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POLIOMYELITIS ERADICATION

Report on the First Meeting of the
European Regional Commission for the
Certification of Poliomyelitis Eradication

Paris, France
7-8 March 1996

1996

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

The first meeting of the Commission for the Certification of Polio Eradication from the European Region was held in Paris on 4-6 March 1996. The composition and terms of reference of the Certification Commission were agreed.

The Commission considered the relevance to the European Region of the guiding principles recommended at the First Meeting of the Global Commission in 1995. Progress towards polio eradication was progressing satisfactorily following Operation MECACAR, with increasing numbers of countries becoming polio-free and fewer foci of polio remaining. There had been improvements overall in surveillance, coverage and outcomes. The Regional Office for Europe's work plan was endorsed. The laboratory network was reviewed and the role of laboratory surveillance in the certification process was considered. The experiences of other industrialized countries (Canada and USA) which had already been certified to have eliminated polio were discussed. The Commission agreed the proposed timetable for certification for the European Region.

Keywords

POLIOMYELITIS - prevention and control
IMMUNIZATION
EUROPE

1. Introduction

The First Meeting of the European Commission for the Certification of Eradication of Poliomyelitis was held at the International Children's Centre (CIE), Paris, 7-8 March 1996. The meeting was chaired by Sir Joseph Smith, Dr D.M. Salisbury served as rapporteur, Dr G. Oblapenko as secretary. Participants at the meeting were welcomed by Dr Marc Danzon on behalf of the Regional Director; Dr Pierre Begue welcomed the participants on behalf of the Ministry of Health, France. A list of participants is attached as Annex 1.

Sir Joe Smith drew participants attention to the Report of the 1st Meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis, against which the deliberations of the Regional Commission should be set.

2. Scope and purpose

The main objectives of the meeting were:

1. to discuss and agree on the terms of reference for the Regional Certification Commission;
2. to discuss and propose the process of certification for the Member States of the European Region of the World Health Organization; and
3. to formulate the main activities to be included in the plan of action of the Regional Certification Commission.

3. Composition and terms of reference of the Certification Commission

3.1 Composition:

The Regional Certification Commission is composed of seven persons with the appropriate training and experience to contribute to deliberations on the regional eradication of wild polioviruses (public health officials, virologists, epidemiologists, clinicians). They do not have direct responsibility for polio eradication activities in their countries and have no conflict of interest in serving on the Regional Certification Commission.

The Regional Commission members were appointed by the Regional Director of the European Region of WHO. The Regional Commission shall be independent of regional or national EPI activities but a member may on occasion attend relevant technical meetings such as the European Advisory Group (EAG) on EPI as observers. The Regional Commission will regularly communicate with the Global Commission through the two members who serve on both certification bodies.

3.2 Terms of reference:

- To validate the plan of action and timetable for certification for polio eradication in the European Region;
- to ratify or change the proposed quality of surveillance for certification in the non endemic, recently endemic and endemic countries of the Region;
- to state the documentation that will be needed from each country of the Region to certify eradication;
- to approve and update as necessary the protocol for the collection of national immunization and surveillance data for certification of polio eradication;
- to develop, if needed, innovative methods for verifying polio eradication in non endemic countries or "high risk" areas in recently endemic and endemic countries, where the established surveillance criteria for certification have not been met;
- to conduct site visits, if required, to review or verify the status of polio eradication activities in individual countries;

- to review the polio eradication documentation of each country/zone on an ongoing basis, and report the findings and required actions to the Regional Director and appropriate national committee;
- to bring unresolved certification issues to the attention of the Global Commission for the Certification of Eradication of Poliomyelitis for discussion; and
- to certify, if and when appropriate, the eradication circulating wild polioviruses from the European Region of the World Health Organisation, and to provide the Global Commission with the documentation necessary to endorse regional certification.

4. Situation analysis: progress and problems.

4.1 Global overview:

4.1.1 Significant progress is being made towards the global eradication of polio by the year 2000. The strategies recommended by WHO for polio eradication are: maintaining high routine immunization coverage; conducting nation-wide mass immunization campaigns; building effective, laboratory based surveillance for acute flaccid paralysis; and localized immunization campaigns (mopping up) directed at the interruption of final chains of virus transmission.

4.1.2 Coverage: In 1985, immunization coverage for three doses of polio vaccine by the first birthday was 48%. This rose to 82% in 1994.

4.1.3. National immunization days: The purpose of national immunization days is to stop wild poliovirus transmission. It is recommended that all children less than 5 years of age be immunized, regardless of prior immunization status. Two rounds of immunization are conducted, normally 4-6 weeks apart. Each round should be conducted in as short a time as possible. NIDs are conducted during the cool, dry season to both decrease operational difficulties and to produce the maximum effect from the doses administered. In 1988, NIDs were carried out by 15 countries; it is expected that by the end of 1996, NIDs will have been carried by 92 countries. In NIDs in December 1993 and January 1994, 82 million children were immunized in single days in China; 87 million were immunized in 1995 in India under similar circumstances. During 1995, it is estimated that 300 million children (half the world's population of children under 5 years) were immunized in NIDs.

4.1.4 Surveillance: Eradication requires that sensitive surveillance systems, capable of identifying all cases of polio, be in place in every country. Because there are no absolute criteria which would permit polio to be identified on a clinical basis, WHO recommends laboratory based surveillance, focusing on cases of acute flaccid paralysis (AFP). AFP surveillance requires immediate reporting of all cases of AFP in children less than 15 years of age. Cases should be investigated rapidly, with collection of clinical and epidemiological information and two stool samples. These must be transported under refrigeration to a laboratory of certified competence which is part of the WHO global polio laboratory network. Each specimen is then tested using uniform techniques and standardized reagents. Any polioviruses isolated must be characterised to determine whether they are wild or vaccine strains. In the advanced stages of eradication, stools from contacts of cases may also be tested. Countries with adequate surveillance systems should find at least one case of AFP each year for every 100,000 children less than 15 years of age.

Since 1988, there has been a 10-fold decrease in reported cases of poliomyelitis, in the face of improving surveillance. It is recognized however that there is still significant under-reporting, perhaps of the magnitude of only 1 in 10 cases being reported. However, there

has been a progressive rise in the number of countries reporting zero cases of polio. Wild virus polio has been eradicated from the Region of the Americas since August 1991: no wild virus has been detected, despite intensive searching. At present, most cases are reported from the South-East Asian Region, next from AFRO, then EMRO, Western Pacific and finally EURO.

4.1.5 Mopping-up: Successful NIDs will reduce poliovirus transmission to a few final chains of transmission, typically persisting in densely populated areas where inadequate health services yield both low routine immunization coverage and poor performance during NIDs. Surveillance data are used to identify these final reservoirs of wild virus infection. Intensive localized immunization campaigns, referred to as mopping-up, are conducted to interrupt these final chains.

4.2 European Regional Overview

Poliomyelitis eradication activities were initiated in the Region in 1985 when the target 5 HFA was formulated and adopted by the Regional Committee. However, implementation of the regional programme started in 1989 when the first plan of action was endorsed. From 1988 to 1995, progress in eradication of poliomyelitis was slow. Initial efforts concentrated on improvements in surveillance and the setting up of active strategies targeted at the interruption of transmission of wild polio viruses in endemic countries.

A detailed account of the present situation as regards progress with poliomyelitis in the European Region is attached at Annex 2.

The work plan for poliomyelitis eradication, previously endorsed by the European Advisory Group, had featured four priority work areas. These were:

1. Improvement in surveillance. AFP surveillance is now undertaken in 24 countries (previously 11); the laboratory network has improved; monthly reporting has improved, with completeness now at 96%, and timeliness 82%. **The planned improvement has been achieved.**
2. Increase in coverage. In 1993, regional coverage for polio immunization was 83%; coverage in 1994 was 88%. It is expected that the coverage for 1995 will have exceeded 90%. **This objective has been achieved.**
3. Improvement in international co-operation. Operation MECACAR has led to the development of an effective anti-polio coalition bringing together political, public health and community-based constituencies. **This objective has been achieved.**
4. Certification process. Although originally planned for 1995, the certification process is now under way with the first meeting imminent.

