Rapid and Thorough Submission of Clinical Specimens/ Isolates to Public Health Laboratories

As part of APHL's Associations Cooperative Agreement work with FDA, the APHL Food Safety Committee convened a Clinical Isolates Work Group* that is attempting to identify and resolve challenges to the rapid shipment of clinical specimens/isolates (related to foodborne illness) to public health laboratories (PHLs) for submission to PulseNet. This report summarizes the work group's findings to date including existing successful partnerships between clinical and public health laboratories, current challenges to rapidly receiving clinical isolates or specimens, workable solutions to these challenges, and proposed next steps for the coming year.

The Issue

One of the core functions of the public health laboratory system is to provide food safety testing for surveillance purposes (1). Critical surveillance systems such as PulseNet and NARMS help form the backbone of our current food safety system. These systems rely on isolates that are almost always coming from clinical and/or reference laboratories. Since many states do not require the submission of foodborne isolates, public health must rely on the voluntary *and* timely submission of such isolates from these laboratories.

When assessing laboratory testing turn-around-times for foodborne illness specimens, the steps from specimen collection to final results can be generally divided into those 'within our control' and those 'beyond our control'. The steps up through clinical laboratory analysis and submission to the PHL are often times beyond PHL control; however, there are ways in which public health can encourage and influence rapid and thorough submission of clinical isolates. The purpose of this work group is to seek out and/or develop successful practices that positively influence providers (clinical or reference laboratories) to submit enteric isolates for public health surveillance in a rapid manner.

Although some state laws mandate the submission of enteric isolates, the laws may not always dictate a time frame for compliance. Many clinical laboratories make the cost conscious decision to batch isolates weekly, bi-weekly or even less often, ensuring compliance with the law but at the unforeseen cost of surveillance. Any delay in isolate submission to public health can severely impact outbreak detection and investigation and prevent disease control efforts.

The more quickly a potential outbreak can be detected, the more likely the subsequent public health investigation will have a successful outcome ultimately resulting in less exposure and illness. With delayed laboratory results, laboratory surveillance- based investigations give way to complaint-based investigations. Relying solely on public complaints or environmental inspection findings reduces the efficiency of the surveillance system as a whole. On the other hand, increasing laboratory capacity and enabling real-time PFGE has a proven track record for early detection of foodborne outbreaks. Laboratory (analytical) testing has been streamlined and many PFGE labs are performing real-time PFGE on STEC, *Listeria* and *Salmonella* isolates. Receiving the isolates in a timely manner is the next logical focal point.

Different jurisdictions handle the issue of isolate submission in different ways. There may not be 'one right way' or 'one way fits all' to address the issue in each jurisdiction, but there are several approaches such as isolate submission laws, specimen transport systems, education and/or relationship building that can be explored and adapted to suit each jurisdiction's needs. This report will provide current findings on isolate submission. We will also review mandatory reporting and isolate submission and

transport systems utilized in some areas. Successes stories will be reviewed as well as ongoing challenges that have yet to be conquered. Finally, we have a list of proposed activities and next steps for this group to take in a continued effort to bridge the gap between clinical care and surveillance activities through rapid isolate submission to public health.

Current Findings

The Clinical Isolates Work Group initially reviewed currently available data and publications in an effort to better understand the overall issue of rapid isolate submission and identify any knowledge gaps and ongoing challenges. Information was extracted from the 2008 APHL *Salmonella* survey, 2008 & 2010 APHL PulseNet surveys, 2011 APHL Food Safety survey, previously identified successes with isolate submission summarized in past issues of APHL's quarterly publication "Lab Matters" and the Council to Improve Foodborne Outbreak Response (CIFOR) Law Project documents.

Mandatory Reporting and Isolate Submission Laws

In APHL's 2011 Food Safety Survey, member laboratories were surveyed about mandatory reporting and isolate submission laws within their jurisdictions for several foodborne pathogens. Mandatory state reporting and isolate submission requirements for six, major foodborne pathogens are summarized in Table 1. Of the 46 state public health laboratories who responded to the survey, 100% require case reporting of *Listeria,* O157 STEC and *Shigella*, 98% require reporting of *Salmonella* (both Non-Typhi and Typhi spp.), 96% require reporting of *Campylobacter*, and only 89% require reporting of non-O157 STECs. Mandatory isolate submission is notably lower with the percentage of states ranging widely from 24-70% according to specific pathogens. The timeframe for submission was not assessed.

