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Report of the 1st Meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis



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Expanded Programme on Immunization
Global Programme for Vaccines and Immunization

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1. Introduction

The first meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis was held in Geneva on 16-17 February 1995, under the Chairmanship of Professor J. Kostrzewski. Drs Salisbury and Ward were elected co-rapporteurs.

In opening the meeting, the Director-General of the World Health Organization (WHO), Dr H. Nakajima, stressed that the process of certification, starting with the first meeting of the global Commission, would not be completed until the final announcement that poliomyelitis had been eradicated throughout the world. He asked the members of the Commission to define the criteria and processes through which that certification could eventually be made. These processes, leading to wild poliovirus eradication will involve the development of effective surveillance and will require the strengthening of national epidemiological capacities aimed at disease control activities.

Dr Nakajima requested that, when appropriate, the Commission should report its findings to the Director-General of WHO, certifying that the global eradication of wild poliovirus had been achieved. He anticipated that this achievement could only be certified following detailed examination by regional Commissions of carefully documented data produced by national authorities, with essential verification through visits by Commission members to key countries.

Dr Nakajima thanked the members of the global Commission for their willingness to undertake the heavy and crucial responsibility involved in the certification of global polio eradication. He particularly thanked Professor Kostrzewski, who had played a vital role in the certification of smallpox eradication, for agreeing to act as Chairman of the Commission.

Dr J. W. Lee, Director, Global Programme for Vaccines and Immunization informed participants that, to date, progress towards global polio eradication has been more rapid than had been anticipated. To a large extent, this has been due to the effective support of a coalition of agencies, WHO, Rotary International, UNICEF, the Centers for Disease Control and Prevention, the Task Force for Child Survival and various bilateral agencies, effectively working together in support of national programmes of immunization and disease control.

Progress has been evident in terms both of a much reduced reported incidence of polio and a decreased geographical extent of known wild poliovirus transmission. In addition, national surveillance systems are improving and the global laboratory network is becoming effective and functional. The target of global poliovirus eradication remains achievable.

Following the detection of the last case of polio associated with isolation of a wild poliovirus, hopefully by the year 2000, there will be a period, possibly of three years, for intensified searching for any evidence of persistent wild poliovirus transmission. If this search is negative, certification of global polio eradication could be completed as early as 2003.

The example of the International Commission for the Certification of Polio Eradication from the Americas has proved a valuable example of possible processes and activities that might lead to eventual global certification.

The guidelines issued by the global Commission may be expected to make a major contribution to the actual processes of polio eradication, strengthening surveillance by establishing quantifiable needs for eventual certification and ensuring the collection of data required for documentation of national progress.

1.1 Terms of reference

The following terms of reference of the global Commission were defined and accepted:

- **To define the parameters and processes by which polio eradication will be certified. These will guide regions and countries in establishing their data collection processes.**
- **To receive and review the final reports of Regional¹ Commissions for Certification of Polio Eradication.**
- **To issue a final report to the Director-General of WHO certifying that global polio eradication has been achieved.**

Certification Commissions have no role in the operational aspects of polio eradication and should not be directly concerned with its achievement. Furthermore, the Commission will have no function if global eradication is not achieved.

1.2 Definition of polio eradication

The definition of global polio eradication is clearly targeted at the wild poliovirus and not at the clinical disease it can cause:

The objective of the global polio eradication initiative is to eradicate all wild polioviruses.

¹ For the purposes of polio eradication, "region" does not necessarily correspond to WHO Regions. Where appropriate for geographical or demographic reasons, certification of polio eradication may be expected to involve Members States of more than one WHO Region within the work of a single Commission. In some parts of the world, in order to make the number of countries or geographical areas more manageable, certification processes may be coordinated at the sub-regional level.

Three qualifications are needed to emphasize the clear objective of the eradication initiative:

1. The elimination of cases of clinical poliomyelitis caused by wild polioviruses is a step towards global wild poliovirus eradication, but is not in itself the ultimate objective of the eradication initiative.
 2. The objective of the initiative, to eradicate all wild polioviruses, means that the occurrence of clinical cases of poliomyelitis caused by other enteroviruses, including attenuated polio vaccine viruses, does not invalidate achievement of wild poliovirus eradication.
 3. The end result of the initiative will, hopefully, include the destruction of any isolates of wild polioviruses preserved in laboratories. However, as with the still preserved stocks of variola virus, limited storage of viruses in secure laboratories should not invalidate eventual certification of wild poliovirus eradication when its transmission in all communities in all countries can no longer be detected.
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2. Background

The initiative for the eventual global eradication of poliomyelitis started with the decision of the Directing Council of the Pan American Health Organization in May 1985, to target polio for eradication throughout the Americas by 1990.

In 1988, the 41st World Health Assembly, through Resolution 41.28, committed WHO to the global eradication of poliomyelitis by the year 2000. The resolution specified that eradication of polio should be pursued in ways that strengthened the Expanded Programme on Immunization, fostering its contribution to infrastructure development and primary health care.

In the 1992 Plan of Action for the Global Eradication of Polio, endorsed by the 1992 World Health Assembly, the objectives for the year 2000 were specified:

- No cases of clinical poliomyelitis associated with wild poliovirus
- No wild poliovirus identified anywhere in the world through sampling of communities and environments
- The process of independent certification of global eradication of poliomyelitis should have begun, so that consideration could be given to stopping polio immunization. It is currently envisaged that a three year period will be required during which active surveillance reveals neither cases nor the circulation of wild polioviruses.

