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WHO

REGIONAL OFFICE FOR EUROPE

CERTIFICATION OF POLIOMYELITIS ERADICATION IN THE EUROPEAN REGION

Report on a WHO Meeting

Vienna, Austria

16–17 December 1997

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1998

EUR/HFA target 5

TARGET 5

REDUCING COMMUNICABLE DISEASE

By the year 2000, there should be no indigenous cases of poliomyelitis, diphtheria, neonatal tetanus, measles, mumps and congenital rubella in the Region and there should be a sustained and continuing reduction in the incidence and adverse consequences of other communicable diseases, notably HIV infection.

ABSTRACT

In order for the global eradication of poliovirus transmission to be certified, each WHO region must be certified free of polioviruses. In 1996, the WHO Regional Director for Europe appointed the European Certification Commission. For regional certification, national committees from each country will submit for formal review all available data in a standardized format to demonstrate the absence of poliovirus circulation for three years or more and the capability of rapidly detecting and limiting any poliovirus importation. This meeting was held to brief the chairmen of the 34 countries requested to first present documentation to the Commission (the Baltic countries and Belarus were briefed separately).

The Regional Commission has requested the national committees to submit documentation by the end of March 1998 from Denmark, Finland, Netherlands and the United Kingdom (Group 1), by the end of September 1998 from northern and western European countries (Group 2) and by the end of December 1998 from southern and central European countries (Group 3). The respective documentation will be reviewed in April 1998, January 1999 and April 1999. Committees from other countries in the Region will submit documentation in 1999 and 2000.

It is anticipated that in 2001 the Regional Commission will conclude that the European Region has eliminated wild poliovirus transmission. The work of national committees and regional commissions will continue and reports will need to be updated until eradication can be certified for the whole world. Effective surveillance will need to be continued until immunization stops. Acute flaccid paralysis surveillance is the standard method in support of certification, with performance indicators that have been well evaluated. Countries embarking on alternative or complementary approaches should ensure that the sensitivity and comprehensiveness of surveillance and laboratory competence are comparable.

Keywords

POLIOMYELITIS – prevention and control
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CONTENTS

Introduction

The first meeting of Chairmen of National Committees for the Certification of Poliomyelitis Eradication in the European Region was held in Vienna on 16–17 December 1997. Dr Donato Greco and Dr Istvaan Dömök chaired the meeting successively; Professor Drozdov was Vice-chairperson, Dr George Oblapenko Secretary and Dr David Salisbury Rapporteur. The programme of the meeting and the list of participants are attached as Annex 1 and Annex 2, respectively.

Professor Sieghart Dittman, on behalf of the WHO European Regional Office, welcomed participants and reminded those present of the similarities with smallpox eradication and the marked differences. In the 1970s, smallpox was already a disease of history in many European countries, apart from rare importations, but even in the 1990s, there have been outbreaks of poliomyelitis in Europe. Whilst the diagnosis of smallpox could be made on clinical grounds, and there was no carrier state, for polio the situation is very different with virological confirmation through sophisticated laboratory services being essential, and non-symptomatic polio far outweighs the paralytic presentation. At this stage in the polio eradication initiative, European countries need to strengthen their surveillance and to set up national committees and, where relevant, support the MECACAR Plus initiative.