Table 1. Percent of state public health laboratories (N=46) requiring mandatory case reporting and/or isolate submission for six of the most common foodborne pathogens.

Foodborne Pathogen	Case Reporting Required by law	Isolate Submission Required by law	Neither Required by law
Campylobacter sp.	96%	24%	4%
Listeria monocytogenes	100%	59%	0%
Salmonella sp. (Non-Typhi)	98%	67%	0%
Salmonella Typhi	98%	70%	0%
Shigella sp.	100%	57%	0%
O157 STEC	100%	67%	0%
non- O157 STEC	89%	61%	9%

Specimen transport to public health laboratories

Courier services provide a means of specimen/isolate transport between the clinical and public health laboratories. The 2010 APHL PulseNet Survey (2) queried members about the use of courier services to transport specimens/isolates to the public health laboratory. The utilization of various courier services remained constant between 2008 and 2010, with the exception of a 21% increase in the use of government-operated couriers (*Table 2*).

Table 2. Comparison of courier service providers that transport specimens/isolates from clinical laboratories to public health laboratories in 2008 and 2010

	Number of laboratories utilizing courier service providers in 2008 (n=61)	Number of laboratories utilizing courier service providers in 2010 (n=56)
FedEx	41 (67%)	42 (75%)
USPS	33 (54%)	30 (54%)
Privately-operated	51 (84%)	47 (84%)
Government-operated	21 (34%)	31 (55%)

Between 2008 and 2010, PulseNet survey respondents reported a decrease in the sole use of government funds and a subsequent increase in the combined use of government and private funds to support courier services (Table 3). Despite decreases in government funding and ongoing economic hardships, PulseNet sites still allocate critical resources to fund specimen transport to PHLs via courier services. A 2008 *Salmonella* Survey conducted by APHL revealed that governmental-funded courier services result in an increase in the submission of enteric isolates from clinical laboratories (3).

Table 3. Comparison of funding sources for courier service in 2008 and 2010

	Number of laboratories in 2008 (n=61)	Number of laboratories in 2010 (n=56)
Government funds (i.e., state/local and federal grants)	22 (36%)	17 (30%)
Private funds	16 (26%)	12 (21%)
State/local or federal grants and private funds (both)	23 (38%)	26 (46%)
Unknown		1 (2%)

Member-Specific Activities and Successes

In order to get a more comprehensive picture of pre-existing partnerships between clinical and public health laboratories and identify any ongoing challenges, several groups were queried about current practices, perceived challenges, and suggested solutions for the rapid and thorough submission of clinical specimens/ isolates to public health. Questions posed included:

i. Please share any activities and/or programs implemented in your jurisdiction that have had a positive impact on clinical specimen or isolate submission or have resulted in a decreased turn-around time in submission of clinical specimens or isolates.
ii. What approaches or ideas do you believe would increase isolate submission and/or decrease turn-around-time in your jurisdiction (e.g. statewide courier system, prepaid shipping supplies, better communication with clinical laboratories, etc.)?
iii. How is your jurisdiction dealing with implementation of culture independent molecular diagnostic assays in clinical laboratories (with regard to isolates and submission to your SPHL)?

The questions were distributed via email to State Public Health Laboratory Directors via APHL's State Laboratory Director (StateDir) listserv, Campylobacter Guidelines public health work group members, PulseNet members via Regional PulseNet Coordinators. The questions were also posed to Food Safety Committee and Clinical Isolates Work Group members during routine calls. Additionally, the questions were posed to foodborne epidemiologists in the OutBreakNet announcements section of CDC's PulseNet SharePoint site; however, no further information was obtained via this last avenue.

Summary of Activities

The work group received responses from 18 State Public Health Laboratories and the New York City Public Health Laboratory. Self-reported activities and/or programs were categorized in one or more areas including courier systems, shipping costs/shipping supplies, mandatory isolate submission laws, education/training, partnerships with epidemiologists, informatics, written guidance/ guidelines, and communication/ relationships. Courier systems were the most frequently mentioned practice among respondents followed by communication/ relationship building activities, isolate submission laws, education/ training, and shipping/ shipping supplies in that order. Specific activities and programs are listed below:

Courier Systems

- State-wide courier systems for enteric isolates
- Pre-existing courier systems for other programs/testing (piggy-backing on such systems)
- Emergency courier service for high priority specimens, outbreaks, etc.