Between 1990 and 1994, reports on poliomyelitis in the European Region had increased, in part through improved surveillance, in part through real increases from vaccine shortages and programmatic difficulties. A decrease in cases was reported in 1995 along with a fall in the number of countries with endemic transmission (only 9); only 40 territories had endemic poliomyelitis in 1995. Although there appeared to be a significant seasonal increase in poliomyelitis reports in the summer of 1995, cases occurred in those countries outside of the MECACAR coalition, occurring predominantly in the Russian Federation as well as one

case in Ukraine and two in Former Yugoslavia. Since Operation MECACAR, the main endemic territories are in the Russian Federation, Turkey, Azerbaijan and Turkmenistan.

Although there has been this gratifying decrease in cases of polio, surveillance indicators for AFP remain sub-optimal. Overall rates of AFP are still too low; cases with AFP are not fully investigated, or are only slowly investigated. However, progress is being made in laboratory surveillance with all countries having access to laboratories which are in turn now linked to reference laboratories. There is scope, however, for further improvement in the laboratory network and too many cases are still classified as of unknown aetiology, in part because of inadequate case investigation.

The priority areas remain surveillance, achievement of interruption of transmission, and strengthening of the laboratory network. To fulfil these priorities, the regional strategy encompasses a commitment to high coverage through routine services, NIDs in order to interrupt transmission, mopping up in high risk areas, improved surveillance to define high risk areas, and meeting of criteria for certification. The operational plans to achieve the strategic objectives are directed to interruption of transmission, improvement in surveillance (AFP, stool sampling, lab proficiency), and the development of the certification process.

5. Laboratories and polio virus surveillance:

5.1 Background:

The regional polio eradication initiative requires a laboratory network made up of national, regional and specialized reference laboratories. Their purpose is to provide accurate and timely information to support the eradication initiative. Through the application of standardized procedures, the laboratories are involved in specimen transport, laboratory methods, provision of reference reagents and supplies, and linking with the reporting system. Laboratories provide training of personnel, advice to the field and collaboration on the integration of laboratory and field information. Vaccine potency is checked for conformity with WHO standards and vaccine lots are tested for level of attenuation and lack of neurovirulence. Laboratories must be able to identify poliovirus as distinct from other enteroviruses and in the former case, identify the serotype, whether wild or vaccine derived virus, and whether indigenous or imported. Serological studies may be undertaken to investigate serological profiles of populations, measure type-specific immunity and ensure that vaccine induced antibodies protect against wild virus. Laboratories will be involved in virological surveillance of samples from man and the environment.

5.2 Laboratory methods:

Present methods (virus isolation, neutralization) are time consuming, laborious and not ideally suited for large numbers of samples. They are particularly cumbersome when mixtures of viruses are present. New laboratory methods are needed for diagnosis, detection and sero-epidemiology. Such methods include intratypic differentiation, RNA amplification (PCR), rapid culture/IF detection, type specific IgM assays and the use of mouse L-cells expressing the polio virus receptor (PVR). Molecular methods are being increasingly used as these provide high sensitivity (for enteroviruses), early rapid diagnosis and investigation of genetic variability of polioviruses; expertise and facilities for molecular methods are becoming increasingly widespread.

5.3 National Reference Laboratories:

The main purpose of National Reference Laboratories is to investigate patients with AFP for virus isolation (including serotyping). National Reference Laboratories are involved in vaccine potency testing, sero-surveys, environmental monitoring, participation in the global network for collection and distribution of virus strains, patient specimens and laboratory information, and provide standardized reporting to national programme managers.

5.4 Regional Reference Laboratories:

These laboratories provide backup services for countries without a national laboratory. They support the development and function of national laboratories by distribution of reference materials (cell lines, virus strains, antisera), and consumables, and assist in proficiency testing and quality assessment. The regional reference laboratories provide a focal point for more advanced testing (e.g. intratypic differentiation) and the evaluation of new technology. There are now 5 regional reference laboratories in the European Region supporting 36 national reference laboratories. The 5 regional reference laboratories are: KTL (Helsinki, Finland), Institut Pasteur (Paris, France), RIVM (Bilthoven, The Netherlands), Institute of Poliomyelitis and Viral Encaphilitides (Moscow, Russian Federation), and NIBSC (London, United Kingdom).

5.5 Specialized Reference Laboratories:

The purpose of the specialized reference laboratories is to prepare and distribute standard and reference reagents, including proficiency panels; to act as a resource for development of training materials and provide assistance in training courses; to undertake definitive characterization of poliovirus isolates and determination of their origin through molecular epidemiology; to develop and evaluate improved methods for diagnosis and detection, and to provide appropriate information and virological expertise to WHO. The 5 specialized reference laboratories are CDC (Atlanta, USA), Institut Pasteur (Paris, France), KTL (Helsinki, Finland), NIBSC (London, UK) and RIVM (Bilthoven, Netherlands).

5.6 Laboratory Network EURO - Plan of Action 1995-2000:

The goal of the plan of action is to establish a network that provides accurate and timely information on the existence of wild poliovirus in support of polio eradication. The activities required by the plan of action include the further development of the laboratory network, the monitoring of performance of laboratories for productivity, timeliness and completeness of reporting, and maintaining standards of quality and effectiveness. This will require proficiency testing, ~~the provision of expert advice, training, and introduction of new technologies.~~ A series of referral channels will need to be set up from national, regional and special laboratories. Laboratory services will need to be integrated into AFP and environmental surveillance services with focus on collection and transport of samples, laboratory methods and linking with clinical surveillance information. National, regional and reference laboratories will need to be actively integrated into the processes for certification. The effective delivery of the laboratory network will require the appointment of a laboratory co-ordinator. The Certification Commission strongly supported the need for such an appointment.

6. Environmental Surveillance:

The global certification of poliomyelitis eradication will require the demonstration that not only do cases of wild virus poliomyelitis no longer occur, but the virus can neither be detected in humans or the environment. The latter task will require the development of methods of environmental surveillance for wild polioviruses. At present this area requires further refinement and development so that its role in eradication processes can be clarified.

Poliovirus infected individuals, whether showing clinical symptoms or not, shed large amounts of poliovirus in the faeces for several weeks or months. The excreted virus can survive outside the human body for considerable periods, especially in cold and temperate climates. Poliovirus circulation can therefore be monitored by examining sewage or other faeces-contaminated environmental specimens. The pooling and mixing of excreta that takes place in the sewage network provides a suitable opportunity for the detection of possibly silent circulation in the general population. However, dilution of the excreta in sewage systems is considerable and daily raw sewage volumes as high as 200 litres per capita exists in European cities. On the other hand, one thousand-fold concentration of raw sewage can readily be obtained using simple and inexpensive 2-phase systems with ultrafiltration cartridges. It is not possible to standardize the sampling procedures or operational aspects and local conditions for sewage collection; these have to be considered in the defining of the procedures of environmental screening.

The sensitivity of detecting wild polioviruses by conventional techniques in environmental samples is affected by the presence of non-polio enteroviruses and OPV-derived poliovirus strains. However, wild polioviruses have been detected in environmental specimens in countries maintaining relatively high coverage through regular OPV immunization. The identification of polioviruses in the presence of non-polio enteroviruses may be facilitated by the use of poliovirus receptor-expressing recombinant mouse cell lines. Wild polioviruses have been detected even in the presence of Sabin-like strains.

Recent experience with environmental sampling was obtained in the Netherlands during the 1992/93 polio type 3 epidemic. Although detected retrospectively, the epidemic virus was found in a river water sample collected 4 weeks before notification of the first patient, from a site a few kilometres up-stream of the home village of that first patient. At the start of the epidemic, it was shown by environmental sampling that the epidemic virus had circulated already in all parts of the risk area where communities of unvaccinated persons lived, although only one case of paralytic poliomyelitis was apparent at that time. Later in the epidemic, it was demonstrated by environmental sampling that virus circulation was confined to the identified risk area only, as all samples from outside the risk area were negative for the epidemic virus. This evidence confirmed that the existing immunization policy (using IPV) was sufficient to prevent circulation of the epidemic virus amongst vaccinated people and the epidemic strain did not spread to unvaccinated people living outside the main risk area.

