Where Does the Right Size Influenza Roadmap Lead Us?

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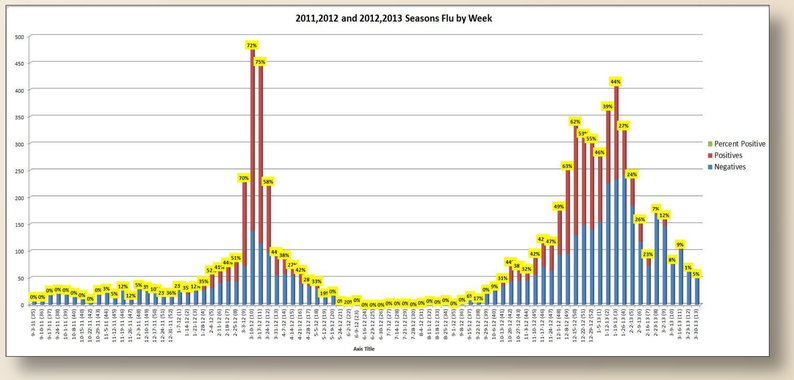
Abstract

Iowa's influenza surveillance program was compared to the Draft Influenza Virologic Surveillance Right Size Roadmap (DIVSRSR) to determine how current practice contrasted with the roadmap. The Iowa surveillance program has grown through the years, not as a result of strategic planning but as a consequence of available resources. To perform the analysis, the State Hygienic Laboratory (SHL) combined efforts with the Iowa Department of Public Health (IDPH) to gather data, analyze outcomes, model performance, and determine the opportunities and barriers to changes that could be made to closely align the existing influenza program to the right size roadmap. Throughout the process, SHL and IDPH used tools, such as the sample size calculator, and other resources provided by the DIVSRSR to identify the optimal influenza surveillance program for Iowa. Recognizing that numbers do not sufficiently determine the optimal surveillance system, the Iowa team looked at critical relationships within the state, such as clinical labs, ILINet (Iowa's Influenza-like-illness network) providers and others to determine the impact of these relationships on influenza surveillance. This project assisted SHL in determining the core capabilities of laboratory services needed to best serve the influenza surveillance program in Iowa. The decisions from this exercise are far reaching for local and state public health in Iowa and also impact national and global surveillance activities from the perspective of Iowa's contribution to these surveillance systems. (This publication was supported by Cooperative Agreement # U60HM000803 from CDC and/or the Assistant Secretary for Preparedness and Response. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC and/or the Assistant Secretary for Preparedness and Response.)

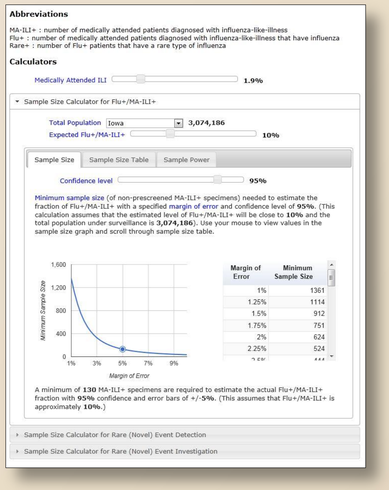
How Iowa Aligns with the Roadmap

Roadmap	Iowa
Sampling	• Clinical labs submit all positives for confirmation at the beginning of the season and until each lab submits 3 confirmed positives; • Surveillance sites (ILINet providers) submit specimens each week; • All specimens from hospitalized patients admitted with suspect influenza are submitted. • The medical examiner submits specimens on any suspect death from influenza. • SHL submits positives to CDC for further characterization for strain types, antiviral resistance and vaccine determination.
Testing	• SHL performs PCR on all submitted specimens and subtypes Flu A positives.
Data Management	• SHL submits results electronically to IDPH and CDC daily; • SHL requests data from every diagnostic laboratory performing influenza testing, weekly.
Partnership	• Influenza testing is a mechanism to build strong partnerships with clinical laboratories throughout the state; • SHL and IDPH provide annual training for clinical labs and ILINet providers.
Quality Systems	SHL influenza testing is part of the overall quality assurance plan.
Surge - Maintain the expertise (a minimum level of readiness) and surge capabilities necessary for pandemic response.	• SHL has a pandemic influenza plan; • When flu testing becomes greater than is manageable, SHL implements its incident command system; • Two 24-well nucleic acid extractors (Biomerieux easyMags) and a 96-well automated extractor (Qiagen BioRobot) are each utilized at least monthly in non-surge time periods so they are always ready for surge use.
Financial Resources	Funding comes through the ELC grant and other supplemental grants. There is no funding from the state or fee for service.



