



National Inventory of Biomedical Laboratories That May Possess Wild Poliovirus Materials

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Abstract

The Department of Health and Human Services, in partnership with other Departments and Agencies of the Executive Branch, has announced a national wild poliovirus inventory of all biomedical laboratories that may possess wild poliovirus infectious or potential infectious materials. The inventory is scheduled to begin October 2002. Responses are due December 31, 2002.

The national inventory alerts laboratories to the anticipated successful eradication of polio and encourages destruction of all unneeded wild poliovirus materials. Laboratories that retain poliovirus materials will be placed on the national inventory and kept informed of eradication progress and when to implement containment procedures.

This paper summarizes information from the WHO Global Action Plan for Laboratory Containment of Wild Polioviruses (WHO, 2002) and the U.S. Strategy for Implementing Phase I of the Global Action Plan: The National Inventory (DHHS, 2002). Additional information can be accessed at the Poliovirus Laboratory Containment Preparedness web site, www.cdc.gov/od/nvpo/polio.

Introduction

Beginning October 2002, the Department of Health and Human Services (DHHS), in partnership with other U.S. Executive Branch Departments and Agencies, will conduct a national inventory of all biomedical laboratories that may possess wild polioviruses.

In this undertaking, the United States joins 122 other polio-free countries that have initiated or completed similar inventories in collaboration with the World Health Organization (WHO).

The wild poliovirus inventory coincides with the Select Agent Registry, also being conducted by DHHS, in cooperation with the U.S. Department of Agriculture. The Select Agent Registry is a requirement of the Public Health and Security and Bioterrorism Preparedness Response Act of 2002. The wild poliovirus inventory is a requirement of global polio eradication, designed to reduce the risk of inadvertent reintroduction of wild polioviruses into the community.

Laboratory containment of wild polioviruses is a stepwise process linked to progress in global interruption of wild poliovirus transmission and consists of three phases: global laboratory inventory, preglobal certification, and postglobal certification.

The global laboratory inventory phase covers the period when the numbers of polio-free countries and regions are increasing, but wild polioviruses continue to circulate somewhere in the world. During this phase, countries implement a national inventory of all biomedical laboratories located in academic, federal government, hospital, industry, private, and state and local government facilities. The purpose of the inventory is to alert laboratories to the impending eradication of polio and encourage the destruction of all unneeded wild poliovirus materials. Laboratories that retain poliovirus materials will be placed on the national inventory.

The preglobal certification phase begins 1 year after detection of the last wild poliovirus anywhere in the world. During this phase, laboratories on the national

inventory are notified to dispose of all infectious or potential infectious materials, or implement biosafety requirements appropriate for the risk of working with those materials. The postglobal certification phase begins after the world is declared polio-free by the Global Commission for the Certification of the Eradication of Poliomyelitis.

Implementing and compiling the national inventories are critical steps leading to global certification. This paper provides an overview of the inventory process.

Progress in Polio Eradication

Polio eradication was initiated in the Americas in 1983 and adopted by the World Health Assembly in 1988. Its initial objectives were threefold: 1) to prevent disease and save lives; 2) to assist in increasing immunization rates of children for all vaccines; and 3) to improve the health infrastructures of developing countries. In the last 14 years, the Global Polio Eradication Initiative, spearheaded by the World Health Organization, Rotary International, U.S. Centers for Disease Control and Prevention, and UNICEF, has made remarkable progress. In 1988, an estimated 350,000 cases of poliomyelitis occurred in 125 countries. In the last 12 months, less than 500 cases were detected in only 10 countries (MMWR, 2002).

When global polio eradication is achieved, biomedical laboratories will be the only sources of wild poliovirus. Containing the virus in the laboratory is essential to reduce the risk of inadvertent reintroduction of polio into the community. The first step toward containment is a national inventory of all biomedical laboratories.

Rational for Laboratory Containment of Wild Polioviruses

Polioviruses may be transmitted, in theory, to persons outside the laboratory through contaminated laboratory effluents released into sewage, solid wastes transported to landfills, spent air exhausted to surroundings, or through contaminated workers' skin or clothing. However, transmission through such routes is extremely difficult to document against a background

of high levels of immunity acquired through natural infection or immunization.

More readily documented are poliovirus infections of laboratory workers with potential for transmission to the community. From 1941 to 1976 a total of 12 laboratory-associated poliomyelitis cases, including two deaths, were recorded. Accounts of 7 of the 12 were unpublished. Most cases occurred in the prevaccine era and before the advent of cell culture.