Shipping/ shipping supplies

- Providing shipping supplies such as mailers and collection containers
- Assisting with or covering shipping costs through FedEx accounts, etc.

Mandatory Isolate Submission Laws

- Mandatory isolate submission laws including specific timelines for submission
- Additional or comprehensive language requiring the submission of clinical materials should an isolate not be available

Education/Training (topics included)-

- Packaging and shipping
- Testing trends
- New technology
- Non-culture methodologies for enteric diseases
- Possible collaborations for evaluating and validating cultureless systems
- Rule out/ referral of biological agents
- Relevant clinical signs for reportable illnesses
- Foodborne-Disease Outbreak Training

Partnering with Epidemiologists

- Conducting active, laboratory-based surveillance through FoodNet
- Close collaborations with state or local epidemiologists
    - Epidemiologists educate submitters as to the proper specimens to submit and how to transport
- Cross-comparing reported cases with isolates received in the laboratory to target those clinical laboratories that do not routinely submit isolates.

Informatics

- Having user-friendly submission forms
- Laboratory Information Management System Outbreak Module
- Setting up an auto alert on automated ID/susceptibility testing systems to say "Send to (S/L)PHL"
- Sending out alerts over statewide systems (e.g. HAN or LRN) whenever there are outbreaks reminding labs to report enteric cases of disease and submit enteric isolates.

Written Guidance/ Guidelines

- STEC Guidelines (4)

Communication/ Relationships

- Establishing relationships with clinical laboratories (through training, educational seminars, etc.)
- Communicating reporting/shipping requirements through website, written guidelines, newsletters, email
    - Periodically reminding clinical labs about isolate submission
- Communicating the value of submitting isolates via newsletters, conference calls, on-site workshops, road shows
- Heightening awareness in congregate settings (e.g. LTCF, Nursing Homes) regarding the need to evaluate stools
- Clinical laboratory referral and communication network
- Outreach Teams that partner with clinical laboratories to help encourage submissions

State-Specific Successes

Minnesota-
Isolate submission laws can positively impact the number of isolates being submitted to PHLs. However, with the increasing availability of culture-independent diagnostics, isolates may be unavailable. Minnesota has worded their reporting rules in such a way as to require the submission of additional clinical materials should isolates not be available.

> "*All medical laboratories shall forward to the Minnesota Department of Health, Public Health Laboratory all clinical materials specified in this chapter upon a positive laboratory finding for the disease or condition, or upon request of the commissioner in relation to a case or suspected case reported under this chapter*".

In Minnesota's rule, "Clinical Materials" is defined as:

> "*A. A clinical isolate containing the infectious agent for which submission of material is required; or*
> *B. if an isolate is not available, material containing the infectious agent for which submission of material is required, in the following order of preference:*
> *(1) a patient specimen;*
> *(2) nucleic acid; or*
> *(3) other laboratory material."*

Additionally, to address the concern of receiving isolates and other clinical materials from out-of-state laboratories, Minnesota added further language placing the burden on in-state medical laboratories that forward clinical materials for testing:

> *If a medical laboratory forwards clinical materials out of state for testing, the originating medical laboratory retains the duty to comply with this subpart, either by:*
> *(1) Reporting the results and submitting the clinical materials to the commissioner; or*
> *(2) Ensuring that the results are reported and materials submitted to the commissioner.*

Colorado-
The Colorado PHL partnered with colleagues in the Disease Control and Environmental Epidemiology Division to design a summer conference series geared at bringing academic, clinical, local, and state public health partners together in a forum to encourage and foster communication, partnership and collaboration. Funding for this series comes from a portion of the Epidemiology and Laboratory Capacity (ELC) grant awarded by CDC coupled with a portion of fee for service funds. In addition to the conference series, Colorado has a statewide courier system in place for getting isolates to the State Public Health Laboratory (SPHL). Officials from Colorado's SPHL meet with the courier annually to review facility submissions and specimen pick-up schedules to ensure that foodborne pathogen isolates are being received from any location within the state.