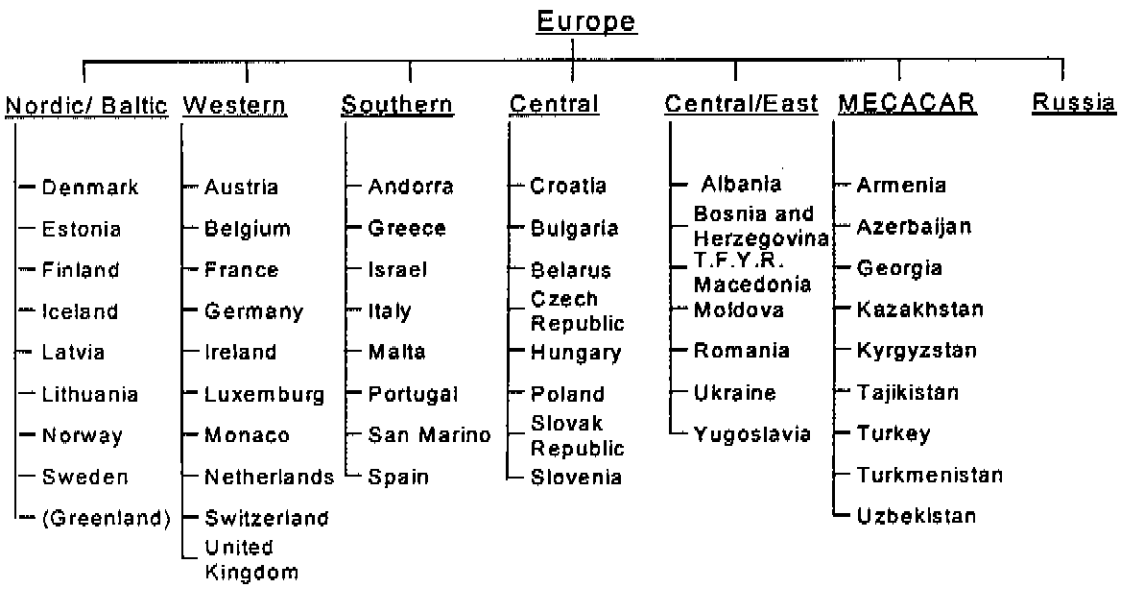
Dr Dömök addressed the meeting on behalf of the Regional Commission for Certification of Polio Eradication, and conveyed apologies from Sir Joseph Smith who was unable to attend the meeting. Dr Dömök reminded the participants that in 1995 the Global Commission had recommended the setting-up of regional commissions and in 1996, the WHO European Regional Director had appointed the European Certification Commission. Its purpose was to:

- validate the process for certification
- propose appropriate criteria
- identify documentation to demonstrate eradication
- review country reports and provide feedback
- undertake site visits
- certify countries if and when eradication was proven, and
- make recommendations to the Global Commission.

The European Commission had reviewed and amended its plan of action and modified the previously agreed zoning for certification review.

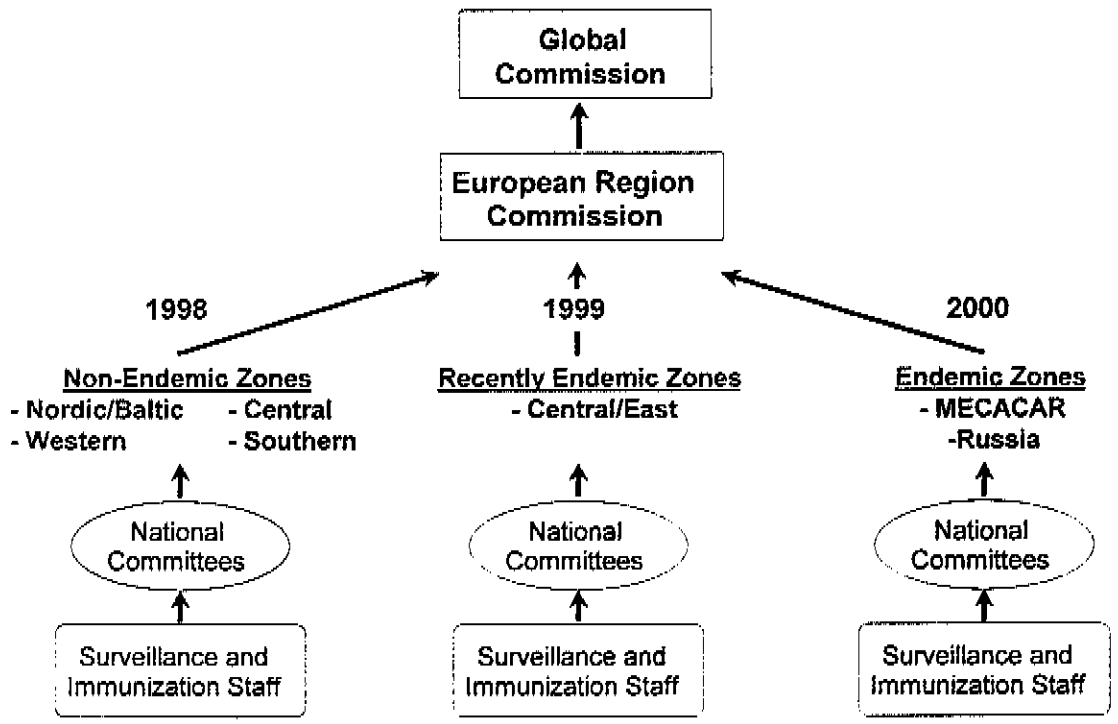
Dr Donato Greco reminded participants of the tasks and responsibilities of national committees – primarily the ability to show with certainty that wild polioviruses are no longer present. Such evidence must be sufficiently robust to support the ultimate cessation of immunization. The time course for this process has become urgent since, according to the time schedule accepted by the Regional Commission, the national documentation for certification should be submitted by the end of March 1998 from four countries (Group 1: Denmark, Finland, Netherlands and United Kingdom); by the end of September 1998 from the northern and western European countries (Group 2); and by the end of December 1998 from southern and central European countries (Group 3). The documentation will be reviewed successively in April 1998 (Group 1), January 1999 (Group 2), and April 1999 (Group 3). The remaining countries will be considered in 1999 and 2000. The submission of such reports does not bring to an end the responsibilities of national committees since surveillance will need to be continued until immunization stops and to be shown to remain effective until global eradication is confirmed. The work of regional commissions will continue and reports will need to be updated until polio eradication can be certified for the whole world.

