Novel Influenza H1N1 (swine-like) Virus: A Look Inside the Laboratory

By: Katie Masterson & Mark Glazier

During a typical influenza season, the Indiana State Department of Health (ISDH) virology laboratory receives, on average, between 250 to 350 clinical specimens. At (what was thought to be) the end of the 2008-2009 influenza season, the lab had received approximately 203 flu specimens; a "light" season for the lab, especially after such a heavy 2007-2008 flu season. Influenza is as unpredictable as the weather, and not much thought was given to this fairly mild season, other than it's rapidly approaching end. Much to our surprise, what we thought was the end, was actually just the beginning.

With the rapid influx of specimen submissions for H1N1 testing, the laboratory was faced with many new and difficult challenges. Processing and testing a large volume of routine samples in a given week is often daunting, but when faced with the task of testing 600 specimens in a week, what was the lab to do? This was undoubtedly new territory, not just for the laboratory but for everyone involved in public health. Were we prepared and up for the challenge?

As expected, when word first broke about the flu concerns, the lab was inundated with hundreds of flu specimens. With the number of samples received, the immediate roadblock we faced was the fear of reagent and supply shortages. Would we have enough reagents and supplies to maintain and continue testing? The short term answer was no. The entire country was dealing with this outbreak and testing supplies and reagents were in high demand. In order to conserve reagents, the lab was forced to become more restrictive in regards to specimen submissions. For a time, specimens were screened and sorted for testing based on travel history and rapid test results. Specimens with positive rapid results and/or appropriate travel history were considered high priority and immediately tested for influenza. Those specimens with negative or no rapid results were considered lower priority and set aside for later testing.

However, with a little help from the Centers for Disease Control and Prevention (CDC) coupled with a lot of help from many dedicated ISDH employees (both laboratory and purchasing), we were able to receive reagents and supplies in a timely fashion and maintain testing. Another challenge the lab encountered during the outbreak was equipment and instrumentation issues. The equipment used on a routine basis for testing has

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ISDH Lab Hosts Packing and Shipping

By: Shelley Matheson

Twenty-nine Indiana Sentinel Laboratorians attended the Indiana State Department of Health (ISDH)-hosted training, "Packaging and Shipping: Division 6.2 Materials." This course was taught by Patricia Payne, Ph.D., MT (ASCP), a consultant to the Association of Public Health Laboratories. Dr. Payne has been conducting these courses throughout the United States for more than six years.

This intermediate-level, one-day program provided a comprehensive overview of regulations applicable to packaging and shipping infectious laboratory specimens and cultures. Dr. Payne provided lectures, demonstrations and allowed participants to perform a hands-on group exercise while in class. These instructional tools

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always been adequate to accommodate even the heaviest of specimen loads. Given that the lab has several automated nucleic acid extraction instruments, we’d be fine, right? Not exactly. The shortage of reagents and supplies, combined with the restrictive nature of CDC’s Federal Drug Administration (FDA) approved Polymerase chain reaction (PCR) procedure for novel H1N1 virus, forced the laboratory to use an extraction instrument not routinely utilized. Because of this, instrument performance issues were initially encountered. These issues required emergency maintenance to be performed so that the instruments would be in top working condition.

Additional laboratory-related challenges faced during this flu event included issues pertaining to our Laboratory Information Management System (LIMS), as well as staffing concerns. The virology laboratory LIMS module in place at the time of the outbreak was designed for normal, routine sample testing, which includes both PCR and virus isolation. A PCR-only LIMS module designed to handle pandemic influenza, was in development and projected to be implemented by the end of the summer. Unfortunately, our need for such a LIMS module turned out to be a necessity before summer! At the beginning of the flu outbreak, specimen reporting was extremely difficult and time consuming, especially given that two sets of results were needed to conclude a sample – PCR and virus isolation. In order to alleviate this problem as well as to increase specimen reporting, ISDH and LIMS staff quickly tested and moved a PCR-only module into production. After the implementation of this LIMS module, many of the reporting issues were eliminated. In addition to LIMS issues, staffing concerns became immediately apparent and it was clear that working a normal work shift was not enough to handle the incoming specimens; after-hours and weekend work was necessary. Asking staff to work extended and weekend hours becomes difficult, especially when stress and tension levels are already elevated and the idea of compensation unknown. But, with a dedicated and highly proficient staff, anything is possible. The ISDH virology staff worked long days and weekends to keep up on testing and help reduce the backlog. In addition, many other ISDH staff members worked extended and weekend hours to help with data entry and specimen reporting. Many thanks to all who contributed during this outbreak!

Even though specimen submissions have decreased, the flu outbreak is not over. There are still so many questions circulating about this particular flu virus. Will we see this virus again in the coming weeks and months? We don’t know. What we do know is that despite the many challenges we faced this time, we will be better prepared and able to handle the challenges that face us in the future. In the words of Confucius, “Success depends upon previous preparation, and without such preparation there is sure to be failure.”

