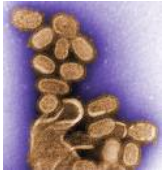


2010 H1N1 Summit February 1 – 2, 2010, Scottsdale, Arizona

Executive Summary



Introduction

The outbreak of Novel 2009 H1N1 Influenza in April 2009 became the 21st Century's first global infectious disease pandemic. Through January 16, 2010 the CDC estimates between 41 million and 84 million U.S. cases occurred, including 183,000 to 378,000 hospitalizations and 8,330 to 17,160 deaths.¹ An unprecedented public health response continues to this day.

To better understand the early response experience of state immunization registry programs – including barriers encountered, best practices, use of technology, and lessons learned – Scientific Technologies Corporation (STC) convened a two-day H1N1 Summit in Scottsdale, Arizona, in February, 2010. Invited participants included twenty-three (23) representatives from seven (7) state Immunization Programs, the American Immunization Registry Association (AIRA), the Association of State and Territorial Health Officials (ASTHO), the Centers for Disease Control and Prevention's Immunization Support Branch, and the Public Health Data Standards Consortium (PHDSC).

This Executive Summary presents Summit highlights organized around the six discussion areas, each describing participant experiences, perspectives and advice concerning Novel 2009 H1N1-related preparations and response.



Topic 1: H1N1 Planning

Planning activities typically included revisiting or revising state and local Pandemic Influenza plans, pre-registering and/or registering H1N1 vaccine providers, and determining vaccine allocation procedures and policy.

What Worked:

- Almost all participants reported a strong working relationship with their Public Health Emergency Preparedness (PHEP) programs. Prior drills and disasters (e.g. Hurricane Katrina) helped solidify these relationships.
- Several Immunization Programs reported receiving funds from PHEP programs to support staffing and registry tools.
- Lead H1N1 response planning was quickly assigned to the Immunization Program office for almost all Summit participating states. In one instance PHEP retained the authority for determining which provider sites received vaccine allocations.

What Didn't Work:

- While about half of participating Immunization Programs indicated that their state's existing Pandemic Influenza Plan worked well and was employed without significant modification, the remaining states had to adjust their plans, particularly in the areas of vaccine allocation procedures, enrolment of new providers, and accounting for differences in multiple versions (e.g. county) of existing pandemic response plans.
- Although about half of participating Immunization Programs were able to require that providers report H1N1 doses- administered to the state's registry, the remaining states did not have an enforcement mechanism and subsequently felt that this negatively impacted reporting to their registry. Several states were able to promote participation through language included in their H1N1 Provider Registration process or their Provider Agreement forms.

¹ U.S. Centers for Disease Control and Prevention, Atlanta, GA. *CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations and Deaths in the United States, April 2009 – January 16, 2010* (Accessed Feb. 12, 2010); Available at: http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm

Challenges:

- All participating states deployed mechanisms for providers to report aggregate doses administered, though several reported varying degrees of compliance and timeliness. Several Immunization Programs reported the need to closely monitor provider aggregate reporting, as well as doses-administered reporting. States without the ability to mandate reporting of adult vaccinations to their registry faced special challenges for securing provider compliance.
- Changes in CDC aggregate reporting requirements (campaigns and tiers) early-on led to confusion, delays, and the repetition of certain work. The ultimate decision by CDC to terminate mandatory aggregate reporting after only a few weeks also led to some confusion and raised the potential for providers to refrain from entering data to the registry or other reporting mechanisms.

What Could Be Done Differently:

- H1N1 planning information from CDC was felt to arrive too close to critical Immunization Program decision-events. In the future, participants felt that such information needs to arrive earlier and leverage lessons learned from the current event.
- Several states reported they felt compelled to compromise on certain reporting requirements, such as lot number reporting, with some providers – in the future they would implement new strategies to promote or incentivize reporting and would take a stronger position on this point. Once current registry data is analyzed, states felt they would have quantitative evidence to support this stance in the future.



Topic 2: Provider Registration

All states managed a program to recruit, register, train, and monitor providers requesting H1N1 vaccine shipments. States also had to determine which providers would receive vaccine doses from among all interested applicants.

What Worked:

- Provider registration was centralized at the state-level in about half of participating Immunization Programs. About half instituted an on-line Web-based registration system, some in a way that allowed data to be uploaded to their state registry.
- Recruitment was accomplished through media advertisements, fax, Web site solicitations, Health Alert Network, and other techniques. Some states reported doubling their participating provider sites – one state indicated a 12-fold increase in participating providers within a three-month period. A significant proportion of newly-participating providers – in most states nearly 100% - were “non-traditional” providers: pharmacies, OB/GYN and Family Practice offices.
- Tribal Nation participation was reported to be near 100% among participating states.

What Didn't Work:

- Provider registration packets were late in arriving from the CDC. This led several states to initiate procedures that had to be either revised or repeated following the availability of these packets.
- Although most participating states successfully secured temporary staff – between 1 to 11 persons per program – to manage elements of their provider registration process, about half reported delays of weeks to months in their procurement process. Temporary staff typically assisted with outreach, data validation, and training efforts.

