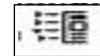


# Report of the second meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis

Geneva, 1 May 1997

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EXPANDED PROGRAMME ON IMMUNIZATION



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# 1. Introduction

The Second Meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis (the 'Global Commission') was held at the World Health Organization in Geneva on 1 May 1997, under the Chairmanship of Professor J. Kostrzewski.

On behalf of the Director-General of the World Health Organization (WHO), Dr R. H. Henderson, Assistant Director-General, opened the meeting. Dr Henderson noted that parallel to the marked acceleration of polio eradication activities worldwide during 1996, the process of certification had been given increasing attention at both the country and Regional levels. Regional Certification Commissions had now been convened in four of the six WHO Regions, with the development and endorsement of Regional certification plans of action and activity timelines.

Dr Henderson observed that in 1995 the Global Commission had clearly defined the principles of certification and the process by which it would be implemented. The high standards set by the Global Commission were proving relevant to all countries, not only those in the last phase of polio eradication. By providing clear guidelines on surveillance standards, the work of the Global Commission was relevant even in those countries where polio eradication activities had only recently begun. It was now recognized that although spectacular progress had been made in the implementation of National Immunization Days during the past two years, in many countries the performance of AFP surveillance systems and polio laboratories required substantial improvement to meet certification standards.

Dr Henderson stated that while the first meeting of the Global Commission had established the basic principles for certification of polio eradication, this second meeting would need to consider the impact that recent advances in wild poliovirus surveillance could have on the certification process.

In welcoming two new Global Commission members, Dr Henderson again thanked all of the members for having accepted a tremendous responsibility, as the Commission's deliberations would ultimately dictate if and when wild poliovirus transmission had been interrupted worldwide. He trusted that the meeting's conclusions and recommendations would again represent a substantial step forward in eventually certifying the global eradication of poliomyelitis.

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## 2. Summary of the conclusions of the first meeting of the Global Certification Commission

During the initial meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis in February 1995, the Global Commission specified the process by which certification of polio eradication would be conducted, the general principles which formed the basis for that process and the criteria that would need to be met at the National and Regional levels for consideration of certification of polio-free status. During this second meeting the Global Commission reaffirmed these criteria, and again stressed the surveillance quality standards that would be required for certification.

In summary, the Global Commission had stated that, as for the certification of smallpox eradication, certification of polio eradication would be based on the principle that the risk of unrecognized virus circulation would rapidly diminish and approach zero after an appropriate period of time had passed during which no virus was detected despite excellent surveillance. Operationally, certification of polio eradication would be conducted on a Regional basis through Regional Certification Commissions established for that purpose. Each Region could only be certified as polio-free after all countries and areas of that Region had met the following criteria:

- a) absence of circulation of indigenous wild polioviruses for at least a three-year period during which surveillance activities had been maintained at the levels of performance needed for certification (see below).
- b) a National Certification Committee in each country had validated and submitted the documentation required by the Regional Commission.
- c) appropriate measures were in place to detect and respond to any importation of wild poliovirus.

At its first meeting in 1995, the Global Certification Commission stated that high quality surveillance for acute flaccid paralysis<sup>1</sup> (AFP), the WHO-recommended surveillance strategy for the detection of wild polioviruses, should also serve as the basis for certification of eradication of wild poliovirus transmission. The Global Commission established that the quality of AFP surveillance needed for certification, as measured by standard performance indicators, was as follows:

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<sup>1</sup> AFP: any case of acute flaccid paralysis among children aged less than 15 years, including Guillain-Barré Syndrome, and any case of suspected poliomyelitis among people of any age.