It appears that surveillance by environmental sampling can, in theory, give information on presence or absence of wild polioviruses in a particular locality. But several key questions remain to be answered: where, when and how often should environmental sampling be applied? What action should be taken if wild virus is detected? What is the prospective value of a negative result? Further experience with environmental sampling will be needed.

Sewage has been regularly monitored for enterovirus circulation in 38 cities of the USSR for more than 20 years. This has covered 23 regions with a population of approximately 30 million individuals. This surveillance has identified the permanent presence of enteroviruses in sewage

(from 29% to 85% of samples), an identical profile of enteroviruses in sewage and stool samples in patients and healthy individuals, and circulation of both vaccine and wild polioviruses. Specific enterovirus types have been identified in sewage before the outbreak of disease caused by that type. Following on from these results, epidemiological monitoring of polioviruses in a number of environments (sewage, surface water, drinking water) has been undertaken in different regions of the USSR - Estonia, Kyrgyzstan, Russian Federation. The regions were selected on the basis of their differences in conditions for geographic, climatic, social and sanitary criteria. Importantly, there had been a complete absence of poliomyelitis cases in Estonia, and continuing registration of cases in Kyrgyzstan and Russia. Polioviruses, both vaccine and wild types, were detected in a number of different water environments. Polioviruses were detected most frequently in sewage and wild polioviruses were observed in all regions, including those where clinical cases had not been detected. These studies, importantly, show that wild virus can be detected in sewage in communities where oral polio vaccine is being extensively used, and that wild polioviruses can be detected in sewage in the absence of clinical cases.

In the Netherlands, approximately 56,000 faecal samples have been tested for enteroviruses. Only one sample was positive for wild polio virus (from a recently adopted child from outside the European Region), a number of samples were positive for vaccine virus, again excreted by OPV immunised adopted children. Similar results had been obtained from France where 27,000 laboratory samples were examined for viral culture and only 14 Sabin like strains had been identified.

7. Certification of polio eradication from the United States:

The certification experiences of the United States are very relevant to a number of European countries because there had been no confirmed wild virus cases for many years and it was considered impractical to implement AFP surveillance.

Routine reporting of cases of wild virus polio from the United States showed that the last cases of indigenous wild virus polio occurred in 1979 in groups who objected to immunization. The last wild virus imported case was in 1986 and although there had been a small number of imported cases in the 1980's, on no occasion did an imported case lead to secondary transmission. Since 1980, between 8-10 cases of vaccine associated polio (contact or recipient) have been reported. This rate has been constant and is commensurate with previous estimates of the expected rates of vaccine associated polio.

Routine surveillance for polio is accomplished through a number of passive systems that include the national poliomyelitis surveillance system, vaccine adverse event reporting, vaccine injury compensation programme, laboratory based enterovirus surveillance, polio reference laboratory, large linked databases and cluster investigations by individual states. A number of special studies were set up. Their purpose was:

- to determine the completeness of polio case reporting,
- to document the absence of wild polio virus during a 12-month period of national enterovirus surveillance from clinical specimens,
- to assess whether wild poliovirus had circulated in the United States following its introduction into Canada in 1993,
- to review hospital discharge diagnoses to determine the rate of Guillain Barre Syndrome by age group,
- to construct a mathematical model to predict the likelihood of continued wild poliovirus circulation in the absence of apparent cases,
- to conduct a population based seroprevalence survey for antibody to the three polioviruses, to evaluate the seroprevalence among inner city populations, and
- to determine polio immunization coverage in pre-school children.

Evidence was based on the above and submitted to the national commission which concluded that the United States was free of indigenous wild poliovirus. This view was accepted by the Regional Certification Committee. The surveillance continues in the United States.

8. Conclusions of the Certification Commission:

The Commission considered carefully the Draft Plan of Action for the certification process. The Commission requested that modifications be made to the composition of the 'zones for certification'. The amended Plan of Action is attached as Annex 3.

Certification of polio eradication from the European Region poses some specific difficulties because of the number of industrialised countries where there has been no wild virus polio recorded for at least a decade or more, and where there is very little prospect of implementation of AFP surveillance. Sophisticated virological services are available in most of those countries but they have not been directed at poliovirus surveillance, in the continued absence of disease. These countries will need to consider carefully the available information that can be used, or collected, in order to show convincingly that if cases of polio occurred, then they would be detected rapidly, and that there is no silent circulation of polioviruses. Such data may include laboratory surveillance of enteroviruses with information on identified polioviruses, and information on the detection rates of vaccine associated poliomyelitis in countries where OPV is used. The continuing ability to detect both recipient and contact cases is encouraging because recipient cases occur usually in the paediatric population and contact cases occur in the adult population. Should wild virus cases occur in such countries, they would most likely affect either adults or high risk groups, such as those refusing immunisation. Details of the surveillance requirements are attached at Annex 4.

The Commission considered the documentation that it expects to receive from national committees and the timetable for the certification process. These are attached as Annexes 5 and 6 respectively. The Commission is keen for national committees to submit outline plans of their certification endeavours as early as possible so that a proactive process can develop. This will allow the Regional Commission to steer national committees to develop appropriate submissions with the highest possible chances of meeting the certification criteria. The work of the Regional Commission will be aided by an up-to-date situation analysis of the polio immunisation programmes, surveillance capacities and incidence of reported polio on a country by country basis, as soon as possible. The Commission recognised that the certification process will depend significantly on the work of the Regional Office, and recommends that the appropriate level of support is made available.

**First Meeting of the European Regional Commission
for the Certification of Poliomyelitis Eradication
Paris, France, 7-8 March 1996**

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Progress Towards the Eradication of Wild Polioviruses in the European Region

1. Immunization Programmes and Reported Cases of Poliomyelitis

The European Region of the World Health Organization is comprised of 50 member states. Routine childhood immunization against poliomyelitis is offered in all 50 of these countries. Polio immunization is compulsory in 31 countries and voluntary in 16, all of which are considered 'nonendemic'; the legal status of polio immunization is not currently available from 3 member states. Of the 48 countries for which information is available, oral polio vaccine (OPV) alone is used in 38, inactivated polio vaccine (IPV) alone in 6 and a combination of the two vaccines in 4. Table 1 summarizes the countries which are known to have a voluntary polio immunization policy and use a polio vaccine other than OPV in their routine childhood immunization schedules.

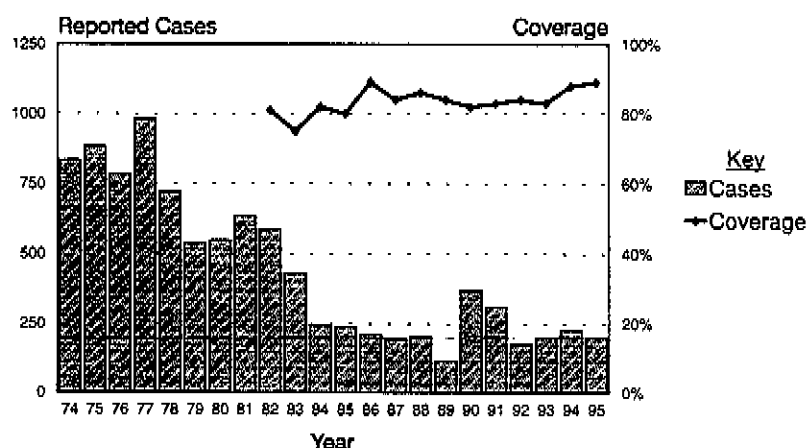
Table 1: European Countries with Voluntary Poliomyelitis Immunization and Which Use Inactivated Polio Vaccine (IPV)