Fig. 1. Zones for certification of wild poliovirus eradication
WHO European Region: 51 Member States*



* revised 1997; Greenland is not a WHO Member State

Fig. 2. Strategy for submission of documentation for certifying polio eradication
WHO European Region



Recommendation

All the countries except those in Group 1 should prepare an action plan in order to reach and maintain freedom from wild polioviruses and to be able to prove it by appropriate documentation submitted according to the time schedule prepared by the Regional Commission. The plans of action should be sent to the WHO Regional Office for Europe by March 1998. There will be interaction between national committees and the Regional Commission to ensure that countries are making appropriate progress. Documents will need to be reviewed on an ongoing basis and site visits will be undertaken if necessary.

Surveillance

Acute flaccid paralysis surveillance remains the "gold standard". The activities necessary for sensitive detection of AFP cases include immediate notification, routine zero reporting ideally on a weekly basis, advocacy meetings with physicians to ensure their support, and regular prompting to maintain active surveillance. The key indicators for AFP are:

- a minimum detection rate of 1 case per 100 000 population under 15 years;
- all AFP cases appropriately investigated, 80% having two adequate stool specimens within 14 days of onset of paralysis, 80% having a follow-up examination at 60 days;
- geographic distribution of AFP cases in accordance with district population density.

Additional features for polio surveillance include laboratory testing for wild polioviruses and demonstration of laboratory competence. Data available so far suggest that high apparent rates of AFP have occurred where facial palsy is included as reportable and it was recommended that such cases should not be included. Countries where the population was small and variations in small numbers of cases could have a large impact on the rate could either present consolidated data for three-year periods or could cooperate with similar and neighbouring countries to expand the size of the population under surveillance.

The laboratory network will extend from global level specialized reference laboratories to regional laboratories and national laboratories, each of which will be required to demonstrate competence in poliovirus and enterovirus identification. The criteria for accreditation will include, for example, use of appropriate methods and equipment, undertaking at least 150 viral cultures per year with achievement of indicators for timeliness, demonstration of proficiency on identification of blind samples, and an ability to isolate approximately 10% of non-polio enteroviruses from faecal cultures.

In addition to AFP surveillance, it is clear that a number of countries will utilize alternative or complementary approaches. Since polioviruses and non-polio enteroviruses share a number of common characteristics – affecting similar patients with similar disease manifestations, having similar sites of replication, similar shedding and transmission, and requiring similar techniques for isolation – so alternative approaches can focus on non-polio enteroviruses as markers for the ability to undertake surveillance for polioviruses. Indicators for non-poliovirus enterovirus surveillance could include the laboratory surveillance for such viruses of the whole country in question, the number of stool specimens each year inoculated onto enterovirus susceptible cells, the number of polioviruses and enteroviruses isolated, the exclusion of polioviruses from non-typable enteroviruses, and the ability to characterize poliovirus strains. Reassurance for the absence of polioviruses would come from data on enterovirus identification from cases with neurological conditions such as paralysis and aseptic meningitis. However, to date performance indicators have

not been established, such surveillance is passive rather than active, and it depends on arbitrary submission of specimens as opposed to specimens from all patients with AFP, and zero reporting is not appropriate as for AFP surveillance.