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- a) **Completeness of Reporting:** documentation of the timely receipt of  $\geq 80\%$  of expected routine AFP surveillance reports, including zero reporting where no AFP cases were seen. The distribution of reporting sites should be representative of the geography and demography of the country.
  - b) **Sensitivity of AFP Surveillance Systems:**  $\geq$  one case of non-poliomyelitis AFP should be detected annually per 100,000 population aged less than 15 years.
  - c) **Completeness of Investigation:** all AFP case should have a full clinical and virologic investigation with  $\geq 80\%$  of AFP cases having adequate<sup>2</sup> stool specimens collected for enterovirus studies.
  - d) **Completeness of Follow-up:**  $\geq 80\%$  of AFP cases should have a follow-up examination for residual paralysis at least 60 days after the onset of paralysis.
  - e) **Laboratory Performance:** all virologic studies on AFP cases should be performed in a laboratory accredited by the Global Polio Laboratory Network.

The Global Commission recognized the potential difficulties in establishing satisfactory AFP surveillance in industrialized countries which had been polio free for many years, and noted that flexibility would be needed in assessing the probability of absence of circulating wild poliovirus in such areas. Further documentation was requested on acceptable 'supplemental' or 'alternative' wild poliovirus surveillance methods for these countries.

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<sup>2</sup> Adequate specimens: two stool specimens of sufficient quantity for laboratory analysis, collected at least 24 hours apart, within 14 days after the onset of paralysis, and arriving in the laboratory by reverse cold chain.

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## 3. Status of the certification process at the WHO regional level

The Global Commission received and discussed detailed reports on the current status of the certification process in each of the six WHO Regions. Regional Certification Commissions had been established in four of the WHO Regions and at least one meeting of the Commission members had been conducted in the Americas, Eastern Mediterranean, European and Western Pacific Regions. Regional Commissions were expected to be established in 1997 and 1998 in the South-East Asia and Africa Regions, respectively. It was noted that the number of Regional Certification Commissions and their geographic responsibilities reflected the WHO Regional structure, to simplify the operational and logistical realities of implementing the certification process. Furthermore, it was recognized that as the certification process progressed it might be necessary to ensure that each Regional Commission received the appropriate documentation on countries or areas that were administratively part of other WHO Regions but which were epidemiologically linked to the countries for which they had certification responsibility.

The order of the following summaries reflect the order in which the Regional reports were presented at the meeting.

### 3.1 Region of the Americas (AMR)

In the Region of the Americas, the eradication of poliomyelitis was certified by the International Certification Commission on Polio Eradication (ICCPE) in September 1994. The deliberations and process of the ICCPE had provided important background material for establishing the principles for global certification. The AMR report to the 2<sup>nd</sup> Meeting of the Global Commission emphasized the need for continued high-quality AFP surveillance, even after Regional certification, to facilitate the detection of importations until such time as eradication could be certified globally. Despite maintaining AFP surveillance at a high level in most AMR countries, no indigenous wild poliovirus has been found since 1991. Although the ICCPE had not been formally convened since its last meeting in 1994, members of the Commission were regularly updated on poliomyelitis eradication and EPI issues in AMR member states and also participated in the meetings of the Regional EPI Technical Advisory Group. It was recognized that additional meetings of the ICCPE would eventually be required to review the status of Regional surveillance prior to certification of polio eradication globally.

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### 3.2 Eastern Mediterranean Region (EMR)

The Eastern Mediterranean Regional Commission for Certification of Polio Eradication was established by the Regional Director in 1995 and first convened on 23 September 1995 in Alexandria, Egypt. By that time the members of National Certification Committees had also been named in many of the member states. During the first meeting of the Regional Certification Commission, the proceedings of the Global Commission and ICCPE were reviewed in detail, with the Regional Commission endorsing the basic principles that were discussed. Proposed activities for the Regional Commission were agreed, along with an outline of an operational plan for the work of the Commission which would eventually include (i) defining whether country-specific responsibilities should be assigned to each Commission member, (ii) activating the National Certification Committees, (iii) establishing the plan for both eradication and certification of countries in difficult circumstances and (iv) determining the appropriate measures to deal with importation of wild poliovirus into polio-free areas.