2.1 Cost benefit of polio eradication

Progress towards the global eradication of poliomyelitis has been dramatic with a number of outstanding successes, notably the achievement of wild poliovirus eradication throughout the Americas and the dramatic reduction in reported cases in China. It is clear that the strategies being advocated for wild poliovirus eradication are highly effective when thoroughly implemented.

The eradication of poliomyelitis will eventually prove highly cost effective, resulting in rapid and tangible benefits within a short period of time. With the potential to eventually stop all immunization against polio, there will be major savings of resources and costs, which can be directed to other priority programmes.

The cost benefit of polio eradication will be greatest the more rapidly eradication is achieved. Should the year 2000 target not be achieved, there will be, as time passes, a progressive build up of susceptibles, requiring a broader age range for essential strategies of supplementary immunization and consequently more expense to achieve eradication.

It is predictable that, if the achievement of polio eradication is delayed, it will prove increasingly difficult to motivate remaining endemic countries to initiate essential strategies at times of competing priorities both within health programmes and generally within development.

2.2 Global certification of smallpox eradication

Since variola virus was only transmitted from man to man, with no carrier state and no animal reservoir, it was possible to assume that the eradication of clinical smallpox also meant the eradication of the virus. This is not true for wild poliovirus which causes subclinical infection in a large majority of cases.

Certification of smallpox eradication was not prevented by the retention of variola virus preserved under tight security in a limited number of laboratories.

In order to confirm the interruption of smallpox transmission, it was necessary to have well documented evidence of effective surveillance with at least two years having elapsed since the last known case. Eradication was certified either on a continental basis or on review in several adjoining countries sharing similar demographic and epidemiologic features. It was not conducted for individual countries in isolation.

Each area was certified by an "International Commission for the Certification of Smallpox Eradication" and was based on data collected and documented by national and regional programmes. In most cases, these data were compiled into a "country report" that was assessed by the Commission. The report consisted of descriptions of the reporting systems in place, active searches conducted, surveys, rash and fever surveillance, the use of "rumour registers", specimen collection and testing, publicity for the reward for reporting cases and public awareness.

Commissions visited all recently smallpox-endemic countries. In those countries they evaluated the reliability of the data presented by its verification at the national level and, through field visits, at its points of collection.

In 1977, the Director-General of WHO convened a consultation of 17 experts to obtain advice on how best to certify global smallpox eradication. During the next two years, most participants in the consultation served as members of the Global Commission for the Certification of Smallpox Eradication and participated in International Commissions in specific geographic areas.

Finally on 26 October 1979, exactly two years after the last known case in Somalia, the Commission, meeting in Nairobi, announced smallpox eradication in the countries of the Horn of Africa and consequently, from the world.

2.3 Certification of polio eradication in the Americas

The certification of polio eradication in the Americas, based on similar principles to those used in the certification of smallpox, was successfully concluded in September 1994 with the announcement by the Chairman of the International Commission for the Certification of Polio Eradication (ICCPE), Professor F. Robbins, that polio had been eradicated throughout the Americas.

In preparation for the work of the Commission, a detailed Plan of Action, aimed at defining activities and priorities inherent within the certification process, had been prepared. The key factors in assessing the possibility that eradication had been achieved related to the time between the last case and the certification process, the effectiveness of surveillance and the diligence of the Commission in its work. In assessing the probability of polio eradication, the key criteria were the absence of cases when surveillance was effective as measured by performance indicators, the absence of detectable wild poliovirus in stool specimens from the highest risk children, the work of national Commissions and the potential to deal with importations.

The ICCPE was composed of 12 members. Two members assumed responsibility for overseeing certification in each of the areas of the region. In early 1994, independent national Commissions were convened in each country to evaluate national data and to report to the ICCPE whether or not poliovirus transmission had been interrupted. The data reviewed included trends in immunization coverage, data on acute flaccid paralysis (AFP) surveillance, an extensive surveillance network, constituted by over 20,000 reporting units on acute flaccid paralysis surveillance, surveillance of wild polioviruses, laboratory results of specimens submitted and immunization campaigns in areas at special risk.

National Commissions were composed of leading scientific figures not directly responsible for programme activities. They remained totally independent to avoid any accusations of bias or self interest in the outcome of certification.

Country reports were standardized on the basis of four key elements of the polio eradication initiative, surveillance for AFP, surveillance for wild polioviruses, active searches and supplementary immunization.

The ICCPE met on three occasions, in July 1990 in Washington, March 1992 in Rio de Janeiro and finally August 1994 in Washington.

The ICCPE made four groups of conclusions:

1. Most countries had sustained OPV3 coverage of over 80%, 6,000 AFP cases had been investigated since the last case known to have been associated with wild poliovirus, 25,000 stool specimens had tested negative for wild poliovirus in that time, surveillance was thought to have been at acceptable levels for the previous 3 years.
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2. All national Commissions had recommended that their countries be certified as polio-free.
3. The ICCPE recognized the extraordinary accomplishments which had been achieved by the countries, resulting in national reports of excellent quality.
4. Based on the evidence, the ICCPE concluded that wild poliovirus transmission had been interrupted in the Americas.

The ICCPE made recommendations on correcting the few deficiencies that existed in a small number of countries, on maintaining the capacity to identify and deal with importations should they occur, maintaining AFP surveillance and urging other regions to intensify their polio eradication efforts.

The Commission in the Americas is perceived as a potential blueprint for other regions in developing appropriate certification processes.