Environmental sampling has also been proposed through examination of sewage for the presence of wild polioviruses. This form of surveillance may be more appropriate for countries where inactivated polio vaccine is used routinely, since the presence of large quantities of vaccine viruses would obscure the detection of wild polioviruses should they be present in sewage. However, this form of environmental sampling has the potential for efficient monitoring of poliovirus circulation in large communities served by organized and centralized sewage systems. For countries that use OPV, laboratory methods must be in place and validated to identify wild poliovirus in the presence of virus of vaccine origin. In areas where AFP surveillance might be relatively insensitive, environmental sampling can selectively target possible high-risk communities and directly detect the circulation of wild polioviruses. Detection of wild polioviruses in this way signals the need for both improved immunization strategies and more sensitive surveillance for paralysed cases, such as AFP surveillance.

Recommendation

It was the view of the Regional Commission that acute flaccid paralysis surveillance remains a valuable and sensitive tool for both developing and industrialized countries and must be done to a high standard. It is an inexpensive and feasible indicator that has been well evaluated; other indicators have not been evaluated to the same extent. It therefore remained the surveillance indicator of choice. Countries embarking on alternative or complementary approaches should identify indicators of sensitivity of surveillance, comprehensiveness of surveillance, and laboratory competence, along with demonstrated ability to distinguish polioviruses from other enteroviruses. Performance indicators have not yet been established whereas for AFP surveillance these have been validated. Nevertheless, in countries where polio has apparently been eliminated for many years, it may prove impossible to establish satisfactory surveillance of AFP and flexibility will be needed in the Commission's assessment of the probability of freedom from circulating wild poliovirus. Here alternative or complementary approaches including supportive data will be appropriate.

Country reports

Denmark

Only half of the Manual of Operations could be completed since there had been no polio transmission in Denmark for 20 years and there was no AFP surveillance. Given the population size, there was considerable concern about the appropriateness of using AFP surveillance. There was a good infrastructure of health care with few risk-groups having low coverage. All suspected polio cases are hospitalized and polio cases are unlikely to be missed. Immunization coverage with sequential IPV/OPV was consistently at 95% or higher. Seroprevalence studies were carried out at 4–5 year intervals. The last imported case had been in 1983 and the last suspected case in 1992. Using environmental surveillance, oral polio vaccine strains were detected regularly and confirmed through intratypic differentiation. Outbreaks of enterovirus infections were detected regularly and it had been estimated that 1 in 5000 of the Danish population was examined each year for enterovirus infection. The enterovirus detection rate was in excess of 10% from faecal samples. This sampling was done through the national laboratories and laboratory accreditation and a formal network was to be established. Hurdles to be overcome were the identification of

resources for formalizing the enterovirus surveillance and the necessary IT facilities for the laboratory network.

Finland

Similar issues as Denmark were identified in the completion of the manual. Since there are only a limited number of sites where paralysed individuals are hospitalized and all virology is concentrated in five laboratories, it is most unlikely that any case of paralytic polio would be missed. There is mandatory reporting of suspected cases and the laboratory network has procedures for alerting public health authorities whenever polioviruses are identified. Immunization coverage is consistently high and seroprevalence studies are undertaken every five years. A limited AFP study had been undertaken but given the population size, reporting has been low, as were second stool sample rates. There was extensive experience with environmental sampling of sewage.

France

Immunization was compulsory and high coverage achieved. IPV was used routinely. Polio is statutorily notifiable. There are 22 virus reference laboratories, part of a coordinated network. Polioviruses that are isolated are confirmed at the National Reference Centre by intratypic differentiation. In 1991 a small, localized seroprevalence study was undertaken. Environmental surveillance of sewage was carried out routinely in Paris between 1975 and 1996. Wild polioviruses have been regularly identified but there have been no cases of paralytic polio detected. There are approximately 7000 positive isolates of enteroviruses each year. Between 1990 and 1996, 1500 cases of aseptic meningitis and 60 cases of GBS were investigated. No wild polioviruses were detected. It was considered that polio had been eliminated from France but there remained a risk from importation, especially from West Africa. It is planned that there will be efforts to accelerate the reporting of suspected cases to improve opportunities for diagnosis, retrospective evaluation of notified cases and continuation of enterovirus surveillance.