In its recommendations to the Regional Director, the Regional Certification Commission emphasized the importance of establishing National Certification Committees where they did not exist and revitalizing the existing ones. Recognizing that the Eastern Mediterranean Region shared geographic borders with four other WHO Regions, and that this could substantially effect certification of EMR, the Regional Certification Commission recommended that interregional mechanisms be established to co-ordinate certification as well as eradication activities. These and other issues were to be considered during the 2<sup>nd</sup> Meeting of the Regional Commission planned for 1997.

### 3.3 European Region (EUR)

The Regional Commission for the Certification of Poliomyelitis Eradication in the WHO European Region was appointed in 1996 and first convened in Paris, France on 7-8 March of that year, during which a Plan of Action was reviewed and revised. For certification purposes, the Region's 51 member states were divided into seven zones, primarily reflecting similarities in the epidemiology of poliomyelitis and delivery of health services. On the basis of 1996 data, the seven zones were classified as endemic, recently endemic or non-endemic for wild poliovirus. While it was clearly stated that high quality AFP surveillance would be the 'gold standard' for Regional certification, it was recognized that 'supplemental' information might need to be considered in the certification of some non-endemic countries which could not establish routine AFP surveillance which met certification requirements. In November of 1996, the WHO European Regional Office convened a meeting in London, England to consider the sensitivity and potential role of a number of these 'supplemental' surveillance methods (particularly virologic laboratory networks, environmental surveillance and aseptic meningitis surveillance).

According to the timetable established for the certification process in the European Region, non-endemic countries in the Nordic/Baltic, Western, Central and Southern Zones would submit initial documentation for review by the Regional Commission in 1998. This would allow time for implementation of additional certification activities if needed prior to the year 2000, the proposed date for Regional certifica-

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tion. Recently endemic countries in the Central and Eastern Zones would be requested to file their initial documentation by 1999, allowing the Commission to focus on the review of the highest risk countries (MECACAR Zone<sup>3</sup> and Russia) in the year 2000.

### **3.4 Western Pacific Region (WPR)**

An eight-member Regional Certification Commission was appointed by the WHO Regional Director for the Western Pacific in 1996. During the first meeting of the Regional Commission in Canberra, Australia in April 1996, a draft Plan of Action for Certification of the Western Pacific Region was discussed, revised and endorsed. Among the key elements of the Plan was the establishment of a single Sub-Regional Certification Committee to undertake the functions of a National Certification Committee for the 20 Pacific Island nations and areas. It was recognized that supplementary surveillance activities and information might be required for the certification of some of the industrialized countries of the Region which had been polio-free for many years and which might have difficulty establishing highly sensitive AFP surveillance.

The proposed timetable for certification of the Western Pacific Region called for the non-endemic countries and the Pacific Islands Sub-region to submit a plan of action for documentation of polio-free status by 1998. Initial documentation from the Philippines, Lao P.D.R., Malaysia, Mongolia and China would be evaluated in 1999. Cambodia, Papua New Guinea and Viet Nam would submit documentation in the subsequent year. It was anticipated that the final documentation of all countries could be considered for Regional certification in the year 2000.

### **3.5 South-East Asia Region (SEAR)**

Preparations were ongoing to appoint a Regional Certification Commission for the South-East Asia Region and form National Certification Committees in each member state. A draft plan of action for the Regional certification process was being prepared, based on the principles established by the Global Commission and adapted as appropriate to the characteristics of the South-East Asia Region. The first meeting of the Regional Commission was planned for 1997, during which the procedure for Regional certification would be established, a timetable of activities would be developed, and the draft plan of action would be reviewed/revised. It was anticipated that for certification purposes some countries of the Region could be considered as part of a larger group, based primarily on the epidemiology of poliomyelitis in each member state. One or two members of the Regional Commission might then have responsibility for overseeing certification activities for each 'group' or area.

While the Regional Certification Commission and National Certification Committees were being formed, high priority would continue to be given to the strengthening of AFP surveillance in each SEAR member state to meet the standards estab-

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<sup>3</sup> MECACAR Zone: refers to the nine countries of the WHO European Region which together with nine countries of the Eastern Mediterranean Region conducted the coordinated polio immunization days known as Operation MECACAR (Mediterranean, CAucasus, Central Asian Republics) in each of 1995, 1996 and 1997.

