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Global eradication of poliomyelitis

Report of the third meeting of the Global Commission for the certification of the eradication of polio, Geneva, 9 July 1998

GLOBAL PROGRAMME FOR VACCINES AND IMMUNIZATION

EXPANDED PROGRAMME ON IMMUNIZATION

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1. Introduction

The third 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 8 July 1998, under the chairmanship of Professor J. Kostrzewski. A list of participants is attached as Annex 1.

On behalf of the Director-General of the World Health Organization, Dr B. Melgaard, Acting Director, Global Programme for Vaccines and Immunization, opened the meeting. Dr Melgaard observed that progress has been rapid in implementing eradication strategies since the last meeting of the Global Commission. Less than a handful of endemic countries were left where full national immunization days (NIDs) had not been conducted, and all of these countries plan for full NIDs before the end of the year. The second series of NIDs has been conducted in most endemic countries in Africa, although much remains to be done for acute flaccid paralysis (AFP) surveillance on that continent. There had also been dramatic progress in surveillance in countries of South Asia – countries which represent one of the main remaining foci of wild poliovirus transmission.

Dr Bjorn Melgaard observed that Regional Certification Commissions had already met in five regions. In addition, two special consultations were held in Geneva since the last meeting with particular relevance for the certification of polio eradication – a meeting on planning and procedures for the eventual containment of polioviruses, and a consultation on the scientific basis for the eventual cessation of immunization against polio.

As requested by the chairman of the global commission, new officers were designated for the global commission: Dr Carlyle de Macedo and Sir Joseph Smith to serve as joint Vice-Chairmen, and Dr Rose Leke and Dr Anthony Adams as Co-Rapporteurs.

Dr Melgaard noted that the Global Commission's expert advice was needed more than ever to guide National Committees and Regional Commissions for the Certification of Polio Eradication, as well as all workers involved in implementing eradication strategies. He trusted that the meeting's conclusions and recommendations would again represent an important step forward towards eventual certification of the eradication of poliomyelitis.

2. Report on progress since the second meeting of the Global Commission

The Global Certification Commission recognized the impressive progress that has been made globally in polio eradication, particularly the steady improvement in the surveillance systems which are essential for providing the information upon which certification of eradication depends. The commission also noted however the substantial work still to be done before global certification can be accomplished. Most of this challenge will be in the large, densely populated countries which constitute the 'global reservoirs' of wild poliovirus and the smaller, but critically important, group of countries in which conflict has delayed the surveillance effort. The commission was much encouraged by the progress that has been achieved by WHO and its partner agencies in meeting this challenge in virtually all of the countries involved.

The Global Certification Commission was updated on the progress towards implementation of the recommendations from the 1997 Certification Commission meeting. All regional commissions, including the nominated commission for the African Region, include individuals from other regions as members. Regional certification commissions have also stressed during their meetings that national certification committees should be independent bodies, without direct programme responsibility. As recommended in 1997, a "proposed global action plan and timetable for safe handling and maximum laboratory containment of wild polioviruses and potentially infectious material" was developed and published in June 1998.

The Chairperson of each regional certification commission (or a WHO regional office representative) commented on the certification process in WHO regions and on activities since the previous global commission meeting. The Chairman of the Global Technical Consultative Group (TCG) on polio eradication reviewed the issues from the 1998 TCG meeting that were relevant to the proceedings and deliberations of the global certification commission.

The **African Region** had prepared a tentative schedule for the certification process, taking into account the situation in each of the region's four epidemiological blocks. It was expected that the Regional Certification Commission would be appointed and meet first in September 1998.

Polio eradication in the **Region of the Americas** was certified in 1994. Although high quality surveillance for AFP and wild poliovirus has continued in most formerly endemic countries, there have been notable exceptions. The regional certification commission has not formally met since 1994. Members of the regional certification commission are updated regularly on polio eradication and EPI issues. It was recognized that additional meetings of the regional commission may be required to review the status of regional surveillance prior to eventual global certification.

The **Eastern Mediterranean Regional Commission** was established in 1995 and has met twice since then. The regional commission has placed particular emphasis on the need for interregional mechanisms to co-ordinate certification activities, in recognition of the fact that the region shares geographic borders with four other WHO regions.

For certification purposes, the **European Region** was divided into seven zones which were classified as endemic, recently endemic or non-endemic for wild poliovirus. While AFP surveillance would be the 'gold standard' for regional certification, it was recognized that supplemental information, such as enterovirus surveillance through virologic laboratory networks, will have to be considered in the certification of some non-endemic countries.

