

## Executive Summary

A meeting was held in August 2010 to review the status of immunization registries. The goal was to determine the best way to establish a network of federal, state, and local population-based immunization registries capable of sharing information with other immunization systems and health information systems, while maintaining privacy and confidentiality. The purpose of an effective network is ultimately to eliminate vaccine preventable disease in the United States. This report provides highlights and next steps from the August meeting.

## Introduction

Promoting the adoption and use of health information technology is a priority for U.S. policy makers as a means of managing health care costs and improving quality. To maximize the benefits of these developments, public health information must be ready to be integrated into electronic health systems to support clinical decision making, identify pockets of need, and integrate population health into clinical medicine. The successful integration of public health data and clinical medicine can ultimately improve access to care, enhance the quality of care and reduce the burden of disease.

The American Recovery and Reinvestment Act (ARRA) authorized incentive payments through Medicare and Medicaid to providers that implement certified electronic health records and can demonstrate their “meaningful use” of health information technology. These criteria are intended to ensure that doctors and hospitals will use health information technology to improve the quality, efficiency, and safety of care. According to an article by Alan Hinman and David Ross in *Health Affairs*, “The clear intent is to assure a future in which essential population health functions, such as immunizations, are incorporated into the fabric of information used to measure progress toward improving and protecting the health of all Americans.”<sup>i</sup>

One element of Meaningful Use criteria is the interface with public health data. Immunization registries, or immunization information systems<sup>1</sup>, provide an opportunity to exchange public health data with doctors and hospitals ([ASTHO Meaningful Use Summary](#)). The ultimate benefit of a successful program is the reduction in vaccine preventable disease. The challenge is how to be prepared for this exchange of data during this period of rapid growth.

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<sup>1</sup> The terms “immunization information system” and “immunization registry” are used interchangeably in this document

## The Summit

### Developing an Action Plan

The Association of State and Territorial Health Officials (ASTHO) convened an Immunization Registries Summit on August 4, 2010 in Arlington, Virginia to begin developing an action plan that would advance the functionality, utility, and interoperability of immunization registries throughout the United States, improving the states' ability to exchange data. The benefits include tracking vaccination records for a mobile society, improving emergency response capabilities, targeting underserved populations, and ultimately reducing the incidence of vaccine preventable diseases. The goal stated during the meeting was :

**Establish a nationwide network of federal/state/local population-based immunization registries that are capable of sharing information with other immunization systems and health information systems, while maintaining privacy and confidentiality, in order to reduce vaccine preventable disease.**

### Participants

Participants from a variety of groups assembled to consider a proposed vision for immunization registries, key strategies for achieving that vision, and priority action steps for advancing those strategies. Summit participants included officials from state health agencies (Kentucky, Indiana, Massachusetts, Michigan, New Hampshire, New York, Oklahoma, Oregon, and Wisconsin), the National Association of City and County Health Officials (Louisville, Kentucky and San Diego County, California), and federal agencies (Centers for Disease Control and Prevention, Centers for Medicaid and Medicare Services, the Food and Drug Administration, Indian Health Service, Department of Health and Human Services, and Office of the National Coordinator for Health Information Technology), individuals from professional and public health organizations (American Academy of Pediatrics, American Pharmacy Association, Association of Immunization Managers, American Immunization Registry Association, Council of State and Territorial Epidemiologists), and private sector organizations (America's Health Insurance Plans, Intel, Merck, National Association of Chain Drug Stores, Sanofi Pasteur, Scientific Technologies Corporation, United Health Care).

