CONSULTATION ON EUROPEAN REGIONAL PLAN FOR LABORATORY CONTAINMENT OF WILD POLIOVIRUSES

Report on a WHO Meeting

Copenhagen, Denmark
13–14 December 1999
EUROPEAN HEALTH21 TARGET 7

REDUCING COMMUNICABLE DISEASES

By the year 2020, the adverse health effects of communicable diseases should be substantially diminished through systematically applied programmes to eradicate, eliminate or control infectious diseases of public health importance

(Adopted by the WHO Regional Committee for Europe at its forty-eighth session, Copenhagen, September 1998)

Keywords

POLIOMYELITIS – prevention and control
CERTIFICATION
CONTAINMENT OF BIOHAZARDS STANDARDS
SPECIMEN HANDLING STANDARDS
LABORATORY INFECTION – prevention and control
POLIOVIRUS PATHOGENICITY
SAFETY MANAGEMENT
EUROPE
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Introduction

A consultation on the European Regional Plan for Laboratory Containment of Wild Polioviruses was held at the WHO Regional Office for Europe in Copenhagen on 13 and 14 December 1999. The Meeting was chaired by Dr D Salisbury; Dr G Oblapenko was secretary. Dr Oblapenko welcomed participants, and outlined the purposes of the Meeting and how it would be a first part in the process of raising the importance of the containment of wild polioviruses. Dr Salisbury identified the challenge that the containment process would pose, particularly in large countries and those where poliomyelitis had been absent for many years. Decentralization and health reforms could make the process even more difficult.

The scope and purpose of the Meeting were to:

- discuss the first draft of the regional plan for laboratory containment of wild polioviruses;
- share common experience in the preparation of national plans of action.

Global action plan for laboratory containment of wild polioviruses

Once poliomyelitis is eradicated, the laboratories of the world will be the only remaining source of the virus. Safe handling and, ultimately, maximum containment of poliovirus and potentially infectious materials in the laboratory are crucial.

Until now, poliovirus biosafety concerns have been minimal. Universal immunization with inactivated polio vaccine (IPV) or oral polio vaccine (OPV) has reduced the risk of disease for laboratory workers and the general public. Current technologies and biosafety practices have further reduced the risks of poliovirus contamination of the environment.

The probability of a laboratory-associated poliovirus infection is small but the consequences of an infection grow greater with time. A chance reintroduction of wild poliovirus from the laboratory into the community after cessation of transmission presents a threat to polio eradication. A chance reintroduction of wild poliovirus after cessation of immunization presents a threat to public health of global proportions.

The world now faces the formidable, but not insurmountable, challenge of locating the many laboratories that have wild poliovirus infectious, or potentially infectious, materials and ensuring that they are adequately contained in the laboratory, rendered non-infectious, or destroyed. The global action plan addresses these responsibilities. It is linked to the major eradication objectives, and consists of three phases:

1. the pre-eradication phase – safe handling of wild poliovirus infectious or potentially infectious materials (biosafety level (BSL) 2/polio);
2. the post-global eradication phase – high containment of wild poliovirus infectious and potentially infectious materials (BSL-3/polio): to begin one year after detection of the last wild poliovirus;
3. the post-OPV immunization phase – maximum containment (BSL-4) of wild poliovirus infectious and potentially infectious materials and high containment (BSL-3/polio) of OPV and OPV-derived viruses: to begin when OPV immunization stops.
The pre-eradication phase

The pre-eradication phase covers the present, when wild poliovirus is decreasing or no longer circulating in many areas of the world. Three tasks are critical to this phase.

(a) countries must identify and list laboratories that have wild poliovirus infectious materials or potentially infectious materials;

(b) laboratories must institute enhanced biosafety level-2 (BSL-2/polio) procedures for the safe handling of all such infectious or potentially infectious materials;

(c) countries must begin planning for implementation of biosafety requirements for post-global eradication.

Implementation of the pre-eradication phase requires two critical steps: surveying all medical/biological laboratories that might possess wild poliovirus infectious and/or potentially infectious materials, and establishing a global inventory system for laboratories that retain such materials.

The purpose of the global survey is to acquaint all medical/biological laboratories with the global action plan; to effect disposal of all wild poliovirus infectious and/or potentially infectious materials no longer needed by the laboratory; to ensure safe handling of all such materials; and to establish a global inventory of laboratories that retain such materials.