2.4 Overview of progress towards global polio eradication

Following the 1988 World Health Assembly resolution, significant progress has been made towards the target of polio eradication by 2000.

The basic policies recommended by WHO if wild poliovirus eradication is to be achieved are:

- To achieve and maintain high routine immunization coverage.
- To improve surveillance systems, including AFP surveillance, establishing a network of virology laboratories with a proven capacity to isolate polioviruses and other enteroviruses from stool specimens.
- To conduct supplementary immunization, both National Immunization Days (NIDs) in all polio-endemic countries and mopping-up immunization in high-risk areas in low incidence countries.

Immunization coverage for OPV3 is currently estimated at 80%, slightly reduced from its highest peak of 85% in 1990. Several countries have failed to reach acceptable levels of coverage and 18 have OPV3 coverage below 50%.

NIDs have been conducted in 58 countries and a further 15 are planning such days in 1995. The establishment of AFP surveillance is proceeding and is becoming the basic requirement for polio case detection.

In 1988, over 35,000 cases of polio were reported to WHO, with reported incidence in 1994 falling below 10,000 for the first time. In 1994, although full information is not yet available, the final reported incidence is expected to be between 6-8,000 cases.

Geographically, in addition to the Americas, five polio-free areas are emerging; Western and Central Europe, Southern and Eastern Africa, the Mahgreb countries of North Africa, the Middle-East, countries of the Arabian Peninsula and the countries of the Pacific basin.

In 1988, over three quarters of polio cases were reported from the South-East Asia Region and Pakistan. In 1993, over 60% of reported cases still originated from the Indian subcontinent.

Within the global context, much initiative aimed at polio eradication is arising from strong regional programmes. This ranges from the complete success in the Americas to the determined drive for polio eradication in the Western Pacific Region. In the African Region, which includes many of the poorest countries who lack strong health infrastructures, there is a determination to plan for, and progress to, eventual freedom from polio. This planning is exemplified in "Six steps towards a polio-free Africa", aiming to structure all programmatic activities for each epidemiological block of countries according to 6 prescribed steps, each step representing one year from 1995 to 2000.

In spite of the excellent global progress, total success remains far from assured. To complete NIDs plus routine immunization, 10,000,000,000 additional doses of vaccine will be needed. Within the next five years, an estimated US \$500 million will be required to ensure the probability of global polio eradication, including approximately \$200 million for laboratory networks, logistics and personnel.

In addition, there remains a continuing need for strong commitment from national leaders, ensuring that problems are resolved and activities supported at the highest level. Finally, continuing conflict and social unrest are severely damaging to public health programmes, making operational activities and, eventually, the certification of polio eradication extremely difficult.

A summary of progress in each of the WHO regions is included in Annex 2.

3. Basis for the certification of global polio eradication

Final evaluation of polio eradication activities and certification of global polio eradication will be the last stage of the eradication process.

Like the eradication initiative, certification of its success involves an infrastructure reaching from the community level, through district and province to the national and international levels. At each level, processes have not only to be implemented but quantified and documented to allow for evaluation. WHO has produced a number of key documents to facilitate eradication, and these can also establish the process of future evaluations.

In the Americas, the International Certification Commission defined four factors that were considered to be particularly important in arriving at a conclusion that, within any area, polio had been eradicated. These were:

- The lapse of time between the last case and the certification assessment.
- The intensity of surveillance.
- The competence and diligence of the national certification committee in reviewing national data.
- The political support needed to comply with the criteria for certification.

These same four factors are equally relevant for certification in other regions, countries and areas.

In addition, the Commission in the Americas defined four criteria, on the basis of which, possible poliovirus eradication could be assessed:

- The absence of virologically confirmed cases for a period of three years in the presence of adequate surveillance.
 - The absence of detected wild poliovirus in tests in stools from healthy children, e.g. from the contacts of cases of acute flaccid paralysis being investigated and, where indicated, from waste water.
 - Evaluation by a national certification committee convened for that purpose in the country, eventually reporting to the regional Commission.
 - Establishment of appropriate measures to deal with importations.
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In each country, a national Commission should be convened to review and oversee pre-certification activities, documenting four strategies as the basis for country reports:

- Surveillance for cases of AFP.
 - Surveillance for wild polioviruses.
 - Active searches for cases of AFP.
 - Documentation of mass immunization in areas of risk.
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4. Basic principles for the certification of global polio eradication

Five basic principles on which global polio eradication will be certified were defined.

- Certification will be on a regional or sub-regional basis by Commissions convened for this purpose.
- The Global Commission for the Certification of Polio Eradication will provide guidelines that will form the basis for the work of regional Commissions to ensure uniformity in the criteria used to assess eradication. The global Commission will establish a timetable within which regional Commissions may be expected to operate. Although all regions need not necessarily be evaluated at the same time, countries already certified as having eradicated the wild poliovirus must continue to immunize, maintain high levels of AFP and virus surveillance and retain the capacity to deal with importations should they occur.
- Certification of polio eradication will be based on assessment of documented evidence, particularly focused on the existence of effective surveillance both for cases of AFP and for wild polioviruses.

It is assumed that, when clinical cases of paralytic polio caused by wild poliovirus can no longer be detected, transmission of the wild virus has probably ceased. At this stage, surveillance for the wild virus will especially concentrate on the human environment, examining specimens from healthy child contacts of AFP cases, with supportive evidence where appropriate, possibly through sampling of waste water.