Voluntary Poliomyelitis Immunization Policy		IPV Alone	IPV/OPV Combination
Austria	Luxembourg	Finland	Denmark
Denmark	Malta	France	Hungary
Finland	Netherlands	Iceland	Israel
Germany	Norway	Netherlands	Lithuania
Greece	Spain	Norway	
Iceland	Sweden	Sweden	
Ireland	Switzerland		
Israel	United Kingdom		

Figure 1 illustrates the reported cases of

poliomyelitis and polio vaccine immunization coverage for the entire Region between the years 1974 and 1995. By 1995, polio cases were being reported from only 40 administrative units (districts, oblasts, etc.) out of 3372 in all of Europe. In Figures 2-4, the recent trend in reported cases is shown for the endemic, recently endemic and non-endemic countries, respectively (the basis for classifying a country's endemicity, as well as 'certification zone' is outlined in the Plan of Action for the Certification of Wild

Figure 1: Reported Cases of Poliomyelitis and OPV* Immunization
European Region of the WHO, 1974-1995



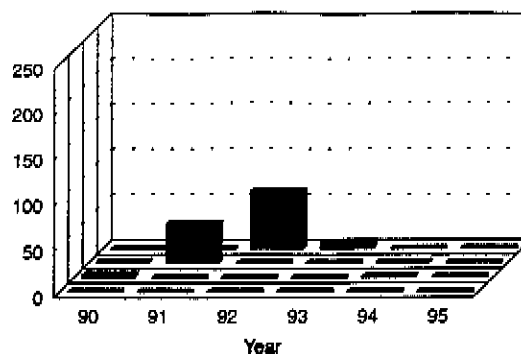
* at least three doses of oral polio vaccine or inactivated polio vaccine.

Poliovirus Eradication in Europe).

Non-Endemic Countries: A total of 33 countries in the European Region are considered non-endemic. For certification purposes, they will be divided into four 'zones': Nordic/Baltic, Western, Central and Southern Europe. In general, these countries have had a long history of good sanitation and high routine polio immunization coverage which resulted in the interruption of indigenous wild poliovirus transmission prior to the global resolution to eradicate the virus in 1988. Figure 2 shows the recent trend in reported cases of poliomyelitis in the 4 non-endemic zones. The cases reported in the Western Zone in 1992-93 represent an

outbreak in the Netherlands which followed the importation of a wild poliovirus from India into an unimmunized religious subgroup of the population. The 1991 cases in the Central Zone were the result of an outbreak in Bulgaria where most cases occurred among the gypsy population whose immunization coverage was markedly lower than that of the general population. These outbreaks demonstrate the need for very sensitive surveillance strategies to detect wild poliovirus importations and targeted immunization activities to achieve high immunization coverage among all population subgroups.

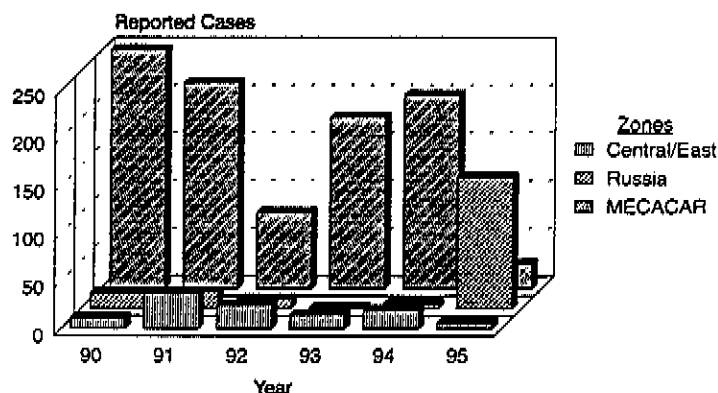
Figure 2: Non-Endemic Countries



Recently Endemic Countries: 7 of the 50 European Region Member States are considered 'recently endemic' on the basis of either ongoing indigenous wild poliovirus circulation within the 5 year period between 1988 and 1993 or insufficient surveillance data to rule out the possibility of indigenous wild poliovirus transmission during that period. The major issues for the polio eradication initiative in these countries are establishing sensitive AFP surveillance systems and conducting mopping-up immunization in areas where there is a high risk of wild poliovirus reintroduction, such as in areas bordering endemic countries or where routine childhood immunization coverage is known to be less than 80%. Figure 3 illustrates the recent trend in reported polio cases in these zones.

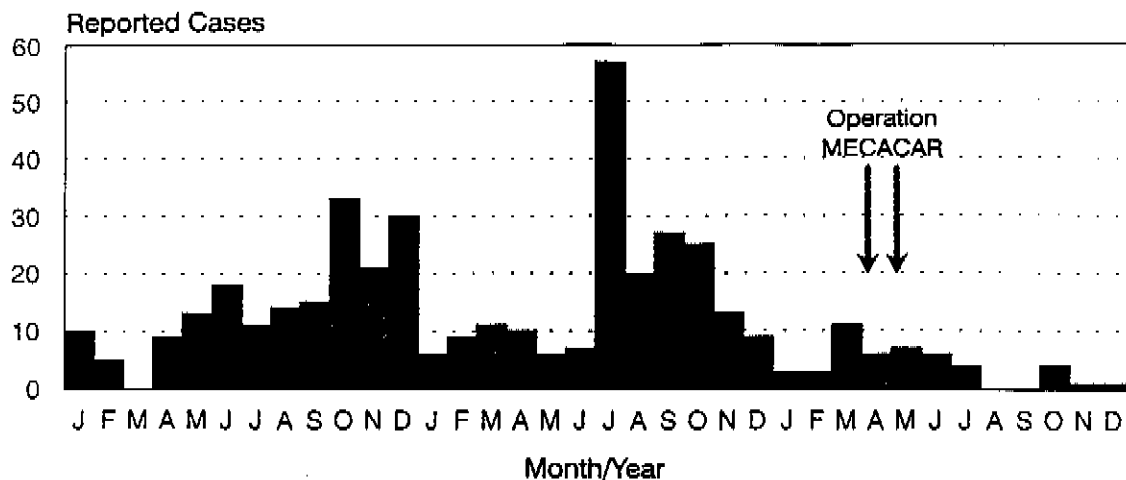
Endemic Countries: 10 countries of the European Region are currently considered endemic for wild poliovirus. These countries include Russia, Turkey, the 5 Central Asian Republics and 3 Caucasus countries. In these countries the immediate concerns of the polio eradication initiative are interrupting wild poliovirus transmission and establishing AFP surveillance to monitor progress and guide future supplementary immunization activities. Figure 3 illustrates the recent trend in reported polio cases in these countries by 'certification zone'. While a number of these countries had undertaken supplementary immunization with OPV prior to 1995, the most important progress towards polio eradication in the region occurred in April and May 1995, when all of these countries except Russia took part in Operation MECACAR. During this operation, 18 countries from the Mediterranean (ME), Caucasus (CA) and Central Asian Republics (CAR) conducted coordinated national immunization days in which over 63 million children aged less than 5 years were targeted to receive 2 supplementary OPV doses 1 month apart, regardless as to their prior immunization status.

Figure 3: Endemic or Recently-Endemic Countries



The impact of Operation MECACAR on the monthly number of reported polio cases in the participating countries is illustrated in Figure 4. The geographic distribution of wild poliovirus appears to have been substantially reduced in MECACAR countries as the number of administrative units (districts, oblasts, etc.) reporting polio cases fell from 64 in 1994 to 33 in 1995.

Figure 4: Reported Cases of Poliomyelitis by Month, 1993-1995
MECACAR* Countries of the European Region of the WHO



* Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyzstan, Tajikistan, Turkey, Turkmenistan, Uzbekistan

Operation MECACAR will be conducted for at least 3 years to ensure the interruption of wild poliovirus circulation in these areas. In 1996 all 10 polio endemic countries in the European Region will participate in Operation MECACAR by conducting coordinated NIDs between March and May.