Challenges:

- Most states registered providers before determining who and how many would receive vaccine shipments. In some instances this may have created unfulfilled expectations on the part of some provider-applicants, with little time and resources available for Immunization Programs to address such concerns.
- Sustaining new provider involvement as long-term registry participants for routine vaccinations was reported to be the near-term focus of most state's recruitment efforts. Most states had not yet had time to evaluate the mix of these providers in their registry reports or to devise and implement a strategy to sustain their ongoing registry participation.
- Enrolled providers did not always participate in registry training, leading several states to anticipate some future data quality issues once they evaluate submitted reports more closely. Provider training was accomplished via Web-based videos (3 states), interactive Tele/Web-conference (1 state), regional and train-the-trainer sessions (2 states), and through Help Desk staff (all states). One state distributed instructional cards affixed to flash-drives containing their Mass Immunization Stand-Alone application. Almost all participating Immunization Programs



created instructional job-aids for new providers. One state required training participation in their Provider/User Agreement. Another embedded their registry URL address within their User Guide rather than including it in the e-mail containing provider's user-name and password.

What Could Be Done Differently:

- States without an online provider registration system desired one in the future.
- Most participating Immunization Programs indicated they would like to create some mechanism to more closely tie vaccine re-supply to vaccine dose reconciliation by providers in an effort to obtain greater accuracy and compliance.



Topic 3: Vaccine Management

Participating states were approximately equally divided between those that centralized the population of vaccine lots for providers and those that required providers to populate their own inventories in the registry upon receipt of vaccine shipments. Three states used a vaccine management tool in addition to VACMAN; all but two states required that lot numbers be reported by providers.

What Worked:

- Most states indicated no major errors in the McKesson files they received, but not all states uploaded these files to their registry.
- Use of a vaccine management system for H1N1 was felt by at least two states to prepare them for its future use to manage routine vaccine management statewide.

What Didn't Work:

- Two states decided not to accept batch uploads for H1N1 doses administered, instead requiring direct data entry by providers. This worked to reduce potential data errors and staff time spent deduplicating records, but also may have been for some a disincentive to provider data submission.
- Tracking vaccine transfers between providers was reported to be a common problem, especially among pharmacies. Pharmacies often resisted entering data to the registry. One state reported that limiting vaccine quantities shipped and using a just-in-time shipping model helped control this problem for some providers.
- A CDC mechanism allowed pharmacy chains to receive vaccine supplies independently of the state's centralized ordering and distribution processes. This circumvented the Immunization Program's ability to effectively monitor inventory and manage vaccine transfers.

Challenges:

- States that received H1N1 doses-administered registry uploads via batch or interface processes reported significant quality assurance efforts to correct data entry errors, especially among newly-participating providers. One state program with a centralized vaccine depot entered all vaccine inventory prior to shipping to providers, the majority of which were new registry enrollees. Provider compliance with lot number entry, and doses-administered reporting was felt to be variable, complicating subsequent vaccine reconciliation and re-supply management.
- Several Immunization Programs commonly observed inaccuracies between the quantity of vaccine shipped, quantity available, and quantity administered for many providers. These discrepancies reportedly were due to gaps in time between the administration of doses and their reporting to the registry, differences in the reporting mechanisms (e.g. paper vs. direct registry entry vs. batch data uploads via provider interfaces), and the relatively large proportion of new and inexperienced providers enrolled.

What Could Be Done Differently:

- One state tied vaccine re-supply to the provider's ability to reconcile doses-administered via their registry. Several states indicated an interest in equitable ways that this might be enforced in the future.



Topic 4: Data Collection

Participants reported using a mix of four (4) data entry mechanisms: 1) Direct entry to registry; 2) Entry to Mass Immunization module; Batch or Interface from electronic medical records systems (about 33% of vaccinations where applicable); and 4) Paper forms (commonly <20% of vaccinations).



What Worked:

- Some states used their Provider Agreements to indicate their required fields.
- At least one state embedded their registry URL Web address within their User Guide, forcing new providers to at least inspect the training materials prior to using the registry.
- One state instituted a financial incentive for certain school-based vaccination providers that seemed to enhance participation, as well as providing an entrée to schools for future routine vaccination efforts.

What Didn't Work:

- Military installations, Veteran's Administration hospitals, and pharmacy chains comprised a set of "carve-out" providers with independent processes that often circumvented state Immunization Program efforts to obtain complete and accurate vaccination reports.
- Summit participants described delays in obtaining timely data and provider-reporting compliance issues. Some states had experience with and advocated for a sanctions-based approach (dose reconciliation before additional vaccine shipments) versus an incentive approach. Incentives suggested included showcasing the benefits of registry participation (e.g. cost-savings associated with back-to-school reporting), provider testimonials, a provider feedback registry snapshot report, and financial incentives.

Challenges:

- The majority of paper forms received by participating state Immunization programs were from newly-participating providers, some who did not have Internet access. A concern common among participants was that H1N1 data entry alternatives (like paper) might impede some provider's from transitioning to direct registry data submission in the future.
- Several Summit participants reported using temporary staff to assist with various data entry or data quality operations. However half of the participants reported staff-procurement delays between 6 weeks to 5 months.