The survey is hierarchical, beginning with notification by WHO and proceeding through ministries of health, agencies and institutions to laboratories. Because many laboratories that might possess such materials are outside the health sector, completion of the survey will require ministries of health to enlist the cooperation of other ministries including education, defence and the environment.

The purpose of the inventories is:

- to document the location and type of wild poliovirus infectious and/or potentially infectious materials being retained;
- to meet the country requirements for WHO regions to be certified as polio free; and
- to maintain an up-to-date list of laboratories to be notified to initiate containment procedures one year after detection of the last wild poliovirus.

Data for the inventory system are obtained from the global survey, beginning with a thorough search by each laboratory for any materials that meet the definition of wild poliovirus infectious or potentially infectious materials. Data from the laboratories are submitted by parent agency/institutions to the national inventory maintained by each country. Data from the national inventory are provided to the national committee for the certification of poliomyelitis as well as to the appropriate WHO Regional Office.

The post-global eradication phase

The post-eradication phase begins one year after detection of the last wild poliovirus, when it is highly probable that all human transmission has ceased.
All laboratories possessing wild poliovirus infectious materials or potentially infectious materials must undertake one or more of the following three options:

- implement containment (BSL-3/polio) procedures, or
- transfer wild poliovirus infectious and potentially infectious materials to repositories designated by WHO, or
- render such materials non-infectious, or destroy them, under appropriate conditions.

All biosafety actions are to be implemented and documented as complete before certification of polio eradication can be considered.

**The post-OPV immunization phase**

The post-OPV immunization phase begins with the worldwide cessation of OPV administration and the subsequent rapid increase of non-immune susceptible children. The biosafety requirements for wild poliovirus infectious and potentially infectious materials increase from BSL-3/polio to BSL-4, consistent with the increased consequences of inadvertent transmission of wild poliovirus from the laboratory to the community. Biosafety requirements for OPV and OPV-derived viruses increase from BSL-2/polio to BSL-3/polio to prevent reintroduction and theoretical circulation of these viruses in unimmunized populations. Procedures will be developed to control or destroy unused OPV in clinics, immunization centres, doctors’ surgeries, and other sites.

**Regional plans**

**European regional plan**

A first draft of guidelines for implementation of laboratory containment of wild poliovirus is now being circulated for consultation. These guidelines cover the laboratory searches and inventories that will comprise the first phase of the action plan for the WHO European Region. The action plan describes two critical steps:

- a national search for all medical/biological laboratories that might possess wild poliovirus infectious and/or potentially infectious materials;
- a national inventory system for laboratories that contain such material.

The national search is hierarchical, beginning with notification by WHO to the highest authority of each country or ministry of health which, in turn, will appoint a focal person/group for containment. This person/group will draw up the national plan for containment and will be responsible for contacting agencies and institutions who, in turn, will make requests to the laboratories. Because many of the laboratories that might possess infectious or potentially infectious wild poliovirus materials are outside the health sector, completion of the search will require the focal person/group to enlist the cooperation of other ministries including education, defence, agriculture and the environment.

Data for the national inventory system are obtained from the national search. Each laboratory identified as containing wild poliovirus infectious or potentially infectious material will submit a complete list of all such materials to its parent agency/institution, which in turn will create an agency/institution inventory. Data from all laboratories listed on the latter are included in the
national inventory, maintained by each country. Summary data from the national inventory are submitted to the WHO Regional Office to be included in the regional inventory which, in turn, will compile the data for the WHO global inventory.

Phases II and III of the action plan call for all infectious and potentially infectious materials listed in the inventories to be rendered non-infectious, destroyed, or properly contained in a WHO-approved poliovirus laboratory.

Completion of a national inventory will be a prerequisite for certification of a country as polio-free.

The suggested schedule for implementation of containment phase I are shown at Annex 1.

**Western Pacific regional plan**

The Western Pacific Region is likely to be the second WHO region to complete certification of polio elimination, and the process of containment has been incorporated into the Regional Certification process. In July 2000 the Certification Commission will meet and review countries’ containment plans. Consideration is presently being given to insisting on completion of the first phase of the containment process as a condition of acceptance of national certification applications.

Experience with the containment process to date have shown that:

- clear communication to countries of the containment requirements is essential;
- a regional level coordinator is critical to successful implementation;
- breaking the printed materials into packets on separate topics has being helpful in avoiding information overload;
- national laboratories have experienced particular difficulty with specimens sent for analysis without information on the possibility of polio infection, as well as those from neighbouring countries where information on the possibility of poliovirus infection is not available.