Evidence of effective surveillance will particularly be required from border zones and other high-risk areas. All documentation must be assessed to establish the effectiveness, completeness and the quantification of the data provided. In finally certifying global polio eradication, there can be no "blind" spots, such as countries in a state of war or unable to be assessed for any reason.

- Certification of global polio eradication will only be made when all regions and, therefore, all countries have been certified as having achieved wild poliovirus eradication. In countries which have been polio-free for many years, innovative methods of assessing that wild poliovirus no longer exists within their boundaries may be required.
 - In any area, final certification of eradication will not be considered until a full three years have passed since the last detected and culture confirmed occurrence of a wild poliovirus. Until global polio eradication is confirmed and in preparation of the certification process, AFP surveillance, data collection and its documentation must continue.
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5. Essential criteria on which certification of polio eradication will be based

The Commission stressed the importance of surveillance for AFP as the basis for surveillance for cases of polio caused by the wild poliovirus. The Commission confirmed that data collected and documented must support the principle that, if polio cases had occurred, they would have been detected, reported and investigated in an expeditious manner. Performance indicators, related to surveillance, should help confirm this to be the case.

Within this principle, the Commission defined two major technical areas within which detailed and accurate data will be required before certification of polio eradication could be considered: surveillance for cases of acute flaccid paralysis and surveillance for wild polioviruses.

5.1 Surveillance for cases of acute flaccid paralysis

Four key criteria were defined, to be met before certification could be considered:

- Documentation of the timely receipt of 80% or more of expected routine surveillance reports, including zero reporting where no AFP cases were seen. Adequate investigation and analysis of the reasons for non-reporting, with appropriate documentation, will identify whether missing reports consistently relate to certain geographic areas, to delays in receipt of reports or other factors.
 - In each country and area within countries, a calculated rate of AFP per 100,000 children aged under 15 years, will indicate the presence or otherwise of adequate surveillance for AFP. Where small populations make detection of such a figure impractical, a conglomerate of adjacent areas should be assessed together. Although identification of an AFP incidence rate above 1:100,000 children aged under 15 years is a clear indicator of probable effectiveness of surveillance, too little is known about possible geographic variations in the rate to allow the assumption that a lower rate indicates inadequate surveillance. In such cases, a wider range of indicators should be used in conjunction in order to determine the quality of surveillance.
 - At least 80% of reported AFP cases should be investigated within 48 hours.
 - All suspected polio cases should be subjected to detailed investigation, including clinical, epidemiological, virological examination and 60 day follow-up examination for residual paralysis. When all examinations have been completed, a final case classification should be made on the basis of the examination results by a committee of experts convened for the purpose.
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In countries where polio has apparently been eradicated for many years, it may prove impossible to establish satisfactory surveillance of AFP as an indicator of polio caused by the wild poliovirus. In such countries, flexibility will be needed in the Commission's assessment of the probability of freedom from circulating wild poliovirus. Further documentation of acceptable techniques in such countries is needed.

5.2 Surveillance for wild polioviruses

The Commission established five criteria related to surveillance for wild polioviruses:

- Assessments should demonstrate that high levels of competence have been achieved by the laboratories certified as part of the global/regional networks, including successful results in proficiency testing. Results of virus isolation tests, including negative results will be accepted only from network laboratories. Isolation of viruses by laboratories outside the network must be confirmed by a network laboratory.
- Specimen collection, transport and testing procedures must be validated through the use of performance indicators and proficiency testing.
- For the previous three years, no wild poliovirus will have been isolated from two stool samples of AFP cases. Two stool samples will have been collected within 14 days of onset of the illness, from at least 80% of AFP cases detected and investigated.
- For the previous three years, no wild virus will have been isolated from stool specimens collected from contacts of cases. Ideally, five contacts under 5 years of age living nearby will have been tested for each AFP Case.
- The highest priority for testing for wild poliovirus in the environment will be the collection and testing of faecal samples from healthy children living near cases of AFP under investigation.

Although testing of the environment through sewage/waste water is not yet entirely satisfactory and in much of the world, especially those countries and areas still endemic for polio, may be impossible, it is expected that, where conducted, it will add evidence to confirm the absence of circulating wild polioviruses.

6. Documentation required for certification of poliovirus eradication

Adequate documentation is necessary at each level to provide the essential data for certification. The basis of this documentation will be data collection and analysis at the country level. It is preferable that these data and the subsequent documentation be standardized between countries within a region.

Each regional Commission will be expected to review country data, using them in association with country/field visits as the basis for the certification process. In turn, regional documentation and subsequent country certification will form the basis for eventual certification of global polio eradication.

The proposed documentation falls into a number of categories:

- Structure, responsibilities and coordination of the national units concerned with polio eradication within the country.
- Demography of the country, including population distribution, urban conurbations, urban/rural population ratios, areas under-served by health services, remote and difficult access areas.
- Documentation of polio eradication activities.
- Documentation of laboratory procedures.