What Could Be Done Differently:

- Some states that allowed newly-participating providers direct registry access indicated that in the future they would restrict access to just the Mass Immunization module until the providers received adequate training. A large percentage of staff time in at least one state was devoted to "cleaning" registry data entered by new providers who had "tested" the system by entering fictitious data.
- Pending American Recovery and Reinvestment Act (ARRA) funds are anticipated to support states working with Health Information Technology vendors to standardize electronic interface requirements. Summit participants agreed that state Immunization Registry systems represent the most mature population-based electronic health record system currently in operation.
- Most states expressed interest in incentives and inducements that would promote increased, more complete, and timely provider data reporting.
- Instituting Bar-Code capability was also supported by the majority of Summit participants. This methodology was not used because this capacity did not currently exist for most states. In addition, some future coding standardization is needed, even if only to standardize certain intra-state non-demographic data attributes such as Vaccinator ID, injection site, etc.
- One state's "Adopt-a-School" program paid providers \$5.00 for each H1N1 school-based vaccination; while successful, the state wished they could have increased the compensation for an even better response.
- Participants suggested a future concerted effort to have pandemic influenza immunization providers, especially pharmacies, start using electronic interfaces to report data with state registries.



Topic 5: Reporting

Approximately three-fourths of Summit participants used "Option 1" as the basis for their CDC aggregate doses administered (CRA) weekly reporting, most without difficulty.

What Worked:

- Most states reported that they did not notice a significant decrease in provider reporting following the expiration of CDC's required aggregate reporting provisions, though most did not inform their providers when these provisions were lifted.
- Two states indicated mostly positive experience with an early Executive Reporting tool. Additional functionality was desired in order to support both routine and pandemic registry data summations.



- Blast-faxing to providers was an effective communication strategy for at least one state. This reportedly aided in establishing and clarifying reporting expectations and procedures, among other topics.

What Didn't Work:

- CDC advised a "least-burdensome" approach to provider data reporting. For some states, this resulted in certain reporting compromises – some data fields were sacrificed, Immunization Program staff entered data on behalf of some providers, and aggregate reporting was of variable quality and timeliness.

Challenges:

- The "novelty" of H1N1 produced a constant demand for various management reports, almost all of which resulted in the creation of ad-hoc scripts. The majority of these ad-hoc reports concerned vaccine inventory disbursement and status or doses-administered quality assurance. A list of reports thought to be most helpful is being assembled. Because of the unpredictability of administrative requests for such reports, most Summit participants indicated interest in additional tools that would facilitate future flexible and rapid report creation.

What Could Be Done Differently:

- Summit participants suggested a variety of additional capabilities that would assist their future reporting efforts. Among these was the ability to better define report geography (e.g. counties), the addition of GIS capacity, the ability to create custom value ranges (e.g. age, date-of-birth), and the use of text messaging to communicate better with a subset of providers and patients.
- Also suggested was a post-H1N1 follow-up survey of providers and patients to characterize their vaccination experience and ideas for improvements.



Topic 6: "Hot" Topics

The final Summit discussion session addressed multiple "Hot" topics. Among these were discussions concerning how Immunization Programs accounted for remaining H1N1 vaccine doses, their experience working with pharmacies, lot recalls, timely data entry by providers, and the use of registry interfaces.

- States reported not having reliable indicators of remaining vaccine supplies in provider offices. This is typically due to a failure of providers to reconcile their doses, or a lag in providers entering doses-administered data to the registry. At least one state is planning a survey to account for doses in provider's inventories.
- Three (3) states described working with national pharmacy chains. Pharmacies represented one of the largest categories of "new" providers, and states reported that many have expressed interest in continuing as "routine" vaccine providers (although legislation would be required in some states). However, states also reported that pharmacies often resisted entering their data to the state registry – at least one state compensated by offering to enter backlogged records if the pharmacy would begin entering future records. CDC's direct-supply of vaccine to pharmacies also significantly complicated state's centralized vaccine management and reporting capabilities.
- States indicated their need to rapidly identify recalled lots and to rapidly communicate about them to providers and patients. One participating state reported that the three recalls to-date have helped ensure provider compliance with required fields-reporting to the registry.
- States that use electronic interfaces with provider's medical records systems face significant continuing problems with vendor data compatibility, interface standards, and timely response. The Immunization Program in one state with 90 providers using electronic exports conducts an annual review of each provider's electronic data submissions. Other states discussed the current federal Health Information Technology efforts as a catalyst for forming closer, more productive relationships between Immunization Programs and state Information Technology offices.

Conclusion

It is important to note that "success" and "failure" can be measured differently from the perspective of the four (4) key H1N1 response stakeholders (federal government, state and local public health, and providers). STC is currently collaborating with states and partnering agencies to capture and disseminate Immunization Program experience with their registry operational procedures, tools, and stakeholders associated with the national response to Novel 2009 H1N1 influenza. Additional information may be obtained by contacting STC at www.stchome.com or by calling our Tucson, Arizona headquarters at 1-520-202-3333.