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lished by the Global Commission. The annual meetings of the SEAR EPI Technical Consultative Group would be one of the main instruments for promoting and improving AFP surveillance in the Region.

### **3.6 African Region (AFR)**

A tentative schedule for the process of certification of poliomyelitis eradication in the African Region was presented. The plan took into account the need to proceed in a phased manner consistent with the situation in each of the Region's four epidemiological blocks, namely the Eastern, Central and Southern blocks, and the four countries which were considered 'in difficult circumstances' for the purpose of the eradication initiative (Angola, Ethiopia, Nigeria and Zaire). It was expected that the Regional Certification Commission for the African Region would be appointed in 1997, with the first meeting of the Commission planned for December 1997.

In 1998, the countries of the Eastern and Southern epidemiological blocks would be the first to establish National Certification Committees, with the Central and Western African blocks and the four countries in difficult circumstances establishing National Committees in 1999. It was proposed that the National Certification Committees of the Eastern and Southern Blocks would submit documentation supporting certification to the Regional Certification Commission in 1999, followed by the Central and Western blocks in the year 2000, and the countries in difficult circumstances in 2001. The WHO African Region planned to convene annual meetings of the Regional Certification Commission.

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## 4. Terminology: definition of polio eradication

The Global Commission noted that since its first meeting in 1995 there had been ongoing discussion of the definition of 'poliomyelitis eradication' in the global, regional and national context. The Commission emphasized the importance of adhering to the original definition of polio eradication as recorded in the Report of the 1<sup>st</sup> Meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis. As noted previously, certification of eradication at the Regional level would only be possible once the *absence* of indigenous wild poliovirus circulation had been demonstrated through high-quality AFP surveillance. The following recommendation was made to clarify the definition of poliomyelitis eradication.

**RECOMMENDATION:** Eradication must be defined as the 'eradication of all wild polioviruses'. At the Regional level this objective should be understood as 'the eradication of regionally indigenous wild poliovirus'. In particular, Regional Commissions should express the concept as demonstrated 'absence' rather than 'interruption' of wild poliovirus transmission.

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# 5. Composition and procedures of Regional Certification Commissions and National Certification Committees

## 5.1 Regional Certification Commissions

The Global Commission stated that there were substantial advantages in ensuring that the membership of each Regional Certification Commission included individuals from outside that Region. The ICCPE of the Region of the Americas had included individuals from outside the Region who had significant experience in the certification of smallpox eradication. Likewise, the Regional Certification Commission for the Western Pacific now included individuals with substantial experience in the process of certifying the Region of the Americas as polio-free. It was concluded that individuals from outside a Region, with an international stature in public health and experience relevant to the certification of disease eradication, could substantially contribute to the objective evaluation of the national documentation submitted to a Regional Certification Commission.

The Global Commission stated that members of Regional Certification Commissions should not be selected by, or represent, their respective governments. Membership on a Regional Commission should be based solely on one's personal merits (i.e. personal reputation and expertise as a scientist or public health official). Regional Certification Commissions were to be independent of WHO and of national governments. The Global Commission noted that the work of Regional Certification Commission members could be compromised if they were also to serve on a National Certification Committee or have individual responsibility for a country's certification.

The Global Commission reinforced the importance of maintaining high-quality AFP surveillance, and continuing supplementary immunization activities wherever necessary, even after a Region had been certified as polio free. Given the difficulty in maintaining high quality surveillance and recognizing that the certification of each Region would occur at different times, the Global Commission was concerned that the quality of surveillance for wild poliovirus could substantially decline in polio-free Regions prior to global certification. Therefore, it was stressed that Regional Certification Commissions would need to continue to monitor the quality of AFP surveillance even after Regional certification had occurred.