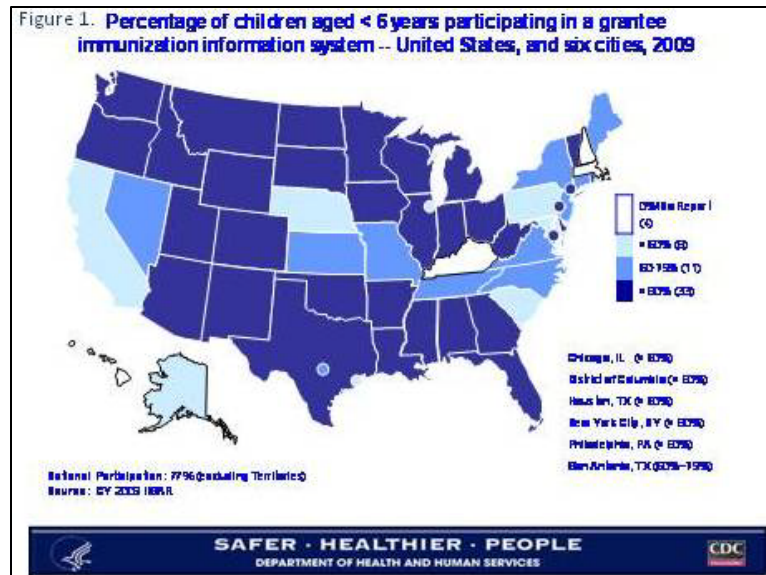
Since the intent was to foster brainstorming and initial prioritization, rather than generate consensus, each participant did not necessarily support each proposed action item. However, the highlights noted here enjoyed broad support and momentum among the diverse individual participants.

The first part of the meeting focused on explaining the current state of immunization registries, their proven benefits, recent examples of success during H1N1, and a proposed vision for the future of registries. The second part of the meeting highlighted some state examples of advancing registries. Finally, the group was challenged to identify next steps on how to move from "here" to "there".

## Where We Are Now

### Immunization Information Systems Update

The CDC is the lead federal agency on the funding and managing of immunization information systems and provides annual funding to 56 immunization programs in 50 states, Washington DC, and 5 large cities. The proposed Healthy People 2020 goals for these systems are to increase the proportion of children under age 6- years who participate in fully operational population based immunization registries and to increase the number of states that have 80 percent of adolescents, with two or more age appropriate immunizations, recorded in immunization information systems. Currently 33 percent of the population (88.5 million people) are participating in such a system, as shown in Figure 1.



As of 2009, 88 percent of public provider sites and 38 percent of private providers were submitting data to an immunization information system.

In 2009 the Health Information Technology and Clinical Health Act (HITECH) was passed to improve health care delivery through the support of meaningful use of electronic health records (EHRs). The integration of public health data and electronic health records is one component of this new law – specifically, for EHRs to submit electronic immunization data to immunization registries or information systems through the use of HL7 messages, a national standard data exchange.

#### Immunization Information System Health Level 7 (HL7) Implemented December 31, 2009

- **Full Compliance** - *able to receive and send messages using HL7*: 30 of 51 grantees or 59%
- **Partial Compliance** - *able to receive or send messages using HL7*: 4 of 51 grantees or 8%
- **No Compliance** - *unable to receive or send messages using HL7*: 17 of 51 grantees or 33%
- **No or Partial Compliance after excluding HITECH awardees** 12 of 51 grantees or 24%
- **Expected Compliance on or before 2012** – 76% (CDC 2009 Immunization Information System Annual Report)

A recent survey showed that roughly 3,618 EHRs are reporting data to an immunization information system. Enhancing the interoperability of EHRs with these systems will improve data quality challenges by addressing accuracy, timeliness, and completeness.

### **The Effectiveness of Immunization Information Systems**

The Task force on Community Preventive Services, appointed by the Director of the CDC, conducted a systematic review of literature to test the effectiveness of these systems in reducing vaccine preventable disease and their ability to effectively support other important public health activities or interventions. The draft findings, issued in June 2010, are as follows:

The Task Force on Community Preventive Services recommends immunization information systems on the basis of strong evidence of effectiveness in increasing vaccination rates. Evidence was considered strong based on the findings from 71 published papers and 123 conference abstracts which demonstrate that IIS have the following capabilities directly related to increasing vaccination rates and reducing vaccine-preventable disease:

- Generation of, or support for, effective interventions such as client reminder/recall, provider assessment and feedback, and provider reminders.
- Generation and evaluation of public health responses to outbreaks of vaccine preventable disease.
- Vaccine management and accountability.
- Determinations of client vaccination status for decisions made by clinicians, health departments, and schools.
- Surveillance and investigations on vaccination rates, missed vaccination opportunities, invalid dose administration and disparities in vaccination coverage.

In addition, there are many studies assessing immunization information systems data quality for use by decision-makers in clinical settings, communities, states, and the nation.