At the time of the third meeting of the global commission, preparations were underway for the second meeting of the **South-East Asia Regional Commission.** While National Committees were being formed in all endemic countries of the region, high priority would continue to be given to the strengthening of AFP surveillance in each SEAR Member State to meet certification standards.

In the **Western Pacific Region**, the Regional Commission was formed in 1996 and established a single Sub-Regional Certification Committee to undertake the functions of a National Certification Committee for the 20 Pacific Island nations and areas. The proposed timetable 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.

Global Certification Commission decisions

2.1 The Global Certification Commission is impressed with the progress made in the past year, both in poliovirus eradication and in the surveillance procedures needed to guide and eventually certify that achievement. It is evident that wild poliovirus transmission worldwide can be interrupted by the end of the year 2000 or shortly thereafter, and that global eradication can be certified by the target date of 2005, provided the resources needed for both efforts are rapidly made available. The Global Commission is most concerned that a lack of resources for surveillance could seriously compromise the capacity to certify eradication worldwide, especially in Africa and Asia. Consequently, the Global Certification Commission Chairman and his designates will meet the incoming Director-General of WHO to request that she lends her full and critically important support to the mobilization of the additional resources that will be essential not only for stopping poliovirus transmission, but for adequate surveillance to be established and the mandate of the Commission fulfilled.

2.2 The Global Certification Commission thanks the Global Technical Consultative Group for the report of their 1998 meeting and endorses the relevant conclusions and recommendations in the areas of surveillance and containment.

3. Wild poliovirus importations into polio-free areas

Many countries now appear to be free of indigenous wild poliovirus transmission. Until polio has been eradicated worldwide, however, all polio-free areas remain at risk of re-introduction and re-establishment of wild poliovirus circulation. For this reason, and as part of the documentation required for certification, all countries need plans of action for detecting and responding to importations of wild poliovirus. These plans of action should be based on standard guidelines. The Global Commission was presented with a country case study (wild virus importation into Canada) demonstrating the threat of importation, especially into industrialized countries. As an example, guidelines developed in the Western Pacific Region on the response to wild poliovirus importation into polio-free areas were also presented.

Global Certification Commission decisions

3.1 In the certification documentation provided by individual countries, there must be a plan of action for dealing with importations of wild poliovirus. Each WHO region should provide Member States with guidelines on the key elements of such a plan, including the following sections 1) monitoring and detection of wild poliovirus importations, with immediate notification to WHO; 2) investigation and enhanced surveillance; 3) immunization response; and 4) documentation of interruption of wild virus transmission.

3.2 In the case of a wild poliovirus importation into a non-endemic country, additional active surveillance for acute flaccid paralysis must be implemented and extended for a period of at least three months beyond the onset of paralysis of the last case or the last wild virus isolation. For example, in industrialized countries that do not have routine AFP surveillance, such surveillance could be implemented in the area of the case for a period of at least three to six months.

3.3 Each WHO region and WHO/HQ must establish a mechanism for the immediate notification of potential importation risks to other countries and Regions.

4. Certification of WHO regions versus sub-regional epidemiological blocks

In countries of the Eastern Mediterranean and African Regions, there have been discussions as to the political and epidemiologic advantages and disadvantages of a sub-regional approach to certification. Each of WHO's six regions contains countries with varying levels of economic development and health care infrastructure, as well as diverse geography and demography. Because of their sophisticated health care systems, high levels of immunization coverage and absence of indigenous polio cases, some countries have argued for individual certification. In some countries and regions this has led to discussions on the potential utility of 'sub-regional' certification. While a number of these countries may indeed be polio-free, many have substandard surveillance systems and are at high risk of both distant and local importations.

Global Certification Commission decisions:

4.1 Because of the considerable political and administrative advantages in implementing the certification process along WHO regional boundaries, these boundaries should continue to form the basis for certification. However, the epidemiology of wild poliovirus transmission in adjacent WHO regions and the risk of those areas serving as reservoirs for the re-establishment of transmission in a certified area, must be considered prior to the certification of any WHO region.

4.2 The global certification commission does not consider it justified to alter its position that regional commissions only confer the status of 'certified polio-free' on entire WHO regions at one time, as stated in the report of the first meeting and subsequently clarified in the report of the second meeting. Nor can regional certification commissions provide formal comment on the 'polio-free' status of any geographic area less than a total WHO region. However, if there are convincing geographic and epidemiological reasons for considering sub-regional certification in the future, these arguments can then be presented to the Global Commission. This data will only be considered when surveillance quality has reached the level needed for certification in the sub-region in question and there is strong data to suggest that the adjacent sub-region is polio-free.