**RECOMMENDATION:** It is strongly recommended that Regional Certification Commissions include individuals from other Regions, especially those which are geographically adjacent. These individuals should serve as full members of the Commission.

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**RECOMMENDATION:** Regional Commission members should not be required to have direct responsibility for the activities of National Committees. The terms of reference for Regional Commission members should not include obligatory participation in meetings of National Committees.

**RECOMMENDATION:** In Regions which have been certified as 'polio-free', the Regional Commission should continue to be convened on a regular basis to ensure that countries maintain the necessary level of surveillance.

## 5.2 National Certification Committees

Following the review of the Regional reports, the Global Commission noted a number of concerns with the certification process at the National level. First, there continued to be difficulties in the selection and appointment of some National Certification Committees. Secondly, in some countries there was ongoing uncertainty as to how National Certification Committees should operate. Thirdly, in countries with limited population size, the establishment of a National Certification Committee for that country alone did not appear to be the most efficient or effective mechanism for collecting and verifying the data which would be needed for certification.

The Global Commission stated that given the complexity of the certification process, the WHO secretariat would need to play an active role in facilitating its proper implementation at the National level. The following recommendations were made to clarify the mechanism for establishing, and ensuring the effective functioning of, National Certification Committees.

**RECOMMENDATION:** National Committees should be independent bodies, appointed by the national government in consultation with the appropriate WHO Regional office.

**RECOMMENDATION:** The National Committee should work closely with the appropriate immunization, surveillance and laboratory personnel within the country, however, committee members should not have direct responsibility for the polio eradication programme in the country.

**RECOMMENDATION:** Where appropriate, consideration should be given to establishing sub-regional Committees for groups of countries with small populations as an alternative to establishing several separate National Certification Committees. Alternatively, such countries should consider inviting the appropriate personnel from neighbouring countries to serve on their Committee.

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## 6. AFP surveillance standards for certification of polio eradication

The Global Commission recognized that since the original standards which defined 'high-quality AFP surveillance' had been established and adopted for certification purposes at the 1995 meeting of the Global Commission, additional information on the sensitivity and efficiency of those surveillance standards had become available. In particular, the Global Commission noted the conclusions and recommendations of the Global Technical Consultative Group for Polio Eradication (Global TCG<sup>4</sup>) and the impact those findings might have on the Certification process. The Global Commission was especially interested in those developments which might reduce the costs of implementing the AFP strategy while ensuring that the sensitivity to detect wild poliovirus circulation was not compromised.

Three of the proposed indicators for defining 'high quality surveillance' were reviewed in recognition of the recent Global TCG recommendations that these aspects of the AFP surveillance strategy be modified on the basis of additional data which had become available since 1995. The three aspects of the WHO-recommended AFP surveillance strategy that were reviewed are as follows.

### 6.1 Collection of stool specimens from case contacts

In 1995, the Global Commission stated that one stool specimen should be collected for virologic analysis from at least five contacts of all AFP cases. Information from AFP contacts had formed an essential part of the evidence accepted by the ICCPE in certifying the eradication of indigenous wild polioviruses from the Region of the Americas. Even at that time, however, it was recognized that the routine collection, transport and processing of specimens from contacts significantly increased the expense of the AFP surveillance strategy. Furthermore, an analysis of data from the Region of the Americas presented at the 1996 Global TCG meeting showed that the routine collection of stool specimens from AFP case contacts did not significantly increase the overall sensitivity of AFP surveillance to identify wild poliovirus infected areas. In fact, in the Americas it was found that the analysis of contact specimens did not detect any wild poliovirus infected counties that were not already recognized as being at high risk and requiring further mopping-up activities. The Global Commission concurred with the recommendation of the Global TCG that the collection and analysis of contact specimens should still be promoted in areas with poor AFP surveillance and in other appropriate circumstances.

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<sup>4</sup> Global TCG: the Global Technical Consultative Group (TCG) for Polio Eradication is convened on a periodic basis to review new scientific or operational developments relevant to the Global Polio Eradication Initiative, and, if appropriate, recommend revisions to the WHO-recommended strategies for polio eradication.