**Country reports**

**France**

A review has already been undertaken of the laws and regulations applying to laboratory practice and the handling and storage of infectious and potentially infectious materials. A new regulation was passed in November 1999 (on the Good Execution of Biological Analysis) and it is hoped that this will facilitate the development of a national inventory. It is also possible that the national quality control laws will help to identify a number of agencies possibly handling polioviruses. However, it has been estimated that there are likely to be more than 5000 laboratories (in the private sector, hospitals, institutes, and for blood transfusion), and all will need to be involved. Meanwhile, the questionnaire sent annually to each laboratory for quality control purposes could be used for specific requests such as will be needed for the national inventory.
Concerns involve the scale of the task, the existing complex regulatory environment, the multiplicity of agencies/government departments, and the number of laboratories outside the health structure. On the more positive side, there is an existing network of laboratories (185 at present) that are collaborating over enterovirus surveillance which are likely to be the most important for the national inventory.

Germany

The National Committee has developed a timetable for the containment process. The next step will involve the Ministry of Health instructing the Viral Disease Association to develop a national draft for the containment plan. This should be ready by February 2000. Compilation of the national inventory will start in June 2000, with a target date of June 2001 for completion.

However, a recent QA exercise covering enterovirus laboratories raised concern about the results of proficiency testing with non-polio enteroviruses and polioviruses. There is therefore some anxiety about laboratories’ competence to identify accurately the viruses they hold and work on.

Although a national plan can be developed, its implementation will be made more difficult by the federal structure and the Länder’s considerable autonomy. Achieving effective cross-Government working will also be challenging. German laws at present cover the handling of infectious agents but not of infectious materials, and it is the latter that will be most relevant.

Netherlands

The Containment Manual has been reviewed in the Netherlands and the tasks required linked to the activities of the National Certification Committee. The inventory will undoubtedly be time-consuming and the provisional date for completion in 2000 is now seen as over-optimistic. It is considered important for laboratories that are included in the inventory to continue to provide zero reports even after they have been listed. The Ministry of Health will be writing to laboratories, institutions, other ministries, public health agencies and relevant national organizations.

Implementation will include a system of quarterly reporting from laboratories to the National Committee. On-site inspections will be carried out, especially looking for samples from 1992–1993, when there was some circulation of wild polioviruses. Two laws will be used to ensure compliance from laboratories, and laboratory accreditation schemes will be used to include safe handling and storage of samples at BSL-2 and then BSL-3.

Russian Federation

The first stage will be an inventory of all laboratories, starting with those known to be doing poliovirus isolation on stools and from environmental samples. These laboratories not only work on polioviruses but also have stocks of samples. The second group to be listed in the inventory will be research laboratories and vaccine producers. The third group will include all laboratories handling potentially infectious materials, and will be the largest group. Since all laboratories need to be licensed by law, and these laws are enforced and monitored, identification of laboratories is relatively straightforward. It is the scale of the task that is daunting. It is estimated that there are 119 laboratories directly managed by the Ministry of Health, 4000 bacteriology laboratories, 4000 parasitology laboratories, 12 000 serological laboratories and 29 agencies or
ministries that oversee microbiological institutes. Ninety-one laboratories are known to be working on polioviruses, of which 10 are outside the Ministry of Health. There are 89 geopolitical units, each of which has a unit for sanitary surveillance and each of these has a laboratory. It is cause for concern that compliance with biosafety standards is poor; after the inventory is completed, therefore, only laboratories that can demonstrate competence at fulfilling BSL-2 will be allowed to work with poliovirus-infected materials. There is a clear need to assign personal responsibility for coordination and implementation at a high political level.

**United Kingdom**

Earlier in 1999, the topic of containment of polioviruses was referred to the Advisory Committee on Dangerous Pathogens and the Joint Committee on Vaccination and Immunisation. Both committees agreed on the importance of this work and noted the implications for laboratories, especially for the research community who may not appreciate the relevance of the samples that they hold. It was agreed that a joint working party should be set up between the two committees, and its work will be made available to the National Certification Committee. The first stage of the inventory is being planned, and will involve contacting public health and hospital-based non-public health service laboratories to find out if they work on wild polioviruses. The research councils and other appropriate institutions will also be approached.