2. Surveillance for Poliomyelitis, Acute Flaccid Paralysis and Polioviruses

2.1 Poliomyelitis Surveillance: Confirmed poliomyelitis is a routinely reportable disease, on either a weekly or monthly basis, in all 50 member states of the European Region of the WHO. Many countries, particularly those which are 'non-endemic', have had a policy of immediate reporting and investigation of suspected polio cases for more than 10 years.

Although the sensitivity of these passive reporting systems is not known, there is substantial evidence that it is quite high in the non-endemic countries as evidenced by the regular detection, investigation and reporting of imported and vaccine associated cases of paralytic poliomyelitis (VAPP). Between 1985 and 1991, 40 cases of VAPP were reported to the WHO from 11 of the 26 nonendemic countries. During the same time period, 24 imported cases were reported from 10 of these countries. Between 1991 and 1996, passive surveillance systems in Germany, the Netherlands, Norway, Sweden and the United Kingdom detected importations. In Italy, a case of AFP in an unimmunized Gypsy was also detected through the routine disease surveillance system.

2.2 Acute Flaccid Paralysis Surveillance: As of February 1996 surveillance for acute flaccid paralysis had been established in 7 out of 10 polio endemic countries, 5 out of the 8 'recently endemic' countries and all 6 of the non-endemic countries of the Central Zone. In addition, one non-endemic country of the Southern Zone was establishing AFP surveillance (Italy, 1995) while one in the Western Zone had conducted a research project using AFP surveillance to verify the absence of wild poliovirus circulation in that country (United Kingdom, 1991-1994). Table 2 shows the progress that has been made towards establishing AFP surveillance in the countries of the European Region. The table also shows the performance of the AFP systems in 1995, using two of the critical indicators: non-polio AFP rate (minimum expected 1/100,000 population aged less than 15 years) and percentage of AFP cases with 2 adequate stool samples collected within 2 weeks of the onset of paralysis.

Table 2: Status of AFP Surveillance in the European Region of the WHO

Zone	Country	Year AFP System Started	Expected non-polio AFP/year*	Reported non-polio AFP in 1995 Cases	Rate	% of AFP with 2 stool specimens
Central	Bulgaria	1991	13	26	1.99	35%
	Belarus	1993	17	32	1.86	100%
	Czech Republic	1991	20	2	0.10	50%
	Hungary	1992	18	0	0.00	0%
	Poland	1992	73	0	0.00	0%
	Slovakia	1992	11	11	1.00	27%
	Total:	NA	152	71	0.47	63%
Central/ Eastern	Bosnia&Herzegovina	NA	7	NA	NA	NA
	Croatia	1992	7	1	0.13	100%
	TFYR Macedonia	NA	5	NA	NA	NA
	Moldova	1995	10	2	0.20	50%
	Romania	1992	36	29	0.81	100%
	Slovenia	1992	3	0	0.00	0%
	Ukraine	1992	84	113	1.34	36%
	Yugoslavia	NA	22	NA	NA	NA
Total:	NA	174	145	0.83	49%	
MECACAR	Armenia	1995	10	2	0.19	100%
	Azerbaijan	1994	24	0	0.00	0%
	Georgia	NA	12	1	0.08	100%
	Kazakhstan	1992	47	9	0.19	90%
	Kyrgyzstan	1995	19	20	1.05	0%
	Tajikistan	NA	30	NA	NA	NA
	Turkey	1991	180	78	0.43	45%
	Turkmenistan	1995	17	0	0.00	0%
	Uzbekistan	NA	98	NA	NA	NA
Total:	NA	438	110	0.25	26%	
Russia	Russia	1992	220	0	0.00	0%

* based on a minimum of 1 non-polio AFP cases per 100,000 pop. < 15 years

It is expected that AFP surveillance will be established in the remaining endemic and recently endemic countries during 1996.

2.3 Poliovirus Surveillance: In addition to routine surveillance for poliomyelitis and/or acute flaccid paralysis (AFP), a number of countries in the European Region conduct regular virological surveillance for polioviruses by a number of mechanisms. In Finland, the Netherlands and Russia there is ongoing routine testing of environmental samples (sewage and/or river water) for polioviruses. In the Netherlands, this environmental sampling detected the wild poliovirus that was responsible for the 1992/93 outbreak more than 2 weeks before the onset of paralysis in the first case.

In a survey of national laboratories conducted by the WHO European Regional Office in 1991, 25 countries reported conducting 'environmental surveillance for enteroviruses'. In 11 of these countries, sewage samples were regularly tested specifically for wild polioviruses; 10 countries regularly monitored river water for wild polioviruses.

During 1995, a total of 11 national laboratories from non-endemic countries submitted regular quarterly reports to the WHO European Regional Office on the results of virological investigations of AFP cases

(Denmark, Estonia, Finland, France, Germany, Greece, Israel, Netherlands, Norway, Portugal, Spain). In the majority of countries, these results were limited to samples submitted to the national laboratory itself and therefore did not represent the entire country. In France, however, a network of laboratory based surveillance has been established through which a number of sentinel facilities regularly submit any positive virological results from patients with neurological symptoms.

3. European Laboratory Network for Polio Eradication

A regional network of laboratories has been established to ensure consistent standards for poliovirus isolation and identification throughout Europe. The network consists of 4 Special Reference Laboratories, 1 Regional Reference Laboratory, 2 Sub-Regional Laboratories and 42 National Polio Laboratories.






Figure 5 demonstrates the network of Regional Reference Laboratories and their principal areas of geographic responsibility. As noted previously, the majority of National Polio Laboratories are responsible for the isolation and identification of polioviruses (type 1, 2 or 3) and submitting the isolates to either a Special Reference Laboratory or a Regional Reference Laboratory for intratypic differentiation (wild versus vaccine viruses). Wild polioviruses may then undergo genetic sequencing at one of the Special Reference Laboratories. All of the national laboratories have either completed or are currently undergoing proficiency testing.

As of March 1996, the most recent wild polioviruses isolated in the European region through the laboratory network were a type 1 (T-genotype 'green' virus) in Moscow in June 1995 and a type 1 virus from eastern Turkey in December 1994. A similar virus to that found in Moscow was isolated in Uzbekistan in July 1994 and Tajikistan in September 1994.

Figure 5: Polio Laboratory Network, European Region of the WHO



Regional Reference Laboratories & Geographic Areas of Responsibility

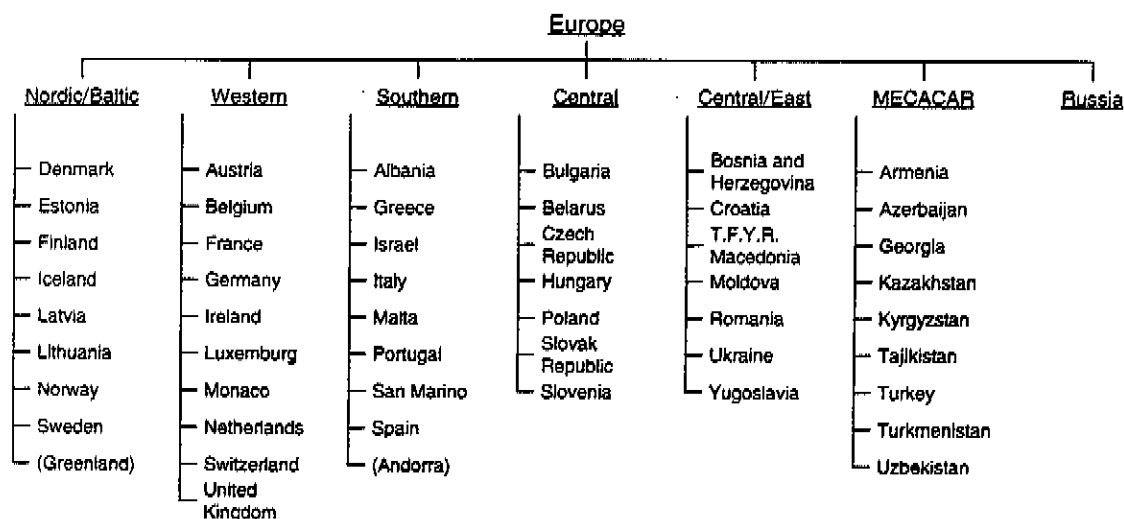
-  National Public Health Institute, Finland
-  Institute Pasteur, France
-  RIVM, The Netherlands
-  Institute of Poliomyelitis & Viral Encephalitides, Russia
-  National Institute of Biological Standards, UK

Overview: Plan of Action for Certification of Polio Eradication in Europe

The certification of polio eradication in Europe will be the decision of a 7 member Regional Commission composed of public health authorities, physicians and scientists. The Regional Commission will base its decision upon the review of polio eradication documentation provided by the National Certification Committee of each member nation. The National Certification Committee of each country will not have the authority to certify their country as being polio-free, but will recommend that such certification be made by the Regional Commission.

