C	C	Provider	State	• Explain benefits
46	Policy	Inconsistencies from IIS and VFC program (federal and state) reporting requirements. Can't always roll the data up. Recommend that you require the same thing across collection format; not legislative requirements. (Depends on UI, paper, EHR based) Note: can't require paper users to comply under current regulations. No statement about how paper based systems will be addressed. The statue is silent on how to make them accountable on dose level eligibility for paper based systems.	C	C	Provider	State	• Interpreting it as requiring same across collection formats; not making legislation requirements the same
47	Policy	Provider buy in, especially states without mandated IIS registries. different based on vaccine funding Note: There are differences based on vaccine funding	C	C	Provider	State	•
48	Resource	More work for the providers.	C	C	Provider	State	•
49	Technical	Time lag from requirements through implementation: if you know you are going to make a big upgrade, communicate that to the EHR teams & staff. We are asking the providers to assign VFC codes to adults as well. Even if you program it today; implementation will not happen for a while.	C	C	Vendor	State	
50	Technical	Need to give the providers a way of getting there; be willing to define what is acceptable for us in the interim as we collectively transition to the future.	C	C	Vendor	State	Guidance from CDC Ample timeline Funding Standardized guidance from CDC on the message of "why"
51	Technical	We may be getting dose level data; but not always accurate, for example patient level being sent as dose level.	C	C	Vendor	State	Quality assurance processes – IIS, site visit, EHR changes Define data differences for direct UI entry, EHR, billing system/flat file
52	Policy	There is a perception that it is the IIS responsibility to pre-populate based on patient level eligibility information providers have already sent. Note: not possible; and may be an education issue.	C	C	Provider	State	Education clarification to providers, EMRs Concrete guidance Funding

ID	Category	Barrier Description	Rank		Stakeholder		Candidate Mitigations
			Serious	Difficulty	Impacted	Drives Mitigation	
53	n/a	Scalability to states with a large provider population. NH Note: the providers have to show us how they know that they are using VFC doses appropriately; and how they are creating the data for us via chart review or provider profile. We did not want our funding to be at risk. Note: NH does not have an IIS.	C	C	State	State	•
54	n/a	We should not punish our providers because of problems in our systems or our data.	C	C	State	State	•
55	Policy	Provider participation and buy in; or they will drop out of my registries.	C	C	Provider	State	• Define benefits and provider messaging
56	Technical	They are implementing while things are changing and we are learning how it works. We are implementing program rules along with technical solutions. E.g. private vs. publicly funded doses.	C	C	Provider	State	• Implement what you know now and have a vision for future enhancements.
57	Resource	"One shoe doesn't fit all" jurisdictions (e.g. size, resources available, policies vary from jurisdiction to jurisdiction).	C	C	Provider	State	• Best practices documentation. • Workgroups with provider focus
58	Flow	When the eligibility status changes the provider may have recorded as private, but then find out it is public and they borrow it regardless of what they are putting in the system. They may not have a choice.	C	C	Provider	State	• Provider education
59	Policy	Difference in VFC eligibility and hierarchy for selecting eligibility. There are overlaps between the two concepts.	C	C	Provider	State	• Training issue within program and outside • Additional staff for training • Different training media
60	Policy	The need of states to resolve the problem that dose level accountability addresses differs by state vaccine purchasing policies. There is a range of funding sources from VFC-only to universal and that impacts how it needs to be addressed. Some states are doing things that result in pages of eligibilities – it is the in between states that will perceive the need for this more than the two extremes.	C	C	Federal	State	• People in the middle come together and harmonize
61	Policy, Technical	We have implemented dose level eligibility, but patient eligibility equals dose level eligibility for all but 5% of the kids in our jurisdiction. We also have concerns about the quality of the data. We suspect we are getting dose level inferred from patient level.	C	C	Provider	State	• Improved communication/guidelines/use cases/ business rules out to the EHRs
62	Technical	Wonder how the vendors will accept this, especially since they don't like differences across the states.	C	C	Vendor	State, National	• Get them involved early so they can provide menus that cover each option • Improved communication/guidelines/use cases/ business rules out to the EHRs
63	Policy	The vendors & providers feel we are hitting them with a lot at once and are changing all the time.	C	C	Provider, Vendors	State, National	• Get consensus within jurisdiction and articulate at the national level
64	Flow	We still cannot get direct ship vaccine lot numbers in a timely manner	C	C	State	Federal	• This may be addressed in the latest version of VTrckS. Investigate/look at VTrckS shipment file per CDC announcement.
65	Technical	Our system has not made it easy to look at past history; this is tracking not eligibility determination.	C	C	Vendor	State	• Identify local product processes (seems like more of a product specific issue)
66	Flow	We have only historically required documentation when it changes for a patient vs. every time which dose level requires.	C	C	Provider	State	• Training and education
67	Policy	We are developing technical solutions where the policies and requirements are not fully identified or understood.	C	C	State	Federal	• Varies by state
68	Technical	We are testing at the dose level, but not testing whether two different dose levels can be sent at the same time.	C	C	Vendor	State	• CDC VFC operations guides shows hierarchy if only one can be captured • Clarity across adults/children • Education