Sweden

Coverage had been consistently high. The last indigenous polio case was in 1977 but there had been occasional imported cases since then. Polio is a statutorily notifiable disease but the occurrence of an undiagnosed case could not be categorically ruled out on clinical surveillance grounds. Six laboratories undertake virological diagnosis with approximately 11 000 enterovirus cultures undertaken in the last three years. Approximately 3–4% of faecal cultures were enterovirus positive and no wild polioviruses were reported.

United Kingdom

Suspected polio is a statutorily notifiable condition and no indigenous case had been reported in more than a decade. A certification committee had almost completed its task although much of the Manual was felt to be not applicable for an industrialized country not using AFP surveillance. A sub-group of the polio committee had reviewed the case records of all suspected cases in the last decade and categorized all of them as diagnoses other than wild virus poliomyelitis. All appropriate data sources – such as hospital discharge diagnoses, have been interrogated and no unreported polio cases discovered. Reporting of vaccine-associated cases was thought to be complete based on rates reported previously from the UK and elsewhere. More than 1000 poliovirus isolations had been performed and subjected to intratypic differentiation: all were vaccine strains. A system for enterovirus surveillance had been developed that included the

paediatric and adult population, with faecal, throat and CSF samples taken. Laboratories undertaking enterovirus surveillance were part of an external quality assurance scheme and all had demonstrated their proficiency.

Recommendation

Four countries (Denmark, Finland, Netherlands and the United Kingdom4) have agreed to submit the reports of their national committees in time for the April 1998 meeting of the Certification Commission. These four countries will be offering non-AFP-based surveillance data to support their conclusions: three countries have used enterovirus surveillance and one has used environmental surveillance through sewage sampling. Their reports will allow the Regional Commission to obtain experience in country report assessment and offer opportunities for non-AFP based surveillance systems to be critically reviewed. After each Commission meeting, the countries reviewed will not be certified as polio-free, but will be advised if their surveillance appears adequate for eventual certification, or if further activities will need to be implemented. After that point, countries already having satisfied the Certification Commission will have to provide updates on their surveillance so that the whole Region can be considered for Regional Certification. It is anticipated that in 2001 the Regional Commission will make recommendations to the Global Commission that the European Region has eradicated wild virus poliomyelitis.

Annex 1

PROGRAMME

Tuesday, 16 December 1997

8.30	Registration	
9.00	Opening: WHO/EURO WHO/HQ Chairman of the Regional Certification Commission Administrative matters	
9.30–10.30	***Session 1: Progress towards eradication of poliomyelitis*** Global overview Regional overview Discussion	 Dr B. Aylward Dr G. Oblapenko
10.30–11.00	Coffee break	
11.00–12.30	***Session 2: Certification of polio eradication – process, basic documents, surveillance*** Standard AFP surveillance for certification: situation analysis and requirements Regional Polio Laboratory Network Discussion	 Dr S. Wassilak Dr G. Lipskaya
12.30–13.30	Lunch	
13.30–15.00	Global Commission for Certification (criteria, policy, certification process) Regional Certification Process Discussion	Dr S. Drozdov Dr D. Greco
15.00–15.30	Coffee break	
15.30–16.30	National documentation required for certification Discussion	Dr G. Oblapenko
16.30–17.30	Surveillance of enteroviruses Environmental surveillance of polio viruses Discussion	Dr A.v.Loon Dr T. Hovi

Wednesday, 17 December 1997

8.30–10.30	***Session 3: Certification of eradication of poliomyelitis:*** **Polio-free Europe by the year 2000**	
	Experience of countries that are already preparing documentation for submission to the Regional Certification Commission in early 1998:	(20 min. for each country, 15 min. presentation and 5 min. discussion)
	Denmark Finland The Netherlands United Kingdom France Sweden	
10.30–11.00	Coffee break	
11.00–12.30	**WORKING GROUP DISCUSSIONS**	
12.30–13.30	Lunch	
13.30–14.00	Reports of Working Groups	
14.00–15.00	Detection of importation and appropriate response (surveillance activities and immunization actions) Discussion	Dr B. Aylward
15.00–15.30	Coffee break	
15.30–15.45	LABNET: inventory, control and containment of laboratory stocks Discussion	Dr A. v. Loon
15.45–16.00	General discussion	
16.00	Closure of the meeting	

Annex 2

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