Statutory responsibility for biosafety in all laboratories and workplaces rests with the Health and Safety Executive (HSE), who have agreed to cooperate on taking forward the necessary steps to change the biosafety level for wild polioviruses to BSL-3 in the first instance. Although this can be done through domestic legislation, HSE’s view is that the simplest way would be through a European Union (EU) directive that would be binding on all laboratories. It is envisaged that the greatest difficulties will be presented by the second stage of the inventory process – contacting all laboratories to see if they hold potentially polio-infected material.

**Conclusions and recommendations**

1. Every country should have a national plan that identifies the location of stocks of wild polioviruses and the arrangements for their safe containment or disposal, and includes an inventory of all laboratories where infected or potentially infected materials might be being held.

2. The best way to take forward the containment process will be through the national elimination certification process.

3. The containment process has implications for the national elimination certification process and hence for the regional certification process. As a consequence, the national certification process will need to be modified according to the stage of the work of the national committees. Where a national plan has already been submitted, the national committee will need to produce a containment plan *post hoc*. This could be submitted as part of a progress report. Countries that have not yet submitted their certification applications will need to consider how their work can incorporate the need for a containment plan to be prepared in conjunction with the national certification application.

4. The task of reviewing national containment plans will need to be taken into account in the work schedule of the Regional Commission.
5. Countries considering the challenges they face in drawing up a containment plan, and the changing obligations regarding the handling of infectious and potentially infectious materials, should consider using legislation to change the biosafety level obligations on those who handle such specimens. Such legislation could bring about a considerable reduction in the number of laboratories that would need to be monitored as part of the containment process. Existing laws or regulations should be actively promoted to assure commitment to the containment requirements.

6. Since there are already EU regulations on biosafety, DG V should be involved as early as possible. A helpful outcome would be an EU commitment to recommend the relevant changes in biosafety for infectious and potentially infectious materials.

7. One of the challenges of implementing a containment plan will be the need to achieve effective cross-departmental working. This may need commitment at a high political level to motivate government departments that may not view containment as a priority.

8. Compiling a list of laboratories that are knowingly holding or actively working on wild polioviruses may be relatively straightforward for a number of countries, but the task of creating an inventory of all laboratories that might be holding infectious or potentially infectious material will be much more challenging. Similarly, it may prove far from easy to ensure the destruction of all infectious or potentially infectious samples. Changing biosafety levels through legislation or regulation may facilitate this task.

9. High-titre samples pose the highest theoretical risk from failure of containment, but these samples are likely to be held in relatively few laboratories where the staff are likely to be best able to handle wild poliovirus materials.

10. Clinical samples are likely to be of relatively low risk from failure of containment. The risk from samples in store will diminish with time, and the possibility of samples being unknowingly contaminated with wild poliovirus also diminishes as eradication approaches.

11. Advice will need to be given to laboratories on methods of disposal of infected and potentially infected materials. Laboratories will need to alert national committees when such samples have been disposed of and when biosafety levels are being met.

12. Documentation for containment procedures should include a pro-forma version of the national containment plan return to the European Commission, appropriately translated. It will facilitate the work of countries and also the work of the European Commission if all returns follow the same format.

13. It may be useful for individual laboratories if there is a national, regional or even global helpline to respond to technical concerns over handling, inventorying or disposal. This might best be done at national level by the national reference laboratories.

14. One person at the WHO Regional Office should be responsible for implementing the containment process.

15. WHO should consider developing a communication strategy for the containment process. Opportunities for working with professional and technical associations, virology groups or research councils could then be used to augment the work of the national committees.
### Annex 1

#### SUGGESTED SCHEDULE FOR IMPLEMENTATION OF CONTAINMENT PHASE I

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<td>4. Ministry of health sends letters to all agencies/institutions asking for their cooperation with the containment effort. The letters should include:</td>
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<td>5. Agencies/institutions notify laboratories under their jurisdiction to begin the laboratory inventory using the flow chart and forms provided. Laboratories should:</td>
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<td>7. Agencies/institutions send completed laboratory and agency/institution forms to national coordinator/group.</td>
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<td>8. National coordinator/group follows up defaulters and visits larger laboratories and those with the most material classified as potentially infectious</td>
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<td>9. National committee meets national coordinator/group to review documents and prepare report to be sent to WHO Regional Office.</td>
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Annex 2

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