### **H1N1 – The Role of Immunization Information Systems in the Response**

Immunization information systems performed a number of useful roles during the recent H1N1 response. They were used for tracking inventory and doses administered, communicating with providers, and helping providers determine proper dosing.

A majority of the states used their systems to report weekly doses administered by age group and by dose number for all clinics in the jurisdiction. Forty of the projects had robust data that matched with national trends. In fact, states that used a data exchange or direct web entry system showed reporting rates higher than the national average.

Registries are starting to show their ability to monitor trends. Early coverage from system sentinel sites focuses on data quality and coverage measurements, and suggests that registries can keep up with active monitoring of doses and give similar results to sample surveys (to be produced in future *MMWR*).

Many states used their registry systems to enroll providers and to track inventory at provider sites. One of the benefits of tracking inventory through the systems was that the information could then be uploaded into the vaccine ordering system to restock providers that were running low. The systems were also used to communicate with providers, reminding them about the need for a second dose of the H1N1 vaccine for the younger children and alerting them to the recall of vaccine due to changes in expiration dates. It was also used to provide general H1N1 information. Finally, some systems were able to assist providers in determining who was eligible for one dose of the vaccine versus two doses, based on a decision algorithm.

### **The PRISM (Post-Licensure Rapid Immunization Safety Monitoring) Network**

Immunization registries in eight states (Michigan, Florida, Georgia, Pennsylvania, Arizona, Wisconsin, Minnesota, and New York) and New York City were used to monitor potential adverse events during the H1N1 response. This project demonstrated the useful role of registries in safety monitoring.

The PRISM linked health plan data and state immunization registry data in a new vaccine safety surveillance network and provided continuous active surveillance for pre-specified outcomes and timely information on unanticipated potential adverse events. The statistical analysis compared the observed number of adverse events in the current season to the expected number based on historical data. Outcomes were monitored based upon biological plausibility. The system monitored for Guillain-Barre Syndrome, Bell's palsy, and seizures, among other potential adverse events. None were found to be statistically significant. By the end of the project, 14 million people were monitored in the registries and 26 million from the health plans.

H1N1 helped to illustrate the potential of immunization information systems not only during a pandemic response, but also during routine vaccine administration.

## **Where We Are Going**

### **The Future of Immunization Information Systems – Proof of Concept**

Immunization information systems have the potential to accomplish a variety of tasks that can lead to increased vaccine coverage and ultimately improve health. Examples of the capabilities of a “gold standard” system could include:

- Tracking immunization records for a mobile society.
- Preventing missed opportunities – when a patient presents at a providers office, the provider can pull up the record and determine if the patient needs any immunizations during the visit.

- Improving emergency response capabilities – tracking doses administered, monitoring uptake of a vaccine in target populations, creating timely and accurate data about vaccine use and inventory.
- Expanding the potential locations for receiving vaccines (i.e., pharmacies, schools) while maintaining a current record of the immunizations that is accessible to the medical home.
- Identifying underserved populations.
- Providing good stewardship of limited public funds – public health agency can use the registry to track Vaccines for Children inventory and document eligibility.
- Providing population based data to assist in the assessment of health care reform on access, disparities, and health outcomes.

Registries serve as a “proof of concept” for how public health information can be communicated with the delivery system. Immunization information systems can serve as a building block for sharing public health information – they can support clinical decision making and provide a comprehensive picture of the population – which is essential for tracking disease trends and treatment outcomes.

The next steps in this process are ensuring that immunization registries are interoperable with quality data, that registries are integrated with electronic health records and that partners from both the public and private sector work together to make this a useful tool that ultimately leads to improved immunization coverage rates and lower disease burden.

The ultimate goal is to establish a nationwide network of federal/state/local population-based immunization registries that are capable of sharing information with other immunization systems and health information systems, while maintaining privacy and confidentiality in order to reduce vaccine preventable disease.

### **An Opportunity to Move Forward – No Time to Waste**

The Department of Health and Human Services’ Meaningful Use criteria set a tight timeline for states to be ready to participate in the exchange of data with doctors and hospitals. The general guidelines for the program are as follows:

#### **2011:**

- To receive Medicare and Medicaid incentives, providers must satisfy core objectives and choose five out of ten menu objectives. The three public health menu objectives include:
  1. Report to immunization registries
  2. electronic laboratory reporting
  3. syndromic surveillance reporting.

