The Poliovirus Laboratory Containment Pilot Survey: The Experiences of Wyeth and Emory University

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Abstract

In October 2002, the United States begins the process of wild poliovirus containment with a nationwide inventory of all biomedical laboratories that may possess wild poliovirus materials in government, industry, and academia. Pilot surveys were carried out in collaboration with the Centers for Disease Control and Prevention, National Institutes of Health, Arizona State Public Health Laboratory, Emory University, and Wyeth, a biopharmaceutical company. Valuable experience gained during the pilots was used to refine the survey materials and procedures and develop additional technical resources. Summaries of the Wyeth and Emory experiences are presented in this paper to assist future participants prepare for the national wild poliovirus inventory. Goals and objectives of the inventory are presented in a companion article found in this issue.

Wyeth

Survey Strategy Formulation

During November 2001 Poliovirus Laboratory Containment Preparedness (PLCP) office invited Wyeth to participate as an industry pilot. The invitation was received by the Biosafety Officer for Wyeth—Massachusetts and authorized by Wyeth's corporate Environment and Safety Department.

During December 2001, the Wyeth Biosafety Officer and Corporate Occupational Health Manager developed and communicated to the PLCP staff via conference calls a strategy for the project. The plan called for the Biosafety Officer to communicate the project to all Wyeth sites, supply the appropriate forms, and serve as a resource to the sites for the duration of the project. During January 2002, the laboratory worksheet and institutional survey form were modified by the PLCP staff, with input from the Wyeth Biosafety Officer, for Wyeth's use.

Survey Implementation

The survey was initiated during the first quarter of 2002. A distribution list was created identifying each site with biomedical laboratories and the biosafety or environmental health and safety professional responsible for implementing the survey at each site. The Wyeth team developed communication materials, which included a cover letter providing instructions, the laboratory worksheet, and a PowerPoint presentation discussing survey goals and objectives and the survey process. These materials were distributed to the site biosafety officers in February 2002 via attachments to an e-mail message from the corporate manager for reproduction on site as required. The laboratory worksheet, which included definitions and examples of wild poliovirus materials, was designed to assist laboratory personnel search for and identify wild poliovirus materials. The Biosafety Officer was the single point of contact for questions and as the recipient of completed site worksheets.

Sites were requested to have a biosafety or environmental health and safety professional ensure that the worksheet was completed and returned to the Biosafety
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Officer by March 1, 2002. As this was a pilot, sites were actively encouraged to provide feedback and ask questions. Cooperation from the sites was excellent with a 100% response within 3 weeks. The results were collected and compiled at the end of March.

Using the results collected on the laboratory worksheets, the Biosafety Officer prepared the institutional survey form in April 2002, and was listed as the contact person for future correspondence with the PLCP staff. The survey form was forwarded to the corporate manager for review and signature.

Feedback Received from Company Sites
Survey administration and data collection were accomplished without difficulty. Participants indicated that this process was not time-consuming. On average it took less than 15 minutes to complete the laboratory worksheet using a current laboratory inventory for reference. Following are a few of the questions and situations that arose during the project.

- Although the definition of wild poliovirus and potentially infectious materials was provided to the sites in the communication materials, there were two questions regarding what materials needed to be reported. Both had to do with whether or not attenuated vaccine strains were required to be reported. The investigators were informed that they do not need to be reported.
- One department head declined to complete the laboratory worksheet since his laboratory did not have any of the materials despite the cover letter indicating that the worksheet must be filled out regardless of whether or not materials were present.
- An initial review of which laboratory personnel to target is important for compliance purposes, as completion of the form was often delegated by department heads. This was evident in many cases as the laboratory worksheet indicated that a member of a laboratory had carried out the inventory rather than the head of the laboratory.
- The definition of a “laboratory” was interpreted in different ways at the different sites. Some sites reported each laboratory by principal investigator, while other sites considered a laboratory to be all laboratory space belonging to one department. The definition of laboratory was left undefined. It was determined that flexibility in implementing the survey and completing the worksheet were desired. The fact that all of the laboratory areas implemented the process was the most important point, not how many laboratory worksheets were utilized to accomplish this goal.

Community Outreach
To share the experience gained from the pilot project, the Biosafety Officer hosted a meeting of the New England Biosafety Association in May 2002. In attendance were two members of the PLCP staff who answered questions and provided resource materials for the upcoming national wild poliovirus inventory.

Lessons Learned
- Strategy should be carefully developed in advance of the survey. This includes creating project timelines, communication materials, and determining points of contact.
- Corporate management plays a crucial role in ensuring compliance.
- Designating one point of contact (Biosafety Officer) to answer questions and manage the project is important.
- Attaching survey materials electronically to e-mail facilitates communication to sites and individual laboratories.
- Establishing specific timelines for receipt of information is important to ensure response.
- Obtaining responses within 3 weeks of receipt of project materials is feasible.
- Encouraging site laboratory department heads to communicate and delegate to their direct reports facilitates the completion of the laboratory worksheet.