Virginia-
The Virginia Department of Health utilized their FDA-funded Food Protection Rapid Response Team to conduct training workshops in four regions of Virginia. The workshops were open to local health

departments, military personnel, hospitals, and clinical laboratories and featured FDA's Food Related Emergency Exercise Bundle (FREE-B) which offers a compilation of scenarios based on both intentional and unintentional food contamination events. Epidemiology and laboratory subject matter experts led various components of the exercise. The food emergency exercises provided state health department staff with an opportunity to outline and stress the importance of timely foodborne disease reporting and specimen/ isolate submission.

Virginia has also developed an outbreak module in their LIMS that allows epidemiologists and laboratorians to track outbreaks including outbreak specimens and/or isolates. When notified of a potential outbreak, VA DOH epidemiologists generate an outbreak notice that is transferred to the Outbreak Module. Each outbreak is assigned a unique ID by which all associated laboratory specimens/isolates are tracked. The outbreak module provides a venue between epidemiologists and laboratorians for sharing pertinent exposure information, specimen/isolate tracking and laboratory testing results. An ELC-funded position has been created for running weekly, monthly and annual reports in the outbreak module as well as conducting ongoing strain tracking.

Indiana-
The Indiana State Department of Health (ISDH) Laboratories Outreach Team collaborated with the ISDH Epidemiology Resource Center (ERC) to develop a year-long training program designed to educate local and clinical laboratorians and providers on the Indiana Communicable Disease Rule (ICDR). Training was offered in ten, pre-defined preparedness districts and encompassed all aspects of the communicable disease reporting process including the importance of submitting clinical material/isolates when applicable. Attendees learned about the epidemiology of disease, why reporting is required and how public health policy can be shaped as a direct result of reporting. The laboratory component focused on how disease clusters are identified, how immunizations are created or modified to protect against new strains of disease and how to properly submit isolates to the PHL. Pre and post-tests were administered to attendees to gauge learning. Funding covered travel costs for training staff and light breakfast for participants. An article providing more details on the trainings can be found on APHL's MRC here.

Wisconsin-
The Wisconsin State Laboratory of Hygiene set up a Memorandum of Understanding (MOU) with a large out-of-state commercial laboratory outlining shipment of Wisconsin residents' isolates to the Wisconsin State Laboratory of Hygiene (WSLH). In addition, the WSLH provides the commercial laboratory with infectious disease shippers and a Fedex number to help defray the costs of shipping. The shipping assistance is funded in part by an ELC grant in combination with CDC FoodCORE and General Funds. With regard to in-state clinical laboratories, the WSLH regularly communicates via telephone, teleconference and a bimonthly newsletter. The teleconferences provide an opportunity for WSLH to update their clinical partners on revised guidelines for enteric pathogens and stress the critical role that they play in public health surveillance. The WSLH hosts annual, regional meetings for stakeholders including local health department, tribal, clinical and military base laboratories. The annual, regional meetings are supported with emergency preparedness money, and allow for some overview and discussion of hot topics such as isolate submission and culture independent diagnostics in addition to bioterrorism issues.

Ongoing Challenges and Proposed Solutions

Public health laboratories continue to face ongoing challenges with the rapid shipment of clinical isolates for foodborne disease surveillance activities. Two of the most profound challenges are cost (for

labor, shipping, and/or shipping supplies) and the rapid development and usage of culture-independent diagnostic test (CIDT) methods. Shipping is time-consuming and expensive and courier systems are even more costly. In addition, CIDTs are becoming more widely available with several multiplex assays either newly available or currently under development. These factors, either independently or collectively, are proving to be problematic or even prohibitive for getting isolates in a rapid manner, if at all, thereby severely impacting foodborne disease surveillance. Those factors that have been identified and possible solutions to overcome them include, but may not be limited to:

1. Cost of shipping clinical isolates or material to the PHL

    a) Work with clinical laboratories that have existing courier systems to use their systems for isolate/material transport instead of PHL-funded transport

    b) Provide a fee exempt courier system and/or shipping materials, when necessary, to clinical laboratories to ensure isolates/ material is submitted; for those outside the state or jurisdiction, provision of a national courier contract or shipping account number may be necessary.

    c) Piggy-back on pre-existing courier systems in other public health programs (e.g. newborn screening or preparedness) in order to reduce the burden of cost to any one program.

    d) Pursue grant funding to offset or help cover costs for shipping clinical isolates or material to the PHL

2. Logistics of shipping/ getting clinical isolates or material to the PHL

    a) Partner with clinical laboratory systems that may reach urban or remote areas of the state or jurisdiction to help get isolates or material to PHL's

    b) Routinely contact out-of-state (or out-of-jurisdiction) reference laboratories that may receive isolates or material from patients in your state/ jurisdiction; request that they send isolates /material to the PHL.