Providers may contact states about how to connect to one or more of these systems. States need to be ready to demonstrate that they are ready to link up and to demonstrate the benefits of the partnership.

- States can require public health objectives. During the first year states are allowed to move public health measures to the core objectives, thus making them mandatory – but states must justify that the readiness is there.
- Providers must report on clinical quality measures of public health significance, including
  1. Hypertension: blood pressure measurement
  2. Tobacco use assessment and intervention
  3. Adult weight screening and follow-up.
- States can require alternate core measures
  1. Weight assessment and counseling for children and adolescents
  2. Preventive care and screening: influenza immunizations for those 50 years old and above
  3. Childhood immunization status.

**2013:** Menu objectives from 2011 become mandatory.

**2015:** More criteria could be added.

**2016:** Last year to add criteria for Medicaid incentives.

As a result of these new guidelines, state public health agencies have an opportunity to demonstrate to providers that they are interested and ready to facilitate the interoperability. Immunization registries are a logical place to start in this partnership. Many states have mature immunization registry systems that are ready to take on new providers. These states can provide leadership on how to facilitate these partnerships. Once a link is established it can be a door to other public health data connections. For example, many states are expanding the systems to include Body Mass Index and newborn screening data.

## How We Will Get There

### Implementing the Vision: Discussion of Key Strategies

Immunization information systems have the potential to improve health outcomes as outlined in the information above. The next section focuses on three topics that were identified as particularly important in improving immunization registries and positioning them to be ready for interoperability with electronic health records. These issues are exchanging data across state lines, incorporating registries in electronic health records, and funding.

Representatives from three states discussed how they have begun to address these issues.

#### **Wisconsin - Exchanging Registry Data Across State Lines**

*Seth Foldy, Health Commissioner, Wisconsin Department of Health Services*

Wisconsin developed a platform for their immunization registry that they have now shared with about 16 states. The benefit is that multiple states have very similar systems with similar capabilities, however, they are not currently able to exchange data across state lines. The primary barrier to sharing data is legal, not technical. Immunization information system data originates from a variety of sources regulated by different state laws. For example, there are restrictions on sharing vital statistics records.

A few states have developed data sharing agreements, but only as a result of a long legal process between the two individual states. No national data sharing arrangements exist, although there is interest in developing one for all states to use.

Recently, the Health Information Security and Privacy Collaboration has developed an “Action and Implementation Manual” summarizing the work of seven other collaboratives. Among other topics, the manual addresses harmonizing state privacy laws, policy options for intrastate and interstate consent, interstate disclosure and patient consent requirements, and inter-organizational agreements. Among the tools developed are a model data-sharing agreement for public health, with a modification specific to immunization information systems, and a model data sharing agreement for private entities.<sup>ii</sup>

### **New York - Incorporation of Registries in Electronic Health Records**

*Gus Birkhead, Deputy Commissioner, New York State Department of Health*

In 2008, New York passed P.L. 2168 mandating the reporting of immunization information by health care providers. Currently the New York state immunization information system accepts standard HL7 messages via batch load (information from multiple patients at a time being transferred) from EHRs. Fifty-six vendors serve 664 practices, while 141 practices use an in-house system. The barriers of incorporating registries in EHRs include lack of bi-directional or real time information exchange, manual systems (the provider has to collect new shot records and have them transmitted to the New York system), and it’s labor-intensive nature. New York is testing its Universal Public Health Node (UPHN), a system designed to facilitate bi-directional data between state departments of health and local health information exchanges across the state for public health functions. Once funding is pieced together, this system will replace the current batch uploads.

New York has also initiated the Child Health Information Integration Project – CHI<sup>2</sup> – to integrate child health data held by health departments and providers. The principles for development are to create standard infrastructure promoting use and information sharing while maximizing infrastructure already in place. The success of this concept depends upon broader thinking by public health and providers about the potential for new uses of data. It will also require overcoming barriers of siloed funding, funding to support system upgrades, development of new systems with interoperability in mind, and addressing the need to operate dual systems until HIE based systems are validated.

The benefit of incorporating the immunization data with child health information is that it creates one system for integration with EHRs, it is a better use of limited funds and provides more comprehensive population data for both public health and providers.