Summary
As a result of participation in the national poliovirus pilot survey, Wyeth realized a number of benefits, as did the national biosafety community. Wyeth was able to complete the survey in a timeframe acceptable to Wyeth and the PLCP staff. Feedback gained in the pilot survey was provided to the PLCP staff, which enabled them to refine the survey materials and provide additional technical resources in preparation for the October 2002 national inventory. This pilot study was conducted for the benefit of future inventory participants. A successful national inventory to identify wild poliovirus materials will facilitate the global eradication program.
Emory University

Survey Strategy Formulation

In late spring 2001, PLCP staff contacted the Director and the Biosafety Officer of the Environmental Health and Safety Office (EHSO) at Emory to participate in the poliovirus pilot survey. Emory University School of Medicine was identified as the Emory University component with the largest number of survey recipients for the poliovirus pilot survey. PLCP was advised by the Director and Biosafety Officer to contact the Executive Associate Dean of the School of Medicine to communicate information about the poliovirus pilot survey and request Emory University’s participation in the pilot survey. The Executive Associate Dean acknowledged and supported Emory University’s involvement in the pilot project.

Survey forms were reviewed and modified via e-mail by the Biosafety Officer and members of the PLCP staff. The survey strategy was discussed during meetings in June and August 2001. Emory Healthcare and the Division of Infectious Diseases faculty and staff were asked by the Director and the Biosafety Officer to help identify laboratories, departments, and divisions for the pilot survey. It was decided that the modified survey forms would be sent to Deans of the Health Sciences, Department Chairs, select health care departments (e.g., clinical diagnostic and pathology laboratories in the Emory University and Crawford Long Hospitals), and all faculty with approval for Biosafety, Chemical, and Radiological protocols.

The survey time frame was discussed and established during the above-mentioned August meeting. October 1, 2001 was selected as the date the laboratory worksheets and survey materials would be mailed via interdepartmental mail. The deadline for completing and returning the worksheet was October 31, 2001. PLCP supplied the survey materials to be distributed, and the Biosafety Officer wrote the cover letter. The laboratory worksheet was made available on the EHSO web site. Information regarding the survey process was published in the Fall 2001 EHSO newsletter available on the EHSO web site and distributed to faculty and staff at Emory University.

Survey Implementation

Survey materials were mailed to 407 laboratories on October 1-2, 2001. Two weeks later e-mails were sent to the corresponding business managers/administrators with a letter describing the survey process and a list of individuals who should have received the initial information and whether they had responded by returning a completed worksheet. A number of business managers/administrators called and e-mailed back requesting more worksheets since several individuals had not yet received them. The business managers/administrators were informed that the worksheet was available on the EHSO web site. Another e-mail was sent to the business managers/administrators in mid-November with similar information and modified lists reflecting the individuals who had completed and returned the laboratory worksheets.

Late December/early January the Biosafety Officer started calling individuals on the initial mailing list who had not returned the completed worksheet. Several of the individuals stated they did not receive the worksheet, but quickly responded by printing and completing the worksheet located on the EHSO web site.

The Director of EHSO went to a Business Manager Meeting on February 14, 2002 and a Clinical Administrators Meeting on February 21, 2002 to discuss the importance of the poliovirus pilot survey, and request the business managers/administrators’ assistance in getting the recipients to complete the worksheets and return them to the Biosafety Officer.

As of March 1, more than 70% of the laboratory worksheets were completed and returned. The lowest response rate was from the cardiology, hematology, pulmonary, and psychiatry laboratories. These laboratories are not likely to work with wild poliovirus materials and were reluctant to respond. The Biosafety Officer continues to follow-up with nonresponders.

Feedback Received

Collecting the majority of completed worksheets at Emory University took 6 months. The initial mailing of the laboratory worksheet was not as successful as the electronic communication. The business managers/administrators and faculty/staff were more receptive to the e-mails and the survey information available on the EHSO web site.
Several barriers were observed during the process. Recipients indicated they did not have the time to fill out the laboratory worksheet. Some recipients were reluctant to complete the worksheet because poliovirus was not present in their laboratory, and others declined because they no longer had a laboratory. One interesting note: The Biosafety Officer had one individual concerned that EHSO was requesting poliovirus immunization information.

**Lessons Learned**

The 6 months needed to accumulate the majority of the laboratory worksheets was based on several factors—selection of individuals, departments, and divisions for the survey; response to interdepartmental mail; and reluctance to complete the worksheets. Narrowing the number of worksheet recipients could have been accomplished by screening the individuals by phone or e-mail before the survey process was initiated.

Computer communication was found to be much more effective than sending the laboratory worksheets via interdepartmental mail. The e-mail communication and worksheets available on the Internet assisted with a more timely return of completed worksheets.

**Summary**

The Emory University poliovirus pilot survey collected 70% of the completed laboratory worksheets over 6 months. The poliovirus information gathered will prepare Emory University for poliovirus eradication by identifying those laboratories that are manipulating poliovirus and/or potentially infected poliovirus specimens at Biosafety Level 2 and informing these laboratories that after polio eradication these items will have to be manipulated at Biosafety Level 3. The lessons learned during the pilot survey process, such as screening recipients before distributing the worksheet and using e-mail, web sites, and other electronic communication systems for timely responses, will assist the EHSO with future information-gathering activities and will provide suggestions to the many academic institutions that will participate in the national poliovirus inventory project organized by the PLCP.