3. Loss of clinical isolates due to implementation of CIDT assays in the clinical laboratory

    a) Work with clinical laboratories to send clinical material (stool specimens) to the PHL when they are determined positive by a CIDT assay for foodborne pathogens.

    b) Prepare (increase staffing, training on culture methods, allocate funding) PHLs for increased workload due to the need to perform bacterial culture in the PHL to isolate suspect foodborne pathogens

    c) Work with state government lawmakers to mandate that clinical laboratories within the state must submit isolates or clinical material, if applicable, to the PHL if determined to be positive by any diagnostic assay for a foodborne pathogen

4. Poor communication and collaboration between PHL's and the clinical laboratories within their jurisdiction

    a) Set up and routinely utilize a messaging network for PHL, clinical laboratories and other relevant partners; regularly share requests for targeted foodborne pathogen submissions from clinical labs to PHL's

b) Seek opportunities to foster communication or collaboration with clinical laboratories and healthcare providers such as through face to face meetings, seminars, webinars or newsletters.

c) Provide pertinent laboratory surveillance data to the clinical laboratories to make them aware of their contributions to public health surveillance and acknowledge their cooperation

5. Lack of a sufficient number of clinical laboratory staff trained in communicable disease reporting/ submission rules and/or certified to package and ship infectious materials.

a) Provide information and/or training on jurisdiction-specific communicable disease reporting/ submission rules and regulations

b) Provide infectious materials shipping information to clinical laboratories via lab messaging, teleconference, webinar, etc.

c) Sponsor infectious materials shipping training workshops for laboratories in your jurisdiction

The challenges listed above may not require public health solutions in the long-term. Scientists at the Centers for Disease Control and Prevention are partnering with commercial diagnostic test developers on next-generation diagnostic and subtyping methods that will not need a clinical isolate to identify, serogroup and molecular subtype. Promising techniques and platforms are on the horizon and show great promise to address current issues and enhance future surveillance effectiveness. Until that time is reached however, PHL's must attempt to creatively maximize foodborne disease surveillance within their state or jurisdiction.

In2013, CIFOR released three, comprehensive documents (5) (6) (7) as part of a law project. This project was aimed at creating tools that agencies and jurisdictions can use to improve their legal preparedness to conduct surveillance for foodborne diseases and respond to outbreaks both within their jurisdictions and across multiple states & other jurisdictional boundaries. The documents include an Analysis of State & Legal Authorities, Practitioners' Handbook on Legal Authorities and Menu of Legal Options.

- ***Analysis of State Legal Authorities*.** This document describes & analyzes the types of state legal authorities currently available to conduct foodborne illness surveillance & outbreak response activities. It demonstrates the "patchwork" of state laws across an array of topic areas—public health, communicable disease, food safety, food regulation, agriculture, environment, & general government authority—on which public health professionals & their legal counsel must rely to conduct foodborne disease outbreak surveillance & response activities. This document is the foundation for the handbook & menu.
- ***Practitioners' Handbook on Legal Authorities*.** This document is a practical guide for public health professionals who perform key roles in foodborne disease surveillance & outbreak response. The handbook presents information & resources for practitioners charged with implementing their jurisdictions' legal authorities related to foodborne illness events. The handbook is a primer on the array of statutes & regulations that may be used to undertake foodborne disease surveillance & other outbreak response activities. It provides practitioners with checklists to help them identify relevant agency actors & laws within their jurisdictions.
- ***Menu of Legal Options.*** This document provides a menu of legal provisions for state public health officials & policy makers to consider when reviewing their jurisdiction's legal authorities to conduct foodborne disease surveillance & outbreak response actions. The menu includes legal provisions relevant to effective performance of each of the principal functions of foodborne disease surveillance & outbreak response: outbreak detection, outbreak investigation, outbreak control, & outbreak documentation. This is intended to be a resource for states to use in filling gaps & in clarifying or enhancing their legal authorities.