The paucity of reports of laboratory-associated poliomyelitis since vaccines were introduced testifies to the effectiveness of vaccines and vastly improved laboratory facilities, technologies, and procedures. However, evidence indicates that the potential remains for transmission of poliovirus from the laboratory to the community. In 1992, a wild-type 1 strain used for inactivated poliovirus vaccine (IPV) production was documented as being transmitted from a worker in a vaccine production facility to his young son. In another incident, a child was reported infected with a prototype strain of type 3 commonly used in laboratories for research or IPV production. The source of this infection was not determined.

IPV is highly effective in preventing disease, but its use cannot be assumed to prevent silent infection among laboratory workers. Oral poliovirus vaccine (OPV) provides a more effective barrier, but silent infections may still occur. The incidence of poliovirus infections without clinical symptoms among laboratory workers is unknown.

In the absence of vaccines that fully prevent non-apparent infection and subsequent transmission, appropriate biosafety measures are crucial to prevent poliovirus infection of laboratory workers and subsequent transmission. Absolute containment cannot be assured. Questions of intentional or unintentional noncompliance will always remain. But effective containment, that is, reducing the risk of inadvertent reintroduction of wild poliovirus into the community, is a realistic goal.

The Inventory Process

In October 2002, all institutions with biomedical laboratories that may possess wild poliovirus materials will receive a yellow inventory form, which provides definitions and examples of wild poliovirus infectious

and potential infectious materials. The form is used to report the institutional inventory results. It asks for the total number of laboratories inventoried, the number of laboratories retaining wild polioviruses, and the approximate number of samples retained. All institutions are encouraged to submit their inventory results via a secure web site.

Even if an institution does not have wild poliovirus materials, the inventory form is to be completed and submitted by December 31, 2002. An important component of a systematic and thorough search is documentation that an institution does not have such materials. The current inventory process assumes all institutions endorse polio eradication and that institutional representatives take this responsibility seriously. Institutions failing to submit the form will receive follow-up letters and phone calls until a completed form is received. Validation of the global inventory process is anticipated before the world is certified as polio-free.

Institutions with Multiple Laboratories

A laboratory worksheet has been designed to assist institutions with multiple laboratories search for and identify wild poliovirus materials. It provides definitions and examples of wild poliovirus infectious and potential infectious materials. The laboratory worksheets are circulated to all biomedical laboratories within an institution by the responsible facility official (RFO). The RFO collects the completed worksheets, which are used to complete the inventory form.

The RFO should be a safety officer, a senior management official, or both, who has been authorized by the institution to complete and submit the inventory. The RFO will receive all follow-up communications regarding the inventory and wild poliovirus laboratory containment.

Disposing of Unneeded Materials

Disposing of all unneeded materials, including those with incomplete information, is encouraged. If poliovirus reference strains are required, authenticated Sabin strains may be obtained from the Centers for Disease Control and Prevention or American Type Culture Collection.

Retaining Wild Poliovirus Materials

Laboratories should take this opportunity to critically evaluate the considerable personal and institutional responsibilities inherent in retaining a virus that will be eradicated. An underlying principle of poliovirus laboratory containment is that most laboratories do not have a need for long-term retention of wild poliovirus infectious and potential infectious materials.

Laboratories choosing to retain wild poliovirus materials will be placed on the DHHS national inventory. Laboratories on the inventory will be kept informed of eradication progress, developments in biosafety, and notified 1 year after the last polio case to implement biosafety measures appropriate for the materials stored and procedures performed. The inventory will not be published but will be provided to the WHO as part of the global certification process. Access to the inventory will be limited to personnel with a need to know in order to perform their official job duties.

Laboratories wishing to keep their materials and continue working with them should do so under Biosafety Level 2/polio. The primary differences between BSL-2 and BSL-2/polio are that laboratories possessing wild poliovirus materials should, in addition to the standard biosafety requirements, restrict access to these materials, maintain accurate records, and ensure all staff entering the laboratory are immunized. Requirements specific to polio are summarized in draft *WHO Global Action Plan for Laboratory Containment, 2nd Edition*, available at www.cdc.gov/od/nvpo/polio.

Summary and Conclusion

Global polio eradication is anticipated within the next few years. The only sources of wild poliovirus will be in biomedical laboratories. Prevention of inadvertent transmission of polioviruses from the laboratory to the community is crucial. The first step toward prevention is a national inventory of all biomedical laboratories. All relevant biomedical laboratories are involved in the inventory process as many may be unaware that they have stored wild poliovirus materials. Resources for completing the inventory form are available at www.cdc.gov/od/nvpo/polio.

References

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