Within the range of documentation, seven subject areas should be assessed:

- i) General documentation:
 - evidence of collaboration between staff of the immunization programme and the laboratory
 - activities in high-risk areas
 - sampling of the environment for wild polioviruses
 - extension of polio-free zones.
 - ii) Documentation on immunization:
 - immunization coverage by district
 - evaluation of the immunization programme
 - details of national immunization days
 - details of mopping-up immunization.
 - iii) Documentation of AFP cases:
 - line listing of AFP cases by district
 - completed case investigation forms for all AFP cases
 - AFP rates by district or groups of districts
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- AFP case classification
 - spot maps of AFP cases and polio-compatible cases.
- iv) Documentation on polio cases:
- polio incidence by district by year
 - spot maps of polio cases
 - case investigation forms for polio cases
 - details of the last outbreaks, including outbreak response and mopping-up immunization.
- v) Documentation on surveillance
- analysis of surveillance indicators, including:
 - % AFP cases investigated
 - % AFP cases investigated within 48 hours of detection
 - % AFP cases reported within one week of onset
 - % AFP cases with two stools tested
 - % AFP cases with two stools tested within two weeks of onset of the illness
 - % routine reports received on time
 - Evaluations of the surveillance system.
- vi) Documentation on laboratories:
- laboratory reports with dates
 - number and source of samples tested
 - evidence of the quality of specimen collection and transport
 - quality control including proficiency testing.
- vii) Documentation on laboratory procedures

Documentation should be retained to confirm the following activities:

- all enterovirus isolates, including polioviruses, retained in store for the last 3 years
 - re-testing in a second network laboratory, of specimens from AFP cases which died
 - re-testing in a network laboratory of specimens originally tested in a non-network laboratory
 - confirmation of easy access by all areas to a network laboratory
 - evidence of an ability to isolate other enteroviruses, including polio vaccine virus.
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7. Process for certification of polio eradication

The global Commission decided that certification of polio eradication should be conducted at three levels, national, regional and global. Regional does not necessarily correspond to WHO Regions and, where appropriate, sub-regional certification may be conducted in the same manner as regional certification.

At each level, it is proposed that the Commission should develop a Plan of Action and timetable of activities, along the lines of that developed for the International Commission in the Americas.

7.1 National level

In each country, national Committees should be convened, at an appropriate time to review and oversee pre-certification activities.

National Committees will be responsible for assessing the documentation prepared by national staff, verifying it, where necessary by field visits. National Committees will have no authority to certify polio eradication in the country, but will refer their opinion as to whether eradication has been achieved, with supporting documentation for assessment by the regional Commission.

Committee members should be independent of the polio eradication initiative and the EPI.

It is expected that the members will be leading scientists, senior physicians or university staff, who will be committed to taking the responsibility of certification extremely seriously. Members should understand that their reputations as scientists or leading public figures will depend on their judgement as to whether the quality of work and its documentation is sufficient for a decision to recommend that certification of polio eradication should proceed. National certification commissions may include members from other countries.

Data should be collected on the full range of activities related to polio eradication, with particular emphasis on intensified AFP surveillance, surveillance for wild polioviruses, immunization achievements, especially supplementary immunization focused on high-risk areas.

7.2 Regional level

Regional Commissions will be the only level below the global Commission with the authority to certify that polio eradication has occurred. Before it certifies eradication in the region, its members must be fully satisfied that wild poliovirus eradication has been achieved throughout all Member States of the region under review.

The decision to certify eradication will be based on the opinion of national Committees, plus their supporting evidence, combined with visits to countries to verify the data provided and to guarantee completeness and accuracy.

Regional Commissions will be appointed by Regional Directors and are expected to include members of the global Commission working within their own regions. The other members are expected to represent a range of skills allied to the needs of assessing whether polio eradication has been achieved, e.g. virologists, neurologists, paediatricians public health specialists, epidemiologists and health planners. As with national Committees, the members must be of a status that is greatly respected and be prepared to stake their reputation on their judgements concerning polio eradication.

The members of the Commission will not have had direct responsibility for polio eradication in the region or their own countries.

Where appropriate, regional Commissions should consider including representatives of adjacent countries or regions in their discussions. Such representatives might be members of neighbouring Certification Commissions.

Commissions to certify polio eradication should be created before the end of 1995, although the timetable of their subsequent work will be largely determined by regional progress towards polio eradication. In large regions, such as the African, it may be appropriate for Commissions to proceed with their work in a phased manner consistent with the progress towards polio eradication being achieved in sub-regions or epidemiological blocks.

7.3 Global level

The global Commission should issue the report of its first meeting as guidelines for regional Commissions.

Certification of global polio eradication will be announced only after all regional Commissions have certified that each region and, therefore, all countries have achieved polio eradication.

The work of the global Commission will be most critical in the phase following occurrence of the last known polio cases caused by wild polioviruses. However, to review progress, to ensure coordination, to identify and correct problems arising, and to update guidelines for regional Commissions, the global Commission will reconvene in 1997.

8. Activities to be pursued before the next meeting of the global Commission

The global Commission identified a number of aspects of the polio eradication initiative, on which further information or development was required. It requested the WHO Secretariat to pursue these subjects and to produce documents for the next meeting of the Commission.

The subjects noted were:

- To review the evidence that there is no reservoir for the transmission of wild polioviruses other than human beings.
 - A report suggesting alternative strategies to confirm the absence of circulating wild polioviruses in countries where polio has been apparently eradicated for many years and in which it may prove difficult to establish effective AFP surveillance. Such strategies must eventually allow for acceptable judgement on whether or not polio has been eradicated.
 - Identify the significance of different rates of AFP/100,000 children as an indicator of the effectiveness of surveillance.
 - Continue to research the possibility of developing a rapid diagnostic test, suitable for use at the field level by non-virologists.
 - Exploring the value of environmental sampling as a means of confirming the absence of circulating wild poliovirus in an area.
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Annex 1 Opening remarks by Dr Hiroshi Nakajima

Ladies and gentlemen,

It gives me great pleasure to open this first meeting of the Global Commission for the Certification of Polio Eradication.

First of all, I would like to thank the distinguished persons who have agreed to serve as members of this Commission. The eradication of polio is an arduous task and your work in certifying its achievement will be most demanding.