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STARLIMS Aids Laboratory Swine Flu Response
By: Carl Rothenbacher

STARLIMS is a laboratory information management system (LIMS) that the lab uses to help automate the process of testing samples throughout a sample’s life cycle. This begins in accessioning, where sample data is entered into STARLIMS and samples are bar-coded. It continues to the testing area, where test result data is automatically imported into STARLIMS for those assays with automated test instruments. Finally, it assists with the release process by generating standardized lab reports. For samples from submitters who have signed up with LimsNet, the lab’s web-based submission and reporting system, data is entered and reports are delivered to submitters electronically, eliminating both the need for manual data entry and the need to mail or fax reports.

During this year’s flu outbreak, the lab experienced a large spike in virology specimens from around 10 samples per week to over 600. The analysts and accessioning staff were working extra hours and recruiting help from other parts of the lab to provide assistance. STARLIMS also helped. Data for a portion of the samples were submitted to the lab electronically, reducing the time-consuming data entry process. STARLIMS also helped track the status and test results of each of the thousands of samples, which would have been an overwhelming task if done on paper.

As useful as STARLIMS was this time around, plans are in the works to make STARLIMS even more effective during the next outbreak. For example:

- Electronic LimsNet submissions accounted for only 20 percent of submissions. For other assays, such as Chlamydia and HIV, that number is above 95 percent. The lab will work with the non-LimsNet submitters to get them signed up and ready to submit electronically.
- An optical character recognition (OCR) module is being investigated, which would allow even paper-based submissions to avoid the data entry step.
- The lab is working with IOT to use a fax server to eliminate the step of printing and faxing reports.

Virologists must currently enter data into three different systems to make it available to the CDC and the epidemiologists at 2 North. Links are being built to lighten the analysts’ loads by making STARLIMS a “one stop shop” that will automatically deliver critical information to not only the original submitter, but to the CDC and epidemiologists as well.

Looking beyond pandemic flu, the lab is in the process of upgrading STARLIMS to provide additional preparedness capabilities, including assays for biological and chemical terrorism. Algorithms for these assays are being built into STARLIMS, along with an automated instrument interface in the case of Chemical Terrorism. STARLIMS will also streamline communication with and provide real time data to CDC and the ISDH epidemiologists.

Preparedness is a core function of the lab, and with STARLIMS, technology is on our side.

Getting the Word Out: Novel Influenza A H1N1 Virus
Outbreak Communications with Sentinel Laboratories
By: Ellie Carter

One of the major players in the influenza A H1N1 response was, and will continue to be, the sentinel (clinical) laboratories throughout Indiana. These sentinel labs—big and small—were faced with running interference between patients and providers who were concerned about whether or not they were dealing with cases of the novel influenza A H1N1 virus.

Due to the uncertainty of all aspects of this particular outbreak posed, the level of concern expressed was certainly valid. Fortunately, the Indiana State Department of Health (ISDH) Laboratory was able to rapidly share information and updates with many of the sentinel labs in the state as a result of newly established relationships with these labs. Beginning in 2008, the ISDH Laboratory has been collecting in-

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A View into the Influenza H1N1 Response-Community Healthcare System: Community Hospital, Munster, St. Catherine Hospital, East Chicago, and St. Mary Medical Center, Hobart, IN

By: Ellie Carter

Nearly all primary healthcare facilities in the U.S. have been affected by the ongoing novel Influenza A H1N1 epidemic which was declared a pandemic in mid-June of 2009. The Indiana State Department of Health Laboratory wanted to get a more in-depth look at its outcome and report on how it affected hospital laboratories in Indiana. To that end, Susan Maio-Hillegonds, Microbiology Laboratory Supervisor at Community Hospital in Munster, Indiana, explained how their hospital system worked to respond to the emerging and dynamic epidemic scenario that played out. She also elaborated on what they have learned in order to continue to enhance their pandemic influenza preparedness plans.

No one can predict exactly how any emergency situation will unfold, but overall, Maio-Hillegonds felt that Community Hospital was rather well-prepared. Their hospital and laboratory already had in place a pandemic influenza policy that was based on preparing for a pandemic of influenza A H5N1. Community Hospital has held numerous planning meetings with representatives from many areas of the hospital. Although the outbreak influenza strain turned out to be different – in subtype and virulence – their policy ended up being good guidance for implementation of their procedures. Some of the laboratory-specific plans included performing all rapid respiratory testing in Biological Safety Cabinets (BSC’s) when available and requiring Personal Protective Equipment (PPE) to be worn by hospital and clinic personnel for collecting and processing of respiratory samples. Where BSC’s were unavailable, the testing staff wore PPE for these activities.