Patient Dose-Level Eligibility Benefits

The list of patient dose-level eligibility benefits was developed by the group via structured brainstorming. These items answer the question, "What are potential benefits or upsides (near or long term) that we hope to result from the implementation of patient dose-level eligibility tracking? E.g. what can we do and what needs can be met with the dose-level data?"

ID	Potential Benefits
1	Should make provider reporting easier.
2	Justified our 317 vaccine program.
3	Does make us take an in depth look at our data quality at the provider level.
4	Allows you to determine educational needs at the provider level.
5	Easier to determine which vaccines are not going to the right place; what is the gap and what went to a child it was intended to.
6	From some of us who are going from Universal, it gives us the data to take to the state legislature to substantiate the gap in funding.
7	Provided greater ability to forecast provider needs; and monitor provider orders.
8	Supports a greater level of accountability for kids that have eligibility in more than one category. It is a good time to look at giving the OIG findings.
9	Facilitate the reporting of under insured data and delegation of authority.
10	Capturing data at more detail level, prepares one for future data requests that are not anticipated today.
11	For states that are doing billables projects, it supports this.
12	Theoretically could drive or eliminate the need for the VFC pop estimates; VFC practice profiles; CAT; and VPET; and possibly spend plans.
13	Having one consistent standard for deriving information from at the higher levels.
14	Additional opportunities for groups like this to get together and discuss policies and other issues surrounding this.
15	This can be the beginning for us to get our messages to the CDC; so that it is clear this fills what feels like a void. Would like to open a dialog with CDC across the branches.
16	Greater alignment among the programs.
17	Will help us track the borrowed doses.
18	If appropriately recorded, this may give us better visibility into our under insured populations.
19	May help us to reduce vaccines from fraud and abuse and waste.
20	Dose level Acct makes us better stewards of our resources; and increases the awareness by the providers and the Medical Assistants; makes it more of a partnership with the providers.
21	Helps us demonstrate stewardship to OMB.
22	This would help us consolidate the list of eligibilities for 317 (from AIM survey results presentation)
23	It may save vaccine money for the VFC programs – fed, state.
24	It may save vaccine money for the VFC programs – providers.
25	Cleaner tie to inventory
26	Supports the replacement method for states who are allowing one stock of vaccine.
27	Identify areas which would like to reprogram funds.
28	Will improve EMR/EHRs. If we get in now, this may help with what we want down the road.
29	Could help Universal states justify seeking additional annual appropriations.
30	Establishes uniformity that benefits all states. Shows a level of maturity relative your peers. Less questions about your program if we are all on the same standard. Universal/VFC only states.
31	It the quality of the data is there, it ensures the right funds pay for the right vaccine Universal/VFC only states.
32	Helps with billing (see above) for Universal/VFC only states.

Candidate Next Steps/Action Items

The group spent a little time brainstorming action items which could be considered if additional work was done to address the implementation of patient dose-level eligibility.

ID	Potential Upside
1	Have a clear idea of what we want EHR to support; a clear documented idea. Or at least where are we right now. By the end of the year. The window closes.
2	Bring in folks from the AIRA standards interoperability group with additional input from the VFC side of the house.
3	Forward results to CDC and other relevant parties.
4	Approach CDC regarding to looking at this for the IPOM next year. Work with AIM on this.
5	There are people not in the room and we need some presentation for them; e.g. Policy People.
6	The output of this session should be written for a wider audience than the participants in this room. Two documents: detail technical and high level policy issues.
7	Having a clear plan and transition and timeline and seeing we are all in this together; and created together.

Side Items

The following items were identified during the session and documented for further follow-up and later discussion outside of the session.

ID	Side Item
1	What is the cost and benefit of implementing patient dose-level eligibility tracking?
2	How many states have the issue?
3	Rationale of the VFC policy directive for 2013-2017 Cooperative Agreement
4	Affordable Care Act and impact on VFC eligibility
5	Meaningful Use Phase 2

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