Tomorrow afternoon, when this meeting closes, your work will only be starting. Today, a process begins which will not end until some years hence, when this group will meet one last time to issue a report to the Director-General of WHO and the World Health Assembly that the transmission of the wild poliovirus has been finally interrupted throughout the world. In front of the whole world, you will bear the responsibility of guaranteeing that the poliovirus transmission has actually stopped.

I am entrusting this Commission with two specific tasks. The first is to define the criteria and processes by which polio eradication can and will eventually be certified. These criteria will guide regions and countries in establishing their data collection process. Building a surveillance system which is capable of detecting and confirming any possible case of poliomyelitis in the world will not only enable us to eradicate polio but help to establish better laboratories and surveillance systems for disease control in general. This will benefit all countries and populations, and be an additional legacy of the worldwide polio eradication effort. In addition, strengthening national epidemiological capacities for planning and evaluating disease control activities will advance primary health care and the control of other diseases. Standardization of the data to be collected will facilitate your work and that of the regional Commissions as they prepare for the final review.

I request you to be both practical and rigorous in defining the requirements for certification. On the road to eradication there can be no short cuts. The same rules and requirements must apply to all, whatever the circumstances. Until you are absolutely sure that all countries have searched everywhere to detect any possible remnant of wild poliovirus, and until you are convinced that their search is conclusive that there remains no trace of the virus, eradication cannot and will not be certified. Thus, I ask you to be clear and concise as you specify the conditions which must be met to prove that eradication has been achieved. You will also have to stand firmly by your guidelines. In this, you can rely on my personal support and that of WHO, including its Regional Offices.

The second task for this Commission is to prepare a final and consolidated report to the Director-General, certifying that global eradication has been achieved. This will be based on your review of the reports submitted by the national programmes and regional

certification Commissions. It will be the work of many years. Some of you will be serving as fully-fledged members of the regional Commissions as well. In any case, I expect that you will all act as observers and advisors at regional Commission meetings. You will have to provide guidance, support and leadership to the regional certification Commissions and, through them, to the national programmes. You will also need to visit key countries to verify reported data.

This is the long-term commitment which you are undertaking today. In establishing this Commission, we are taking an historic step into the future, both for WHO and for the world. We are marking the beginning of the end of poliomyelitis. Your certification of polio eradication, and the work and judgement behind it, will eventually make it possible for all nations to stop immunization against poliomyelitis, thus freeing millions of dollars of resources each year for other uses, including new and urgent health priorities. It is for you to decide how much time should elapse between the last case of polio caused by the wild virus and the point at which you can certify global eradication. Once again, I wish to thank you for your willingness to shoulder this heavy and crucial responsibility.

Professor Jan Kostrzewski of Poland has kindly agreed to my request that he should serve as your chairman. Professor Kostrzewski served as vice-chairman of the Global Commission for the Certification of Smallpox Eradication and was chairman of the International Commission for the Certification of Smallpox Eradication in India, Bhutan and Nepal. Dr R.N. Basu is with us today as a consultant; he was also a member of the Global Smallpox Eradication Commission. I would like to thank them both for their renewed dedication to the work of the Organization. Their experience and advice will be most precious to us all.

Ladies and gentlemen, I would now like to turn the meeting over to Dr Lee and Professor Kostrzewski.

Annex 2 Summaries of status of polio eradication by WHO Region

1. African Region

Reported annual polio incidence in the African Region decreased from about 4,000 cases in the early 1980s to less than 2,000 cases in the 1990s. Polio is still endemic in most countries of the Region. However, twelve countries reported zero cases in 1992 and 1993, with some reporting no cases since the mid-1970s.

Southern, Eastern and North Africa, which represent emerging polio-free zones in the African region, each reported 2% of the total polio cases. Countries of the Central African Epidemiological block reported 4% of cases. Most cases were reported from the West Africa epidemiological block (22%) and the block of countries in difficult circumstances, which includes Angola, Ethiopia, Nigeria and Zaire (68%).

Late country reporting still remains a serious problem. Only 50% of expected monthly reports for August 1994 have been received at AFRO by February 1995.

AFP surveillance has been introduced in 8 countries of the Region; Algeria, Botswana, CAR, Malawi, Namibia, South Africa, Tanzania and Zimbabwe. To date, the number of reported AFP cases in these countries remains well below the minimum expected level of one case per 100,000 children aged below 15 years.

AFRO has developed a field guide and a facilitator's guide on disease surveillance and control of EPI diseases for district health staff. It has initiated training of district level staff.

The regional polio laboratory network currently includes two regional reference laboratories, in Ghana and CAR and five national laboratories in Kenya, South Africa, Uganda, Zambia and Zimbabwe. A post of Regional EPI virologist has been established.

In 1995, Algeria, Angola, Mauritania, Mozambique, Namibia and South Africa have implemented, or plan to implement, supplemental immunization. A number of other African countries are considering the implementation of mass campaigns.

The Regional Office has developed "Polio Eradication by the year 2000; Six steps to a Polio-free Africa" This would allow to 1) place all regional and national polio eradication activities within the six steps corresponding to the years between 1995 and 2000; 2) better direct and coordinate efforts within each specific step; 3) ensure continuity in building up on the progress already achieved and 4) obtain national commitment and to keep polio eradication in the centre of public attention.