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**RECOMMENDATION:** The routine collection and analysis of stool specimens from contacts of AFP cases should not be required for certification. However, contact stool specimens should be collected in special circumstances such as where there is a failure to collect adequate specimens from the case itself and in high risk areas with poor surveillance (e.g. refugee populations). Some countries may need to collect contact specimens to ensure adequate specimens for maintaining laboratory proficiency.

## **6.2 Collection of one vs. two stool specimens from AFP cases**

The operational realities of collecting a second stool specimen from each AFP case (at least 24 hours after the first specimen was collected) has been recognized as one of the most difficult and potentially inefficient aspects of the WHO-recommended AFP surveillance strategy in some geographic areas. For this reason, there has been an ongoing effort at the global and regional levels to determine the increase in sensitivity to detect wild poliovirus circulation that is gained with the collection of a second stool specimen from every AFP case. The Global TCG on Polio Eradication reviewed the available data in both 1996 and 1997. At the 1996 Global TCG meeting an analysis of historical data from the Region of the Americas demonstrated that the collection of a 2<sup>nd</sup> stool specimen did not increase the sensitivity of the Regional AFP surveillance system to detect a wild poliovirus infected geographic area. A mathematical model presented at the same meeting, however, suggested that this finding was not immediately generalizable to other WHO Regions due to differences in both the prevalence of wild poliovirus and the maturity of the laboratory network (collection of a second specimen would substantially increase 'population sensitivity' primarily in areas where 'specimen sensitivity' was intermediate). Subsequently, in 1997 the Global TCG reviewed data from the Western Pacific and African Regions which showed that the collection of a second stool specimen still increased the probability of detecting wild-virus infected individuals and areas in those Regions (by at least 20% in the Western Pacific).

**RECOMMENDATION:** Two adequate stool specimens should be collected from all AFP cases. The number of specimens may be reduced to one in Regions which have been certified as polio-free and where Regional virological data demonstrates that infected areas would not have been missed if only one stool specimen had been collected.

## **6.3 AFP case classification: the importance of 'Expert Committees' and polio compatible cases**

The Global Commission noted that with the improvement in AFP surveillance worldwide, an increasing number of countries were moving from the use of 'clinical' to 'virologic' criteria for classification of AFP cases as polio vs. non-polio. In countries which were using virologic criteria alone, only those AFP cases from which wild poliovirus was isolated were being confirmed as 'poliomyelitis'. The Global Commission recognized, however, that there sometimes remained a substantial risk of wild poliovirus infection in those AFP cases which were virologically 'negative' but from whom adequate stool specimens had not been collected.

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Subsequently, the Global Commission endorsed the recommendation of the Global TCG that if such cases did not have evidence of complete resolution of their paralysis, as documented in a 60 day follow-up examination, they should be carefully scrutinized by a national Expert Committee in each country. These 'Expert Committees' should then discard only those cases in which the diagnosis of wild poliovirus infection could be ruled out with some degree of certainty after the consideration of all available clinical, immunologic, virologic, epidemiological and other appropriate data. The remaining cases should be classified as 'polio compatible'<sup>5</sup>. The Global Commission went on to state that a high level of competence of Expert Committees was essential to the certification process and that there should be evidence that these Expert Committees met on a regular and ongoing basis. Furthermore, as 'polio compatible cases' represented a failure of the surveillance system to collect adequate specimens in a timely manner, Regional Certification Commissions must be satisfied that all possible measures were employed to rule out wild poliovirus circulation in the geographic area of such cases.

**RECOMMENDATION: In their review of AFP surveillance data, Regional Certification Commissions should pay particular attention to the scrutiny of cases of AFP which have been classified as 'polio compatible'.**

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<sup>5</sup> Polio compatible case: an AFP case which is negative for wild poliovirus, but which has the combination of (i) inadequate stool specimens, (ii) loss to follow-up, residual paralysis or death, and (iii) review by a national Expert Committee which could not discard the case as 'non-polio' AFP after a review of all available data.