To facilitate the certification process, the 50 member nations of the European Region of the WHO will be divided into 7 zones, reflecting similarities in their current epidemiology of poliomyelitis as well as common geographical, climatic and historical characteristics. Other considerations also contributed to the categorization of countries, particularly factors which affect the certification process: immunization coverage, the structure of health services and poliovirus surveillance capabilities.

Figure 1: Zones for Certification of Wild Poliovirus Eradication
European Region of the WHO: 50 member states*



* Andorra and Greenland are not WHO member states

The various zones can be considered as endemic, recently endemic or nonendemic as of 1996. In general, the zones (and countries) are categorized as follows:

- 1) **Endemic:** countries with virological and/or epidemiological evidence of indigenous wild poliovirus circulation within the past three years.
- 2) **Recently Endemic:** countries with virological and/or epidemiological evidence of having interrupted indigenous wild poliovirus circulation between 3 and 8 years ago.
- 3) **Nonendemic:** countries with virological and epidemiological evidence of having interrupted indigenous wild poliovirus circulation more than 8 years ago.

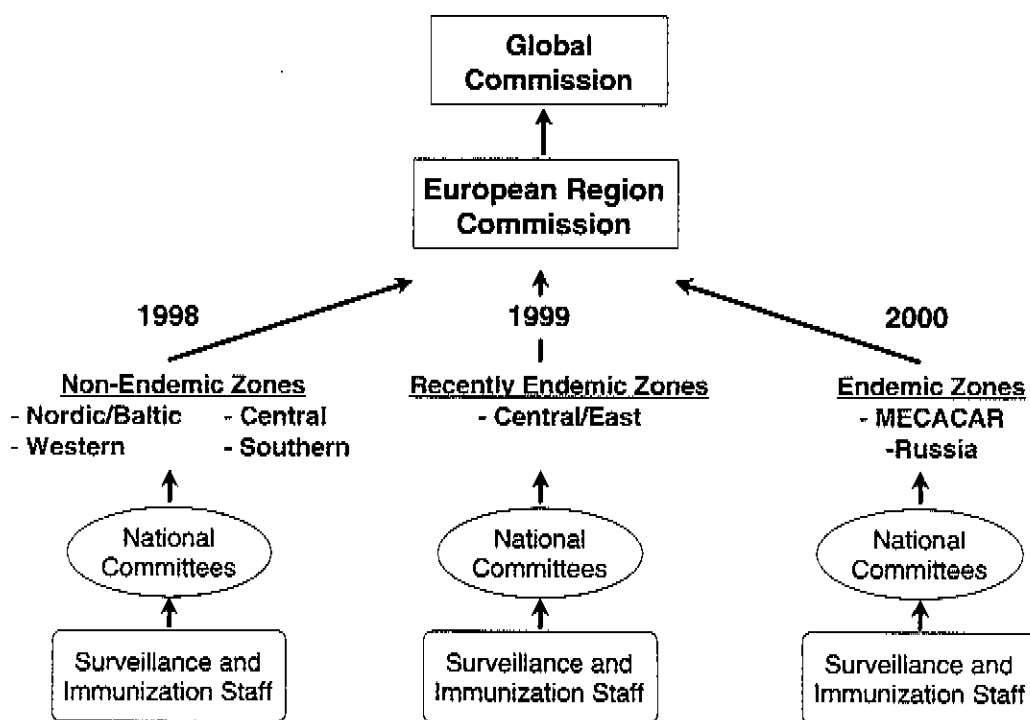
The European Region as a whole will not be certified as polio-free until all countries report the interruption of wild poliovirus transmission for at least three years, in the presence of excellent surveillance. The certification process, however, will begin immediately, with the appointment of National Certification Committees in each country and the finalization of the documentation that will be required.

While the minimum AFP surveillance documentation from endemic and recently endemic countries has been well defined for certification, it has been proposed that some non-endemic countries could be certified using alternate surveillance strategies. For this reason, and to facilitate the workload of the Regional Certification Commission, non-endemic countries (Nordic/Baltic, Western, Central and Southern Zones) will be requested to submit their documentation for certification for review by the Regional Commission in 1998. The Regional Commission can then determine whether the proposed certification strategy of individual non-endemic countries is sufficient, while allowing time for the implementation of additional certification activities if needed prior to the year 2000, the proposed date for regional certification.

Recently endemic countries (Central/Eastern Zone) will be required to submit the same documentation as endemic countries, but will be requested to file their documentation with the Regional Commission by 1999. This will allow the Regional Commission to concentrate on the highest risk countries (MECACAR Zone and Russia) in the year 2000. At the end of the year 2000, the Regional Commission is expected to certify Europe as being free of wild poliovirus circulation and file its recommendation with the Global Commission.

Figure 2 outlines the strategy and timetable for the submission of documentation from each National Certification Committee for review by the Regional Commission.

Figure 2: Strategy for Submission of Documentation for Certifying Polio Eradication
European Region of the WHO



The National Certification Committees will be responsible for working with the national immunization and surveillance personnel in their respective countries to verify the documentation needed to prove that polio has been eradicated. Upon verification, the documentation will be forwarded to the Regional Commission for consideration. As noted above, the Regional Commission will only consider confirmation of polio eradication in the region after all member nations have reported zero cases of paralysis due to wild poliovirus for at least 3 years, in the presence of adequate surveillance.

Surveillance Quality Required for Certification

The eradication of wild poliovirus in a country can only be confirmed when the performance of the surveillance system has met the specific standards set by the Global Commission. For countries with an established Acute Flaccid Paralysis surveillance system and polio laboratory services, there are standard indicators that are used to monitor performance (Annex 2). While the indicator targets were originally designed for strengthening AFP surveillance systems, a subset are being used in the certification process.

In exceptional circumstances the Regional Commission may authorize the use of alternative surveillance activities to confirm the eradication of wild poliovirus circulation in countries, or areas of countries, where AFP surveillance does not meet the level of performance established for certification. However, certification will always require incontrovertible evidence that national surveillance systems and laboratory services can detect and respond to wild poliovirus circulation.

7.1 Quality of AFP Surveillance and Laboratory Services:

The Global Commission for Polio Eradication has stated that six indicators should have precedence in demonstrating that an AFP system meets the level of performance required for the certification. In the European Region, national AFP surveillance systems should meet the specified performance levels for a minimum of 12 months prior to certification. The indicators and performance levels that are required are as follows:

- i) At least 80% of expected routine AFP surveillance reports should be received on time.
- ii) The AFP surveillance system should detect a non-polio AFP rate of ≥ 1 case per 100,000 population aged less than 15 years.
- iii) At least 80% of reported AFP cases should be investigated within 48 hours of the case being reported to the level which is responsible for conducting investigations.
- iv) All virus isolation tests, including negative results, must be performed by certified laboratories.

Comment: All AFP stool specimens and other diagnostic specimens must be processed by a laboratory which is certified as part of the global network of laboratories for polio eradication. Isolation of viruses by laboratories outside of the network must be confirmed by a network laboratory.