## **Michigan - Funding Needs and Resources**

*Bob Swanson, Director, Division of Immunization, Michigan Department of Health*

The Michigan Care Improvement Registry (MCIR) has maintained a high functioning system through a variety of funding sources. Michigan spends approximately \$3.5 million a year on the registry. Funding comes from the Healthy Michigan Fund (tobacco tax), Medicaid Match (50/50 cost sharing from Medicaid dollars), Sickle Cell Program (case management system currently being applied to prenatal Hepatitis B case management), State General Fund, BMI Development, and MCH Block. Last year the state legislators proposed to cut the Healthy Michigan Fund, which pays for almost half of the total budget, but providers rallied around the benefits of the registry and funding was restored.

The Michigan registry integrates well child visits, newborn screenings (genetic testing data), early hearing program, and the sickle cell program, which all link back to the registry. Vital record feeds are uploaded to the registry daily, and WIC clinic information is updated on a monthly basis. MICR attention is divided amongst vaccine preventable diseases, parental Hepatitis B prevention, and education and outreach. This integration of services into the registry helps sustain the entire system with additional funding sources.

According to Mr. Swanson, an important contributor to increased immunization rates is the Michigan immunization registry.

The cost of implementing electronic health records has been a long-standing concern and an impediment to their widespread adoption. This cost is typically borne by the institution or practice implementing the records. Immunization information systems have been largely funded through federal immunization grant funds authorized by Sec. 317 of the Public Health Service Act. Health information exchanges have secured funding from a variety of sources, both public and private.... financing is still a concern but is no longer the leading concern. The American Recovery and Reinvestment Act provides billions of dollars for health IT projects (the midrange estimate is \$20 billion over five years). This sum will include support for individual practices to implement electronic health records as well as grants to states to facilitate and expand the use of electronic health information using nationally recognized standards. It is not yet possible to determine the impact of this infusion of funds.<sup>iii</sup>

## **Development of Action Items**

### **Proposed Strategy Areas**

Presenters and participants considered the following areas for broad action needed to advance the vision outlined above:

1. Exchanging immunization registry data across state lines
2. Integrating immunization registries and electronic health records
3. Leveraging existing resources and mobilizing to secure additional funds needed to support the above strategy areas

Participants explored the first two areas in intensive small group discussion, with funding as a cross-cutting need.

### **1. Exchanging Immunization Registry Data across State Lines**

Interoperability of registries between states is needed to accommodate the contemporary needs of an increasingly mobile society, while meeting numerous public health goals, including enabling appropriate and timely response to local emergencies and major disasters, and reaching vulnerable populations that may fall through the cracks of the health care system. A federation of state, local, and federal systems should be established with a focus on phasing in interstate data transport while guided by national standards.

Discussion highlighted the fact that the technology to make these connections exists, but there are policy barriers and capacity barriers holding it back. There are challenges in state legislation on privacy and confidentiality that need to be addressed, federal laws limit the ability to share certain data, there are a variety of restrictions on sharing data between states, and there is an imbalance in existing registry systems due to the variations in platforms, capabilities, and time of creation.

Specific ideas for moving forward on this issue center around identifying what the legal barriers are, finding examples of how other groups have overcome similar barriers, developing a roadmap for states to follow in overcoming the barriers and looking for incentives to drive interest and momentum. They are outlined in the last section of this document.

If the challenges of exchanging data across state lines can be addressed, it will go a long way in demonstrating the benefits of the immunization registries to both providers and the public.

### **2. Integrating Immunization Registries and Electronic Health Records**

Successes should be showcased and replicated nationwide. The urgency of integrating not only immunization registries, but public health data in general, with electronic health records was clearly described at the summit and in the summary sections above. The challenge is how to accomplish it to meet the requirements of the HITECH Act. Some states, like Michigan, have demonstrated the benefit of the partnership to providers, evidenced by providers fighting to save state funding for the Michigan system.

During the breakout session, a number of ideas were generated for follow-up (See Chart 1). Participants affirmed that immunization registries are the most advanced public health data systems and can be used as opportunities to expand to other important public health data sets in the future – as a proof of concept of the benefits of sharing data with public health and bolstering public health systems. There is

wide variability in the sophistication of immunization information systems in different states, resource and manpower issues in both state and provider offices, and potential legal hurdles to overcome.