There were also some roadblocks the Community Hospital laboratory encountered. Some of these issues were likely common among healthcare facilities throughout the country: difficulty finding space to segregate patients presenting with respiratory symptoms in the emergency department and outpatient waiting rooms and an overwhelming volume of samples requiring rapid testing. Maio-Hillegonds explained that part of their plan, had the epidemic closed local schools, was to use those facilities as overflow sites. However, since school closures did not occur, Community Hospital is considering making available temporary, tent-style enclosures on-site that can be quickly erected in the future if necessary. A unique conundrum that Community Hospital faced was whether or not to continue using the pneumatic tube system to transport samples to the laboratory. In light of no clear guidance available to address this, it was decided to temporarily discontinue using the pneumatic tube for transport of respiratory samples.

Undoubtedly, every healthcare facility touched by this continuing pandemic has learned many lessons and can now assess how to modify their plans and policies should this influenza virus re-emerge in the fall or for an entirely different virus. Maio-Hillegonds expressed that there were several benefits that this experience afforded Community Hospital. An overarching benefit was “testing the system, plans, and policies” that they had worked so hard to develop and zeroing in on the areas that they could improve upon. She also explained that since their pandemic influenza policies have many similar components to their bioterrorism preparedness policies, they will be able to improve upon those plans as well.

The Community Hospital is not the only laboratory or healthcare facility that deserves accolades for their continued exemplary response and performance during these challenging times. The Indiana State Department of Health owes sincere gratitude to all individuals and organizations for their diligence, cooperation, and patience through these trying times. Together, we are all part of protecting the health of Hoosiers!

Packing and Shipping

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provided knowledge on complying with international, federal, and local transportation regulations. Participants learned how to properly classify, mark, label and document infectious materials for shipping by land, air and United States mail. Participants were tested on their knowledge of the regulations and received documentation of their attendance and testing. Once signed off by their employers, participants were certified for packaging and shipping infectious substances for up to three years.

The April training was an overall success and participants were impressed with the training. Dr. Payne did an outstanding job, and all 29 participants passed their exams. One participant commented, “As a non-technical associate, it helped me to understand different types of specimens and how to package.” ISDH Laboratories will be facilitating three encore packaging and shipping trainings in October with two of them being at offsite locations in Indiana.

Participants of Packing and Shipping get ready for the final exam.
Greetings from the Central Accessioning Laboratory!

By: Chris Grimes

We are normally a busy area, since we receive and process each HIV, Hepatitis, Syphilis, Chlamydia/Gonorrhea, Herpes, Influenza, Mumps, Measles, and Rubella sample that arrives at the ISDH Lab. However, even we were surprised at the explosive nature of the influenza submissions we received in May. When the word went out about the possibility of Novel H1N1 Flu being in Indiana, submissions jumped significantly. The jump was exponential, too, since we doubled the number of flu samples we received each day for that first week!

Fortunately, we have a diligent and dedicated group of people in the ISDH Lab who are committed to making sure the customers get accurate results promptly. Employees from all Laboratory divisions were able to lend a hand and help the cause. These employees pitched in to help with opening packages, labeling specimens, entering data, and handling logistics. During this hectic time, we were able to maintain the normal work with the serology and Chlamydia samples, too.

I am proud to be a member of this dedicated work force, where the customer comes first.

“Influenza Sample Load”

Judy Kerst in Central Accessioning checks in an Influenza Specimen submitted to the Indiana State Department of Health Laboratory.
Communication with Sentinel labs

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formation from sentinel labs including staff contact information, labs’ access to technology, testing availability and test methodologies. Getting to know these sentinel labs has proven to be advantageous in many ways, but most important has been that two-way communication has opened up from a relatively moderate trickle to a much wider and faster flow. For several months, the ISDH Lab has been sending out weekly "ISDH Lab Info" email messages to various laboratory staff. The messages take the form of informational, educational, and/or important/urgent alerts such as with the IHAN (Indiana Health Alert Network) messages.

On Friday, May 24, the ISDH Lab sent out an initial alert to sentinel labs immediately following an IHAN message released about eight cases of novel A (H1N1) swine influenza strain that had been recently reported to the Centers for Disease Control and Prevention (CDC) from two states; California reported six cases from the San Diego area and Texas two cases. This turned out to be just the beginning of a regular stream of information passed on to the sentinel laboratorians-and beyond. The goal of these messages was to keep the labs up to date on information being released that was most relevant to them. The topics focused on influenza sample collection and submission, laboratory safety in processing samples, use of rapid influenza test results, updates on the scope of the outbreak, number of cases in Indiana and the U.S. These efforts were just part of the complete ISDH response which included hotlines for both health care providers and the general public, information available on the ISDH website, as well as regular press releases.

Indiana has begun operating in a surveillance mode of testing which has given the ISDH Lab the opportunity to evaluate the effectiveness of the communications. Thus far, the feedback has been positive along with some constructive suggestions on how to improve communication during emergent situations. The ISDH Lab looks forward to continuing developing relationships with sentinel laboratories in order to ensure the health of Hoosiers and beyond.