Right Size Sample Size Calculator

The Influenza Sample Size Calculator uses statistical methods to determine the appropriate number of flu samples to test based on thresholds of detection, acceptable confidence levels, population size and acceptable error rate. The calculator has inputs for population size which can be at the national level, state level, county level or even a local level. It also has inputs for expected prevalence rate, based on flu positives per medically attended influenza-like illness (ILI). Additionally, slide bars exist to allow easy adjustments to the inputs to visualize a range of outputs in a graph, table form and also a power graph. Within the calculator are three sub-calculators that allow statistical assessment for current situational awareness (table 1), detection of a rare (novel) event (table 2), and rare (novel) event investigation (table 3).

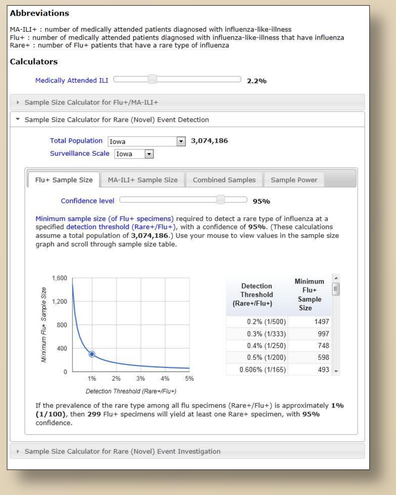


I. Situational Awareness:

Week 41 (10-13-2012) = second week when Flu+/ Flu+/MA-ILI+ rate was equal to or greater than 10%. SHL tested 49 specimens, which resulted in a 95% confidence level and an 8.32% margin of error that the true rate was 10%. To be at a 95% confidence level with a 5% margin of error, SHL would have needed to test 131 specimens, or 335 specimens to be at a 95% confidence level with a 3% margin of error.

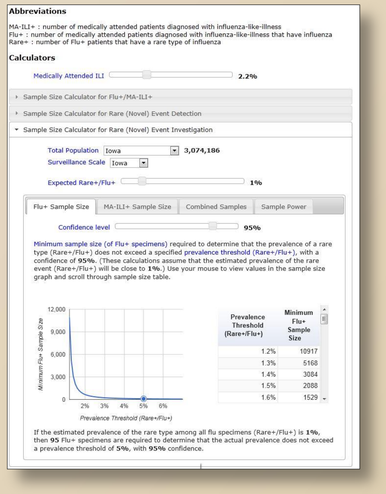
II. Detection of Rare (novel) event:

Using Iowa population data (3,074,186) to detect a novel strain circulating, and assuming a prevalence of 1% and a confidence level of 95%, SHL would need to test 299 Flu+ specimens to detect the novel strain. This type of calculation is very useful and would add to the discussion of the surveillance system for a novel influenza virus like H3N2v or H7N9.



III. Investigation of rare (novel) event:

If a novel strain is detected, SHL would need to test 95 Flu+ specimens to determine that the prevalence threshold of 5% is not exceeded, with 95% confidence level. The Sample Size Calculator was used in an actual event in Iowa when a novel influenza virus (H3N2v) was detected in a small eastern county. The calculator gave Iowa good information about the number of samples that should be collected.



Lab and Epi Tabletop Exercise

This was attended by management staff from the laboratory and epidemiologists. The attendees arrived at several strategies to implement the Right Sizing program:

- Using scenarios as examples of what we are trying to accomplish may help translate the art into science.
- The calculator was useful in that it generated good discussion. It gave structure to the conversation and placed it into the realm of scientific observation with less dependence on past experience.
- The calculator might be most useful to determine distribution among regions at a given point in the season.
- The calculator would be more useful if used for regional data or local data, rather than by state.
- The project facilitated a valuable discussion between lab and epi that probably would not have occurred otherwise.
- Participants concluded that it is critical for lab and epi to work together more frequently to make the program successful.

Laboratorian Tabletop Exercise

Another tabletop exercise was conducted for lab analysts. The outcomes of this tabletop exercise included the following:

- Analysts who perform this testing vary in their knowledge of the influenza program. The clinical analysts in general lack an awareness of how the results they produce are used in the surveillance system.
- The lab is the link between the program and the submitters through incoming phone calls regarding submission requirements.
- The lab leadership needs to provide more education and training to convey the influenza surveillance goals. It was recognized that clinical analysts and epidemiologists need to have discussions about the program regularly to share information and understand the goals.
- Analysts have insight into the needs of sample submitters.

Conclusion

Influenza surveillance fills multiple roles at the national, state and local levels. Iowa found real value in participating in this process to analyze the program much more thoroughly than it had ever been done in the past. The discussions about the goals, and the value of activities led to a better understanding of the program's importance and how to more effectively manage the program in possible future outbreak situations and funding constrictions.