2. Eastern Mediterranean Region

Tremendous progress towards polio eradication has been achieved. The overall immunization coverage under one year of age is approximately 80% through routine immunization. Supplemental immunization activities, particularly NIDs are being implemented in an increasing number of countries. As a result, there is an evident pattern of decrease in the number of cases of poliomyelitis, with less than 1000 cases in 1994. Eleven of the 22 Member States had no cases reported during 1994, five of which for three consecutive years.

A number of initiatives relevant to polio eradication were undertaken in the region:

- Establishment of three polio-free zones encompassing 16 countries. These zones are showing excellent achievements.
- Strengthening surveillance. Missions were fielded to assess national systems, especially for AFP surveillance. These missions were followed by workshops addressing issues that needed strengthening and then by follow-up missions. Surveillance indicators are being monitored. A monthly bulletin (POLIOFAX) is issued regularly as feed-back.
- Establishment of a regional laboratory network with 13 laboratories, of which four are regional reference laboratories.
- Efforts to achieve self reliance in OPV supply through supporting the three main vaccine producers in the region.
- Establishment of regional and national Commissions for the certification of polio eradication.

The programme is facing some major difficulties particularly in a few countries, mainly due to civil unrest and premature cessation of external support. In addition, the political commitment secured for polio eradication is being inadequately translated into action, with appropriate financial support.

3. European Region

Only minor and slow progress was observed in the European region in the field of polio eradication during 1993-94.

A slight increase in the incidence of the disease was observed during the 1994, with 206 cases reported. Poliomyelitis remains a rare disease for most countries throughout the region, with endemic disease occurring in only 64 geo-political units (districts) in eleven countries of the region. In 1994, approximately 90% of reported cases originated from just four countries, Azerbaijan (17 cases), Tajikistan (23), Turkey (24) and Uzbekistan (117 cases).

Surveillance of AFP has been gradually expanded and is in place in 16 countries. The rate of AFP detected varies from 0.3 to 0.8. The regional laboratory network consists of 39 national laboratories, 2 regional reference laboratories and 3 Specialized reference laboratories. The laboratory network in the Newly Independent States (NIS) needs to be considerably strengthened. Action is required to establish closer cooperation between epidemiological and laboratory staff, with increased emphasis on monitoring of quality indicators for surveillance, including laboratory performance.

The difficult economic situation in many NIS, wars and civil unrest, combined with a lack of political will and commitment to EPI and to polio eradication remain the major obstacles to progress, resulting in insufficient resources being made available, including shortages of OPV for both routine immunization and that needed for supplementary immunization strategies.

WHO/EURO and WHO/EMRO are planning the implementation of a synchronized mass immunization campaign across regional and national boundaries (Operation MECACAR) in order to interrupt transmission and to accelerate the creation of a polio-free inter-regional zone.

4. South-East Asian Region

Immunization coverage in most countries, including India is now being reported at the district level.

Analysis of disease reporting from 1987 to 1994 demonstrates a decreasing trend in the number of reported cases of the three EPI targeted diseases, polio, measles and neonatal tetanus.

For polio, most of the effect of this decreasing trend is attributable to India, where most of the regional population resides. There was a remarkable 54% reduction in the number of polio cases reported in India, from 9,203 reported in 1992 to 4,236 in 1993. From 1993 to 1994, there was a 9% reduction in the number of polio cases reported in India, from 4,236 in 1993 to 3,867 in 1994. In the summer of 1994, large outbreaks occurred in the States of Gujarat and Karnataka. These states had previously reported very high immunization coverage with OPV.

Trend analysis of reported polio cases by month suggests that perhaps India has reached a national level of control, where the occurrence of paralytic poliomyelitis is predominantly approaching an endemic rather than epidemic pattern of disease. However, unless there is a nationwide intensification of campaign strategies, i.e. an Indian National Immunization Day, additional large outbreaks, as happened last year in Gujarat and Karnataka may be expected.

Surveillance of acute flaccid paralysis needs urgent attention. Six out of eleven Member States, Bangladesh, Indonesia, Mongolia, Nepal, Sri Lanka and Thailand are conducting AFP surveillance. Thailand and Sri Lanka are the countries which most consistently monitor and evaluate AFP reporting rates, the timeliness of AFP reporting and investigation, the collection of stool specimens, and the provision of results to where they are most needed. Bangladesh, India, Indonesia, Mongolia and Nepal are currently taking steps that will significantly elevate the sensitivity of reporting.

In 1994, Thailand was the first country in the region to conduct an NID. Sub-national immunization days were conducted in India in the State of Delhi and in the Maldives. NIDs are planned for 1995 in Bangladesh, Indonesia and Thailand. In addition, NIDs are being planned for Mongolia and Myanmar for 1995. In March 1995, Nepal has scheduled a sub-national immunization day.

There is a critical need to expand and improve the capacity to provide adequate public healthy laboratory services for polio eradication in the region. EPI/SEARO estimates that nearly \$198 million will be required to cover unmet resource needs to eradicate polio from the region within the next five years. Recruitment of funds and securing political commitment will be the biggest challenges within the regional polio eradication initiative in 1995. Information being received on their interest in conducting NIDs in Myanmar is very encouraging. Urgent implementation of NIDs in India will be critical for achieving polio eradication in the region of South East Asia.