There was also discussion around challenges in the Family Educational Rights and Privacy Act (FERPA) and the Health Insurance Portability and Accountability Act (HIPAA) and the need to work with the appropriate federal agencies to remove existing barriers for sharing data with schools. Fortunately, new attention and resources from the federal government provides an opportunity to address some of these challenges and improve current data systems, which in turn can lead to improvement of health outcomes.

### 3. Funding

The American Recovery and Reinvestment Act provides a new source of funding, in addition to the federal Sec. 317 grant program, for the improvement of immunization registries. This funding can help states capitalize on the movement toward integration of public and private data systems. However, additional federal resources are needed and states also have to be creative in developing sustainable funding systems – one of which may be the integration of various public health data systems.

## Proposed Next Steps

A summary of action items suggested by the Summit attendees is listed below.

<b>Chart 1. Action Items Suggested by Summit Attendees</b>		
<b>Activity</b>	<b>Who</b>	<b>Expected Outcome</b>
<b>Distribute summary of summit proceedings</b>	ASTHO	Increase awareness of benefits of registries and awareness of the importance of linking to electronic health records
<b>Develop ASTHO position statement in support of linking public health data to electronic health records</b>	ASTHO	Illustration of state health official support of the link as a useful tool for improving health outcome
<b>Build a value case for registries from the providers perspective</b>	TBD	Illustrate the benefits of the link to public health data
<b>Work with federal agencies to address the exchange of data in light of HIPAA and FERPA</b>	TBD	Identify the perceived barriers and working towards a solution so that schools can participate in registries.
<b>Make Prevention Task Force research information widely available to providers</b>	PTF will publish and put on web	Illustrate the data in support of the many benefits of uses of immunization information systems
<b>Develop a white paper on the link between registries and vaccine safety</b>	TBD	Summarize the PRISM project as an example of how registries can serve as a tool in monitoring vaccine safety
<b>Convene a work group to move the recommended actions forward</b>	TBD	Have one group take the lead on moving the agenda forward either through existing mechanisms or by identifying new avenues

<b>Identify legal barriers to the sharing of data across state lines</b>	TBD	Have a comprehensive list of the legal barriers as a first step in developing a solution for overcoming them
<b>Draft Model legislation for sharing IIS data across state lines.</b>	TBD	Create a resource for states to use when attempting to develop agreements for sharing data.
<b>Ensure public health is actively engaged with the federal government on the HIT goals and standards</b>	ASTHO/ CDC/ DHHS	Keep state health entities apprised of the latest developments and ensure that the recommendations can be achieved and are useful for public health
<b>Work with vendors at the national level to establish baseline requirements or data sets for IIS</b>	TBD	Develop consistency across states – helps the second wave of states know what to expect and it helps national or regional providers to have consistent practices across all states.
<b>Develop effective information architecture and develop a migration roadmap that is integrated with other public health information systems.</b>	TBD	Develop the ideal system for states to work towards and a clear path for how to get there
<b>Identify states that are ready to link with EHRs</b>	ASTHO	Catalogue which states are ready, which are in fact linking up with providers – this will be helpful for the next wave of states to know who to contact for guidance.
<b>Identify best practices/lessons learned from the 1<sup>st</sup> wave of state health departments that connect with EHRs</b>	ASTHO	Provides useful information for those states that are working on linkages
<b>Ensure adequate funding</b>	All parties	
<b>Identify creative approaches to long-term funding</b>	TBD	Help states see other possibilities for funds such as Medicaid, MCH, WIC, etc.
<b>Develop a business case to illustrate the value of having federal funding for categorical public health programs be flexible enough to allow cross-program collaboration</b>	TBD	Provide flexible funding

In the short-term, ASTHO will

- Make the information from the immunization information system summit widely available.
- Create a standing work group of interested Summit participants to continue the work identified, funding permitted
- Circulate a revised vision statement for potential sign on by interested parties.
- Confer with the partners and determine which of the recommended actions to focus on moving forward, with appropriate sequencing, timelines, responsible lead and contributing parties, and expected outcomes.

<sup>i</sup> Hinman, Alan R., and Ross, David A. Immunization Registries can be Building Blocks for National Health Information Systems. *Health Affairs* 29 No. 4 (2010) 676-682.

<sup>ii</sup> Ibid.

<sup>iii</sup> Ibid.