- v) At least 80% of the specimens from AFP cases must be suitable for analysis upon arrival in the laboratory.
- vi) All AFP cases should have full clinical and laboratory investigation with a 60-day follow-up exam for residual paralysis.

Comment: A full clinical and laboratory investigation includes the collection of 2 stool samples 24-48 hours apart within 14 days of the onset of paralysis. Cases should also have a clinical follow-up exam at 60 days after the onset of paralysis to determine whether they have residual paralysis. Finally, a panel of experts should be convened on at least an annual basis to make the final classification of AFP cases as confirmed polio, discarded non-polio, or polio-compatible¹.

¹ polio compatible cases are indicative of a surveillance weakness in that insufficient laboratory samples were collected for definitive classification.

7.2 Additional Activities in Areas with Poor Surveillance and/or at High Risk:

The Regional Commission may require additional surveillance activities if the standard of AFP surveillance is not homogeneous throughout a country. For example, in large geographical areas (i.e. states or provinces) the non-polio AFP rate and the percentage of AFP cases with 2 adequate stool specimens should reach certification standards. Also, certain areas may require heightened surveillance due to characteristics which put them at a high risk of ongoing unrecognized wild poliovirus circulation, such as:

- borders with countries which are known to be polio-endemic,
- large minority populations which have frequent contacts with similar populations in polio-endemic countries,
- underdeveloped health care services which result in low immunization coverage and incomplete disease reporting,
- recent cases of laboratory confirmed polio cases.

In these high-risk areas, or where the standard of AFP surveillance is low, additional surveillance activities may be required to demonstrate the absence of wild poliovirus circulation.

i) Active Surveillance: active surveillance requires establishing a mechanism for conducting regular (i.e. weekly) visits to health care facilities to identify and investigate unreported cases of AFP. Active surveillance sites should include at a minimum: pediatric hospitals, infectious disease hospitals and referral hospitals with pediatric wards.

In countries where the routine AFP surveillance system cannot meet the requirements for certification, a nationwide active surveillance system may be needed.

ii) Stool Specimens from Contacts of AFP Cases: stool samples should be collected from contacts of AFP cases, particularly if samples cannot be collected from the AFP case itself. Ideally, samples should be collected from five contacts aged less than 15 years of age. In areas where the detection of AFP cases is difficult due to the local geography/demography or a poor surveillance infrastructure, the collection of stool specimens from contacts of AFP cases may provide additional evidence of the absence of wild poliovirus circulation. Contact samples should definitely be collected if the AFP case is detected more than 2 months after the onset of paralysis.

iii) Stool Surveys: in geographic areas where AFP reporting and investigation is unreliable and there are known contacts with polio-endemic areas (e.g. due to large minority populations, traditional trade routes, religious pilgrimages), stool surveys may be required to demonstrate the absence of ongoing wild poliovirus circulation due to either imported or indigenous virus. The most appropriate target age group for stool sampling will depend upon the local epidemiology of polio and the OPV immunization activities which have been conducted. It is recognized that up to 3000 negative stool samples could be needed to statistically rule out wild poliovirus circulation in an area.

7.3 Additional Surveillance in Non-Endemic Countries:

Given the possibility that some non-endemic countries which have been polio-free for many years may not be able to establish routine AFP surveillance which meets the requirements for certification, additional/alternative data may be required. The Regional Commission will make the final decision as to the acceptability and validity of data from sources other than that of an established AFP surveillance system.

In the Americas Region of the WHO, two countries were certified without having established conventional AFP surveillance (Canada and the United States of America) while other non-endemic countries did not meet the established level of surveillance quality needed for certification. Both Canada and the USA, however had been polio-free for many years, had achieved and maintained high OPV coverage and had high levels of sanitation. Furthermore, surveillance for suspected polio cases and polioviruses was excellent and special studies were conducted to support the eradication of poliomyelitis.

In all nonendemic countries, the following evidence could contribute to establishing polio-free status:

- a mandatory polio reporting system and evidence of its sensitivity through detection of imported cases,
- a vaccine-associated adverse events surveillance system which has demonstrated its capacity to identify cases of vaccine-associated paralytic poliomyelitis in either OPV recipients or their contacts,
- immunization data which demonstrates very high coverage with at least three doses of polio vaccine among both the general population and high risk groups,
- results of serological studies which demonstrate a very high level of population immunity to polioviruses.

This evidence alone, however, will not be sufficient for certification of polio eradication in a nonendemic country, regardless as to the time since the last confirmed case. In the European Region, therefore, non-endemic countries should:

i) establish AFP surveillance through:

- an active surveillance system that identifies AFP cases at pediatric hospitals, or,
 - an active surveillance system that identifies AFP cases through regular contacts with pediatric neurologists, neurologists, or pediatricians,
- or,
- an active surveillance system that identifies AFP cases through other medical, rehabilitation or public health systems,
- or,
- a hospital discharge summary database that identifies cases of AFP which can be subsequently confirmed as non-polio.

ii) ensure poliovirus surveillance through:

- systematic monitoring of enterovirus data through existing networks of public health laboratories,
- or,
- systematic monitoring of enterovirus data through existing networks of hospital laboratories,
- or,
- other established and proven methods for monitoring the circulation of wild polioviruses.

iii) demonstrate the absence of wild poliovirus through:

- the systematic collection and intratypic differentiation of all poliovirus isolates from laboratories in the country over a 3 year period.

iv) conduct special studies which may include:

- stool sampling of healthy persons among 'high risk' populations such as:
 - populations with low immunization coverage,
 - populations in areas bordering endemic countries,
 - ethnic minorities at risk due to poor utilization of health care facilities,
 - minority or other populations with known contacts with persons from currently or recently endemic countries.

(such stool surveys should demonstrate at least a 10% enterovirus isolation rate in the absence of wild poliovirus)

- environmental sampling in areas which are at high risk of wild poliovirus.

The Regional Commission will make the final decision as to the acceptability of evidence certifying the elimination of wild poliovirus circulation in those non-endemic countries which do not meet the established criteria for AFP and poliovirus surveillance. Even in the presence of the data suggested above, however, the Regional or Global Commission may require additional evidence.

Documentation Required from Each Country for Certification

Each National Certification Committee must provide sufficient documentation to support the statement that the country is polio-free and that wild poliovirus importations could be readily detected. The purpose of the documentation is to provide the Regional Commission with a set of standard, internationally accepted data upon which it can base its decision whether or not to certify the country as polio-free. If and when the Regional Commission certifies the European Region as polio-free, the country documentation will be used by the Global Commission as a basis for endorsing the decision of the Regional Commission.

The documentation must cover five general subject areas:

- Country background information: demography and geography.
- Structure of the polio eradication initiative in the country: immunization, surveillance and laboratory services.
- Immunization activities related to polio eradication.
- Surveillance activities conducted for polio eradication.
- Laboratory services for polio eradication.

The information required under each of these subject areas is explained in the following sections.

8.1 Country Background Information

Purpose: to rapidly familiarize Regional and Global Commission members with the basic demographics and geography of a country that are relevant to polio eradication and its certification.

This section should include information on the population of the country, relevant vital statistics and major population centers. Minority populations should be reviewed along with other groups which may not fully utilize the health services or who are known to have low immunization coverage. Remote areas, areas with difficult access, and areas which border polio endemic countries should also be specified.

The country background information should include a national map which indicates the major population centers, bordering countries/oceans, and principal geographic features (mountain ranges, high plateaus, rivers, etc.).

8.2 Structure of the National Polio Eradication Initiative

Purpose: to familiarize the Regional and Global Certification Commissions with the organization of the polio eradication initiative in each country (immunization, surveillance and laboratory services).

This section should include information detailing the personnel who are responsible for polio immunization, AFP and polio surveillance, and enterovirus (poliovirus) laboratory services. This section should also explain the relationship between these units or departments and outline the interaction between the different groups. It is of particular importance to:

- demonstrate how AFP/polio notifications are transmitted to those responsible for undertaking the case investigation, stool sample collection and implementation of appropriate control measures, particularly in the event of an imported polio case or wild poliovirus detection.
- demonstrate how both positive and negative laboratory results are transmitted to those responsible for initiating a response, whether it be supplementary immunization activities or adjusting routine immunization strategies.