The documents will serve as a great resource for jurisdictions looking to propose or enhance pre-existing isolate submission laws. The Menu of Legal Options provides specific framework for constructing such laws and provides the user with sample language as well as all components that should be considered including timeline, what specific materials should be submitted, accompanying case information that should be included, etc. More information on the law project documents can be found on CIFOR's website here.

Next Steps

To date, the biggest successes appear to be courier systems, comprehensive, mandatory isolate submission laws, and good communication and collaboration with clinical laboratories. Anecdotal evidence suggests that courier systems are very effective at getting enteric isolates to the PHL in a timely and thorough manner. However, courier services are very expensive with costs varying widely based on population density, pre-existing courier infrastructure, and several other factors. There is no one size fits all courier model. Given the complexities and expense with courier systems, the work group decided to forgo that activity as a potential pilot project for the coming year.

Similar to courier systems, there is no one size fits all communicable disease reporting and mandatory isolate submission regulation among state and local public health agencies and jurisdictions. As outlined previously, CIFOR has spent a great deal of time developing three comprehensive documents that are designed to provide users with the tools necessary to craft regulations that will best suit their needs.

Several public health laboratory members have reported that good communication and collaboration with their clinical laboratory partners has helped to increase enteric isolate submission for routine public health surveillance and outbreak detection and investigation activities. Some of the more notable successes have resulted from face to face meetings. Member-based resources for face-to-face meetings are readily available; therefore, the Clinical Isolates Work Group proposes to use these resources to support additional jurisdictions to implement face-to-face meetings between public health and clinical laboratories.

If funding allows, APHL will identify and contract with sites willing to organize and carryout a one-day, in-person conference modeled on the Colorado Department of Public Health and Environment Summer Conference Series. The summer conference series is geared at bringing academic, clinical, local, and state public health partners together in a forum to encourage and foster communication, partnership and collaboration. Pilot sites will have access to sample materials including past conference agendas and formal invitations and will be expected to carry out a similar experience in order to foster collaboration with clinical laboratory partners within their jurisdiction.

In addition to the proposed pilot project, APHL will continue to gather and develop tools and resources that will assist states in implementing activities to improve rapid isolate submission. The tools and resources will be placed on APHL's Member Resource Center (MRC) which is available to all members, and will be marketed through a variety of mechanisms including blast emails, a weekly electronic newsletter (E-Update) and APHL's quarterly publication Lab Matters. Tools and resources may include, but are not limited to training topics and outlines, specimen collection and submission guidelines, newsletters, laboratory specimen/ sample submission forms, sample meeting agenda(s) and topics, and cost analysis worksheets for courier systems and other similar types of programs.

APHL has a dedicated Culture Independent Diagnostic Subcommittee and continues to work closely with CDC, CSTE, clinical laboratories and other key partners to address the issue of CIDTs and their impact on public health surveillance. Those activities fall outside the scope of this work group.

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* Members of the APHL Clinical Isolates Work Group:

Work Group Lead**- Amy Woron**- Tennessee Department of Health: Laboratory Services

Work Group Members-**David Boxrud**- Minnesota Public Health Laboratory**; Deborah Sheehan**- PulseNet Technical Consultant**; Deborah Rutledge**- Delaware Public Health Laboratory**; Hugh Maguire**- Colorado Department of Public Health and Environment- Laboratory Services Division**: Robyn Atkinson** (APHL Food Safety Committee Chair)- Unified State Laboratories: Public Health (Utah)**; Timothy Monson**- Wisconsin State Laboratory of Hygiene**; Tracy Stiles**- William A. Hinton State Laboratory Institute (Massachusetts)

Federal Liaisons- **Peter Gerner-Smidt** (CDC Liaison)- CDC Enteric Disease Laboratory Branch (EDLB)**; Don Sharp** (CDC Liaison)- CDC Food Safety Office **; Don Burr** (FDA Liaison)- FDA Center for Food Safety and Applied Nutrition (CFSAN)**; Tim McGrath** (FDA Liaison)- FDA Office of Regulatory Affairs (ORA)

APHL Staff **– Kirsten Larson** (Lead); **Dare Akingbade**