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## 7. Certification of non-endemic industrialized countries

Although AFP surveillance was endorsed by the Global Commission in 1995 as the basic strategy for certifying the absence of wild poliovirus circulation, it was recognized that the establishment of high quality AFP surveillance might not be possible in some countries which had been polio-free for many years. The Global Commission was particularly concerned about the feasibility of establishing such surveillance in some industrialized countries. While the Global Commission recommended that such countries continue their efforts to establish AFP surveillance, it also requested the evaluation of other surveillance strategies which might contribute 'supplementary' information to the documentation needed for certification.

Since 1995, the WHO Regional offices for the Western Pacific and European Regions had worked with their industrialized member states to identify existing enterovirus surveillance systems that might prove useful in the certification of wild poliovirus eradication. The European Region had also convened an informal consultation of experts to review the potential role of three of these systems: aseptic meningitis surveillance systems, environmental surveillance schemes, and networks of diagnostic virologic laboratories. The Global TCG for Polio Eradication subsequently reviewed and agreed with the three primary findings of the consultation. First, if the appropriate preconditions were met, data from virologic laboratory networks could be particularly valuable as 'supplementary' surveillance data in the certification process. Secondly, aseptic meningitis surveillance offered little if any advantage over AFP surveillance. Thirdly, environmental surveillance would seldom, if ever, provide data which was geographically and temporally representative of entire populations.

During the evaluation of these 'supplemental' surveillance strategies it was found that 'suspected poliomyelitis' was not an immediately notifiable condition in a number of industrialized countries. Even confirmed polio cases did not require immediate reporting to public health authorities in some countries. Furthermore, few countries had a mechanism in place for ensuring that all poliovirus isolates, regardless as to the source, were immediately submitted for intratypic differentiation in a WHO-accredited laboratory. Recognizing that some industrialized countries might concentrate only on 'supplemental' surveillance strategies and overlook the essential need for ensuring high quality surveillance of at least 'suspected' polio cases (if not all AFP cases) a 'certification framework for industrialized countries' was presented to the Global Commission. The framework stressed that in the absence of routine AFP surveillance, an industrialized country would need to demonstrate the following:

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- (i) high quality routine surveillance for 'suspected' poliomyelitis (with evidence of the sensitivity of such surveillance);
  - (ii) high quality surveillance for wild poliovirus (including the appropriate virologic analysis of specimens from all suspected poliomyelitis cases as well as other sources); and
  - (iii) all relevant virologic results either came from or were confirmed by a laboratory which was accredited as part of the Global Polio Laboratory Network.

The Global Commission welcomed the work that had been done on the establishment of guidelines for the certification of polio-free industrialized countries which lacked AFP surveillance. It was requested that additional work be conducted to determine the sensitivity of 'supplementary' surveillance strategies to detect wild poliovirus.

**RECOMMENDATION:** The Global Commission reaffirms that the absence of wild poliovirus for three years in the presence of high quality routine AFP surveillance among children aged less than 15 years should be regarded by all countries, regardless of to their endemic status, as the gold standard for certification of polio eradication.

**RECOMMENDATION:** Non-endemic industrialized countries which have been polio-free for a prolonged period and in which it is not practical to establish routine AFP surveillance should ensure that the documentation that is submitted for certification demonstrates adequacy of surveillance in three general areas:

- surveillance for individuals with suspected paralytic poliomyelitis,
- surveillance for wild poliovirus, and
- laboratory competence to isolate and identify wild polioviruses.

**RECOMMENDATION:** With respect to surveillance for clinical poliomyelitis, all non-endemic industrialized countries should at a minimum:

- ensure immediate reporting and proper clinical, virological and epidemiological investigation of all 'suspected polio' cases and,
- conduct a study to demonstrate that individuals with acute onset flaccid paralysis (AFP) would receive an accurate final diagnosis and that a diagnosis of poliomyelitis would not have been missed.