8.3 Immunization Activities Related to Polio Eradication

Purpose: to demonstrate to the Regional Commission that high routine polio immunization coverage has been maintained and/or that supplementary immunization activities have been implemented to interrupt wild poliovirus circulation, where appropriate. This data should also demonstrate the capacity to limit the spread of imported wild polioviruses by maintaining high levels of population immunity.

This section should contain full information on both the routine and supplementary polio immunization activities that have been conducted in the country. The history of polio immunization should be outlined, including the routine immunization schedule, the polio vaccines that have been used and the immunization coverage that has been achieved.

National immunization figures should be provided for as many years as possible. Immunization coverage should be provided by province/state for the previous 3 year period to demonstrate homogeneously high coverage. In those areas with low immunization rates, there should be evidence of targeted measures taken to improve coverage.

Data on supplementary polio immunization should include:

- National Immunization Days,
- other mass campaigns (Sub-National Immunization Days or Mopping-up),
- special activities in high risk areas (i.e. house-to-house immunization),
- catch-up immunization campaigns, and
- outbreak response immunization policy and practice.

8.4 Surveillance Activities for Polio Eradication

Purpose: to demonstrate to the Regional Commission that disease surveillance is of a sufficient standard to detect any cases of paralysis due to either indigenous or imported wild poliovirus.

The data covered in this section should serve as the basis, in conjunction with the information on Laboratory Services (see below), for certification of a country as polio-free. This section should include information on both the results and performance of AFP/polio surveillance.

Historical data on the confirmed number of polio cases must be provided, including summaries of the most recent cases. Details of the performance of the AFP surveillance system should be provided using the standard performance indicators. Particular attention should be given to demonstrating that surveillance performance has reached the standards set by the Global Commission (see 6.1 Quality of AFP Surveillance, above). The clinical or laboratory diagnosis of all discarded cases should be reviewed.

NOTE: The reasons for classification of AFP cases as polio-compatible must be explained. A full explanation of the investigations that were undertaken to rule out wild poliovirus infection must be provided for each polio compatible case. A spot map of polio-compatible cases should be included for each of the previous 3 years, with identification of any clusters of polio compatible cases (2 or more cases in the same geographic area within the same 2 month period). Special investigations that were undertaken to rule out wild poliovirus as a cause of compatible clusters must be documented.

8.5 Laboratory Activities for Polio Eradication

Purpose: to demonstrate to the Regional Commission that laboratory services could isolate and identify wild poliovirus in the stool of a paralyzed child.

This section should begin with identification of the national laboratory responsible for polio eradication, documentation of its accreditation in the WHO Polio Laboratory Network and the results of all proficiency

testing that the laboratory has performed (minimum level of 80%). A copy of each independent assessment of the laboratory that was performed should be included in the documentation for the Regional Commission. Only laboratory results from network laboratories, or results which have been confirmed by a network laboratory, can be considered in the certification process.

The standard laboratory performance indicators should be documented for each year during which it served as the national poliovirus laboratory (a minimum of three years of performance indicators should be provided).

For as many years as possible, but a minimum of 3 years, the following documentation will be required from each national laboratory:

i) Laboratory Process and Results:

- the total number of stool specimens received, the total number of AFP cases from which stool specimens were received and the total number of stool specimens that were processed each year,
- the total number of non-polio enteroviruses that were isolated and the nonpolio enterovirus isolation rate,
- the total number of polioviruses that were isolated, the total number of isolates that were sent for intratypic differentiation, and the total number of AFP cases that had results sent for intratypic differentiation,
- the results of all intratypic differentiation studies, by specimen and AFP case.

ii) Missing Laboratory Data:

- the reasons for each instance in which a specimen that was received in the laboratory was not processed,
- the reasons for each failure to send a poliovirus isolate for intratypic differentiation,
- the reasons for each missing intratypic differentiation result.

While summary data will be needed for the Regional Commission, the National Committees should review and comment on the data management system in the national laboratory and ensure that all specimens can be tracked, if necessary.

**Tentative Timetable for the Certification Process
For Polio Eradication in the European Region**

1996	Jan	Appointment of the Regional Certification Commission by the Regional Director
	Mar	1st Meeting of the Regional Certification Commission: <ul style="list-style-type: none"> - briefing of the commission on the latest developments in polio eradication, - review of the terms of reference for the Commission, - review/updating of the Plan of Action for certification, - consideration of special activities which may be required for certification of polio eradication in non-epidemic countries where AFP surveillance does not meet international standards.
	Mar	Translation into Russian of the 'Report of the 1st Meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis'.
	Mar	Preparation of the report of the 1st meeting of the Regional Certification Commission and Plan of Action for publication (English version).
	Apr-May	Translation of the Regional certification documents into French, German, Russian (the meeting report and Plan of Action).
	Jun-Jul	Publication of the Regional documents for the certification of poliomyelitis eradication.
	Nov	2nd Meeting of the Regional Certification Commission <ul style="list-style-type: none"> - review of revised Plan of Action for regional certification, - evaluate proposed documentation materials for use by National Committees, - briefing on poliovirus surveillance in non-endemic countries.
	Apr-Dec	Establishment of a National Committee for Certification in each Member State of the European Region.
1997	Jan-Jun	Initial meetings of National Committees: <ul style="list-style-type: none"> - review of certification protocol and documents, - decision on timetable.
	Jun-Sep	3rd meeting of the Regional Certification Commission: <ul style="list-style-type: none"> - review of the timetable for the certification process, - evaluate needs for special surveillance activities in non-endemic countries of Europe, - review initial National Committee reports of progress towards certification, difficulties in implementation of strategies and potential solutions.
	Oct	Workshop for chairpersons of National Certification Committees on preparation of documentation for certification.
1997-1998	Oct-May	Preparation of documentation for certification focusing on the countries of the Nordic/Baltic, Western, Central and Southern zones.

- 1998 Mar- Jun Field visits by members of the Regional Certification Commission to certain countries (as appropriate, to verify certification activities).
- May- Jun 4th meeting of the Regional Certification Commission:
 - evaluate documentation prepared for certification by the non-endemic countries of the Nordic/Baltic and Western zones,
 - specify additional surveillance activities that will be required in the non-endemic countries based on experience of the evaluation,
 - report to the Regional Director on the action required for certification of polio eradication by the year 2000 in the Region.
- Oct- Nov 5th meeting of the Regional Certification Commission:
 - evaluate documentation prepared for certification by the non-endemic countries of the Central and Southern zones,
 - specify additional surveillance activities that will be required in the non-endemic countries based on experience of the evaluation,
 - report to the Regional Director on the action required for certification of polio eradication by the year 2000 in the Region.
- 1998-1999 Preparation of documentation for certification focusing on countries of Central/Eastern (recently endemic) zone.
- 1999 Mar- Jun Field visits by members of the Regional Certification Commission to certain countries (primarily of the recently endemic zone).
- Sep- Oct 6th meeting of the Regional Certification Commission:
 - evaluate the documentation prepared for certification by countries of the Central/Eastern zone,
 - evaluate the quality of AFP surveillance in the Region,
 - Report to the Regional Director on the action required for certification of polio eradication by the year 2000 in the Region.
- 1999-2000 Final Stage of the preparation of the documentation for certification focusing on countries of Operation MECACAR and Russia.
- 2000 Mar- Jun Field visits by members of the Regional Certification Commission to certain countries of the endemic zones.
- Aug- Sep 7th meeting of the Regional Certification Commission:
 - evaluate the documentation prepared for certification by countries which participated in operation MECACAR and Russia,
 - re-evaluate all documentation,
 - report on decision to certify the European Region as polio-free to the Regional Director and on the action required for certification of polio eradication by the year 2001 in the Region.
- Sep Present the report on Certification to the WHO European Regional Committee.