5. Certification strategies

During its third meeting, the Global Commission considered several specific issues pertaining to certification strategies in more detail - the alternative surveillance strategy of using networks of diagnostic laboratories for enterovirus surveillance, a proposed manual of operations to assemble the national documentation for the certification of polio eradication, and the need for alternative approaches to certification in countries affected by conflict and civil unrest.

a) Enterovirus surveillance in non-endemic countries

While the principles for certifying global eradication of poliomyelitis have now been established, it will not be possible to implement the standard surveillance strategy (AFP surveillance) in a number of industrialized countries that have been polio-free for many years. An alternative strategy for certification that is being considered by many countries is the combination of high quality surveillance for 'suspected polio-cases' and enterovirus surveillance through diagnostic laboratory networks. A case study from the Netherlands was presented to the Global Commission to illustrate the use of diagnostic enterovirus laboratory networks in the certification of non-endemic countries. WHO is currently supporting a study to look at the relative sensitivity of AFP surveillance and enterovirus laboratory network data to detect circulating wild polioviruses.

Global Certification Commission decisions

5.1 The Global Certification Commission recognizes that certain industrialized countries that have been polio-free for prolonged periods cannot establish high quality routine AFP surveillance. It is increasingly apparent that a combination of sensitive surveillance for 'suspected poliomyelitis cases' and enterovirus data from diagnostic laboratories or laboratory networks can provide relevant evidence for the certification of polio eradication.

5.2 At the next meeting of the Global Polio Laboratory Network, the technical basis and criteria for accepting enterovirus data for certification purposes, from diagnostic laboratories or a laboratory network, should be established. The recommendations of that group should be reviewed and, if appropriate, endorsed by the Global Technical Consultative Group prior to presentation at the next meeting of the Global Commission.

5.3 The Polio Laboratory Network and Global Technical Consultative Group should also provide the Global Certification Commission with guidelines for countries to use in demonstrating the sensitivity and validity of their enterovirus laboratory network data when it is submitted as part of the documentation for certification. The guidelines should include at least the following areas:

- external quality assurance of the national network laboratories,
- evidence that the network data is geographically and temporally representative of the population,
- evidence that the number and type of specimens being processed is at least as sensitive as AFP surveillance,
- evidence that the network also samples the appropriate population subgroups and neurological conditions at high risk of poliomyelitis, and
- demonstration that all poliovirus isolates are submitted for intratypic differentiation at a WHO accredited laboratory.

b) Manual of operations - national documentation for the certification of polio eradication

Prior to stopping polio immunization, it will be necessary to certify the absence of wild poliovirus circulation from every country of the world. When all countries of a region report to have been free of indigenous wild poliovirus for a period of at least three years in the presence of adequate surveillance, Regional Commissions will analyse the final documentation from all national certification committees. To ensure consistency and facilitate the work of Regional and Global Commissions, the national documentation for certification should be as standardized as possible. The Global Commission reviewed a prototype manual of operations for national documentation for the certification of poliomyelitis eradication.

Global Certification Commission decisions

5.4 The Global Certification Commission appreciates the utility of the proposed 'Operation's manual for national documentation for the certification of polio eradication' which is currently being used by three WHO regions. Recognizing the utility of standard documentation, the Global Commission requests that the general concept of the existing manual be maintained in regions where such a manual has not yet been developed.

c) Certification process in countries and areas with ongoing conflict

Wild poliovirus transmission is now concentrated to South Asia and sub-Saharan Africa. Transmission appears to be most intense in three specific areas composed of large, densely populated countries: south Asia (Bangladesh, India, Nepal, Pakistan), West and Central Africa (especially the Democratic Republic of Congo and Nigeria) and the Horn of Africa (Ethiopia, Somalia, Sudan). Each of these 'reservoirs' also contain countries or areas that are severely affected by conflict, further complicating the implementation of eradication activities (e.g. Afghanistan, southern Sudan, Somalia).

During the first meeting of the Global Commission in 1995, the process was established by which certification of eradication would be conducted. The basic criteria for certification were stated as follows: i) absence of circulation of indigenous wild polioviruses for at least a three-year period during which surveillance activities have been maintained at the levels of performance needed for certification, ii) a National certification committee in each country has validated and submitted the documentation required by the regional commission, and iii) appropriate measures

are in place to detect and respond to importations of wild poliovirus. In countries and areas that are severely affected by conflict or civil unrest it is not currently possible for the countries themselves to implement certification activities, particularly the establishment of a National Certification Committee for validating and submitting the documentation required.

Global Certification Commission decisions

5.5 For countries and areas without a government structure or the capacity to establish a National Certification Committee, WHO should prepare and validate the documentation needed for certification of polio eradication.