**RECOMMENDATION:** With respect to laboratory competence to isolate and identify wild polioviruses, non-endemic industrialized countries should ensure that at a minimum, all poliovirus results are confirmed by a WHO-accredited laboratory, with intratypic differentiation of the virus.

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## 8. Laboratory containment of wild polioviruses

As the Global Polio Eradication Initiative progresses toward certification of wild poliovirus eradication, the safe handling and eventual containment of existing stocks of wild polioviruses has become increasingly important. The Global Commission was alarmed by documented cases of wild poliovirus infection in the community which were traced to laboratory stocks. Wild poliovirus is currently held in many virological laboratories worldwide, for a diversity of reasons ranging from basic research, to vaccine quality control, to the manufacturing of inactivated polio vaccine (IPV). These poliovirus stocks could present a formidable threat to the ultimate success of the eradication initiative unless strict guidelines for their safe handling and a plan of action for their eventual containment are established and implemented as soon as possible.

The Global Commission recognized the close relationship between the containment and certification processes but noted that the roles, responsibilities and timeline for containment had yet to be finalized. It was suggested that regardless of the final mechanism that was established for implementing and verifying the containment of wild polioviruses, the Global and Regional Certification Commissions must be kept informed of the process and its outcome on an ongoing basis.

**RECOMMENDATION:** the control of laboratory stocks of wild poliovirus is essential to the global eradication of poliomyelitis. A plan of action for the inventory, control and containment of laboratory stocks should be developed as soon as possible.

**RECOMMENDATION:** prior to Global Certification, Regional Commissions should demonstrate to the Global Commission that Regional laboratory stocks of wild poliovirus have been properly contained.

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## 9. Resources for the certification process

The Global Commission commented on the 1997 finding of the Global TCG, that implementation of AFP surveillance was lagging behind supplementary immunization strategies in many countries. It was particularly concerned that some countries were substantially underestimating the resources needed for both improving and sustaining surveillance. The Commission noted that delays in implementing high-quality AFP surveillance, whether due to insufficient resources or other reasons, would also delay the certification process.

The Global Commission was also concerned as to the sustainability of high quality surveillance in those WHO Regions which were certified as 'polio-free' but which remained at risk of polio importations until such time as wild virus circulation was interrupted worldwide. Substantial human and financial resources were needed for many years after Regional certification to maintain high quality surveillance in the absence of wild virus circulation. Experience in the Region of the Americas, had demonstrated that a concerted effort at both the national and international level was required to ensure that such resources continued to be available.

**RECOMMENDATION: Countries should ensure that sufficient national resources are committed to sustaining high quality AFP surveillance after Regional Certification has occurred and until such time as Global Certification has been confirmed.**



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# Annex 1:

## List of Commission members and participants

### Commission members

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# Annex 2: Agenda

**Thursday, 1 May 1997**

## **A. Introduction**

09.00	Opening	Dr R. H. Henderson
09.10	Administrative Announcements	Dr H. Hull

## **B. Progress to date**

09.15            Reports from the Regional Certification Commissions  
*(10 minutes per report, 5 minutes discussion)*  
American Region  
Eastern Mediterranean Region  
European Region  
Western Pacific Region

Plan for Regional Certification Commissions  
*(5 minutes per report, 5 minutes discussion)*  
African Region  
South-East Asia Region

10.30            Coffee

## **C. Technical issues for certification**

11.00	Collection of stool specimens from AFP cases and contacts	Dr M. Pallansch
11.30	Framework for Certification of Non-endemic Countries	Dr B. Aylward
12.00	Non-human Reservoirs for Polioviruses Laboratory Containment for Wild Polioviruses	Dr W. Dowdle
12.30	Lunch	

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## **D. Discussion and recommendations**

- 14.00 Discussion of TCG Recommendations
- 14.30 Review of Certification Recommendations
- 15.30 Coffee
- 16.00 Conclusions
- 17.00 Meeting adjourns