5. Western Pacific Region

The reported number of poliomyelitis cases in the Western Pacific Region for 1994 is provisionally expected to be around 750. This is a marked reduction from the 1990 total of over 5,000, and a reduction of over 30% from 1993. Over 75% of the cases in 1994 were found in the Mekong Delta of Viet Nam and Cambodia, thus poliomyelitis has been reduced from widespread to focal endemicity in only 4 years. This dramatic reduction in disease is due to large scale supplementary immunization with oral poliovirus vaccine (OPV). By March 1995, 5 of the six polio-endemic countries (Cambodia, China, Laos, Papua New Guinea, Philippines and Viet Nam) have had at least one season of National Immunizations Days, and the Philippines has conducted NIDs for 3 years. During 1995, as the region approaches the target of zero polio, plans will be made to determine the extent of supplementary immunization that will follow three consecutive NIDs in the polio-endemic countries.

Although the situation varies from country to country, there has been much progress in AFP surveillance in the Western Pacific Region since 1991. In 1994, almost 4,000 cases of AFP were reported throughout the region, and 90% were investigated. Using a background indicator rate of 1 non-polio AFP case per 100,000 children under 15 years of age in the region, AFP surveillance is now over 70% effective. Nearly 60% of these AFP cases had at least one stool sample sent for analysis, 35% had two stool samples and 55% were followed up at 60 days.

With the strengthening of the regional laboratory network since 1991, wild poliovirus isolation is now being accurately mapped in the region, showing that most of the provinces of China have been free of the wild poliovirus for over one year, as has the Philippines. As AFP surveillance indicators continue to improve, countries can move from clinical to laboratory-based classification criteria, in the first steps towards certification of eradication.

Annex 3 List of background documentation

Working documents

EPI/CERT/WP/95.1	Certification Processes for Eradication of Smallpox
EPI/CERT/WP/95.2	Certification Processes for Eradication of Poliomyelitis
EPI/CERT/WP/95.3	Update on Poliomyelitis - Global Situation
EPI/CERT/WP/95.4	Update on Poliomyelitis - African Region
EPI/CERT/WP/95.5	Update on Poliomyelitis - American Region
EPI/CERT/WP/95.6	Update on Poliomyelitis - Eastern Mediterranean Region
EPI/CERT/WP/95.7	Update on Poliomyelitis - European Region
EPI/CERT/WP/95.8	Update on Poliomyelitis - South-East Asian Region
EPI/CERT/WP/95.9	Update on Poliomyelitis - Western Pacific Region
EPI/CERT/WP/95.10	Clinical Aspects and Differential Diagnosis of Poliomyelitis
EPI/CERT/WP/95.11	Epidemiologic Features of Poliomyelitis
EPI/CERT/WP/95.12	Virology of Polioviruses
EPI/CERT/WP/95.13	Use of Indicators to Monitor Progress - Oman
EPI/CERT/WP/95.14	Use of Indicators to Monitor Progress - United Kingdom

Background documents

WHO/EPI/POLIO/92.2	Global Poliomyelitis Eradication by the Year 2000 - Plan of Action. Revised 1992
EPI/POLIO/93.1	Certification of the Global Eradication of Poliomyelitis, Meeting of a Working Group, Geneva, 7 March 1993
1994 - 000029	Third Meeting of the International Commission for the Certification of Poliomyelitis Eradication (ICCPE), Washington, USA, 22-25 August 1994. Final Report - Conclusions and Recommendations.
WHO/MNH/EPI/93.3	Acute Onset Flaccid Paralysis
WHO/GPV/POLIO/94.1	Progress Towards the Global Eradication of Poliomyelitis, Status Report, March 1994
The Lancet, vol 343 May 28, 1994	Paralytic Poliomyelitis: Seasoned Strategies, Disappearing Disease
	Incidence of Poliomyelitis 1988-1994
PAHO Special Report	Strategies for the certification of the eradication of wild poliovirus transmission in the Americas. Bulletin of PAHO 1993; 27(3): 287-296

Annex 4 List of participants

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Dr J. Andrus, SEARO
Dr R. Basu, Consultant, c/o WR, Bangladesh
Dr J. Bilous, WPRO

Annex 5 Agenda of the meeting

Thursday, 16 February 1995

A. INTRODUCTION

08:30 Registration

09:00 Opening

Dr H. Nakajima, Director-General, WHO

Dr J.W. Lee, Director, Global Programme for
Vaccines and Immunization, Executive Secretary of
the Children's Vaccines Initiative

09:30 Group photograph

B. CERTIFICATION PROCESSES

09:45 Smallpox

Dr J. Kostrzewski

Poliomyelitis

Dr J. Kostrzewski

10:30 Coffee

C. PROGRESS TO DATE

11:00 Global Update

African Region

American Region

Eastern Mediterranean Region

European Region

South-East Asia Region

Western Pacific Region

12:30 Lunch

D. BACKGROUND

14:00 Clinical aspects and differential
diagnosis

Dr M. LaForce

Epidemiologic features of
poliomyelitis

Dr H.F. Hull

Virology of polioviruses

Dr B. Hull

15:30 Coffee

16:00 Eradication initiative Dr N.A. Ward

 Use of indicators to monitor
 progress Dr M. Sulieman Ali Jaffer
 Dr D. Salisbury

17:30 Adjourn

Friday, 17 February 1995

E. INFRASTRUCTURE OF GLOBAL ERADICATION

09:00 Principles Dr N.A. Ward

 Criteria for certification Dr C. de Quadros

 Experience in the Americas with
 certification Dr C. de Quadros
 Dr J.M. Olivé

10:30 Coffee

11:00 Working Group on Certification Dr N.A. Ward
 Dr D. Salisbury

 Documentation Dr H. Hull

 Process of certification Dr J. Kostrzewski

12:30 Lunch

14:00 Conclusions and Recommendations