5.6 The Global Certification Commission stresses that unless national capacity becomes established in such countries, the commitment of United Nations agencies to establish and maintain surveillance and certification activities will need to be sustained beyond Regional Certification and at least until global certification occurs.

5.7 Given the progress toward establishing effective AFP surveillance in areas as diverse as Afghanistan and Somalia, this strategy should continue to be considered as the basis for certification in areas affected by conflict. The Global TCG should evaluate the sensitivity of AFP surveillance in such circumstances and provide the Certification Commission with recommendations on what, if any, additional surveillance activities might eventually be required in areas affected by conflict.

d) Coordination of certification and poliovirus containment processes

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. Wild poliovirus is held in many diagnostic and research laboratories worldwide; these poliovirus stocks could present a serious threat to the ultimate success of the eradication initiative unless strict guidelines for their eventual biocontainment are established and implemented.

Ensuring the containment and safe handling of polioviruses will be a demanding exercise, requiring extensive expertise in the area of biosafety. A plan of action for the safe handling and containment of polioviruses has therefore been established and is being circulated for public comment. However, the mechanism for implemention of this plan has not been finalized and the roles/responsibilities of groups inside and outside of WHO, such as the Regional Certification Commissions, remain to be defined.

A special Task Force for Containment of Polioviruses may need to be established by the Director-General of WHO to advise both WHO and the Global Certification Commission on the implementation and completion of this task. The issues to be addressed by the Task Force include: development and management of laboratory inventory systems, the identification and accreditation of maximum containment facilities, the designation of repositories, and the policies and procedures for verification of compliance with containment requirements. The most appropriate role of Regional Certification Commissions may be to ensure that all countries have a containment plan of action, with the responsibility for monitoring the implementation

of that plan resting with biosafety experts. As the EMC (Emerging Diseases) Division within WHO is currently responsible for containment and biosafety issues, this group may need to play a much larger role in polio containment.

Global Certification Commission decisions

5.8 WHO should in the near future consider the establishment of a Task Force or other mechanism on poliovirus containment, with the appropriate expertise in polio eradication and biosafety, to advise the Global Certification Commission on the containment process for wild poliovirus. Such a Task Force might also advise the Global Certification Commission on the timetable for the containment process, and the technical basis for that timetable. The terms of reference of a Task Force or other body will include informing the Global Commission when maximum containment of wild polioviruses has occurred and providing the Commission with the appropriate documentation demonstrating that the process is complete.

5.9 In accordance with the proceedings of the first and second meetings of the Global Certification Commission, adequate containment of wild polioviruses will be a precondition of Global Certification. For regional certification, all countries will need to provide evidence that the activities described in 'Phase 1' of the Proposed Global Plan of Action for the Safe Handling and Maximum Containment of Polioviruses have been implemented (i.e. Biosafety Level 2/polio procedures have been implemented in enterovirus laboratories; a national inventory of laboratories/facilities with wild polioviruses is completed; a plan of action has been established for either destroying or moving such materials to a 'high containment facility' in Phase 2). Global Certification will require that Phase 2 containment activities for wild poliovirus have been implemented worldwide (i.e. destruction or transfer to a high level containment facility as determined in the final version of the *Global Action Plan for Laboratory Containment of Wild Polioviruses*).

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Annex 2: Agenda

Thursday, 9 July 1998

08:30-08:45	Opening Introductions and Election of Officers Administrative remarks
08:45-09:00	Progress report on 1997 meeting Status and Timeline of the Global Certification Process
09:00-09:15	Certification of WHO Regions vs. Sub-Regional Epidemiologic Blocks
09:15-09:30	**Discussion**
09:30-10:00	Implementation of the Certification Process in Countries & Areas with Ongoing Conflict or Civil Unrest
10:00-10:15	**Discussion**
10:15-10:30	*Coffee break*
10:30-10:45	Detection, Investigation and Response to Wild Poliovirus Importations into Polio-Free Areas:Proposed Guidelines
10:45-11:00	**Discussion**
11:00-11:15	Enterovirus Surveillance Data and the Certification Process Minimum criteria for use in non-endemic countries
11:15-11:30	**Discussion**
11:30-11:45	Co-ordination of the Certification and Containment Processes - role and responsibilities of the Certification Commissions
11:45-12:00	**Discussion**
12:00-14:00	*Lunch*
14:00-14:15	Manual of Operations: National Documentation for the Certification of Polio Eradication
14:15-14:30	**Discussion**
14:30:14:45	Review of the Conclusions and Recommendations
14:45-15:00	Closing
15:00-15:15	*Coffee break*
15:15-16:30	Closed Meeting of the Global Commission & Secretariat