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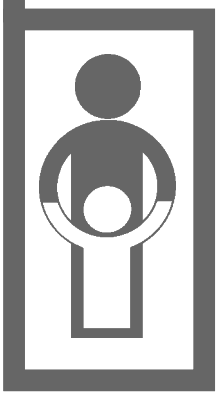
Certification of the Global Eradication of Poliomyelitis

Report of the fifth meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis

Geneva, 9 May 2000



DEPARTMENT OF VACCINES AND BIOLOGICALS

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Abbreviations

AFP	acute flaccid paralysis
AMRCC	American Regional Certification Commission
ARCC	African Regional Certification Commission
CSF	cerebro-spinal fluid
EMRCC	Eastern Mediterranean Regional Certification Commission
EURCC	European Regional Certification Commission
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
NIDs	national immunization days
RCC	Regional Certification Commission
SEARCC	South-East Asia Regional Certification Commission
TCG	Global Technical Consultative Group for Poliomyelitis Eradication
WPRCC	Western Pacific Regional Certification Commission

1. Introduction

Sir Joseph Smith and Dr Carlyle de Macedo, the co-deputy chairs of the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC), convened the fifth meeting of the Commission on 9 May 2000, in Geneva. All GCC members present had also attended the fifth meeting of the Global Technical Consultative Group for Poliomyelitis Eradication (TCG), which preceded the GCC meeting.

Welcoming members of the GCC on behalf of the World Health Organization (WHO), Dr Bjorn Melgaard expressed his hope that the GCC would again provide help and guidance to facilitate the successful continuation of the global and regional process towards eventual certification of poliomyelitis eradication.

GCC members attending were:

- African Region: Dr Rose Leke, Chair, African Regional Certification Commission (ARCC), Professor F. Nkrumah;
- Region of the Americas: Dr C. de Macedo; Dr F. Robbins, Chair, American Regional Certification Commission (AMRCC), was unable to attend;
- Eastern Mediterranean Region: Dr M. S. Ali Jaffar, Chair, Eastern Mediterranean Regional Certification Commission (EMRCC), Dr A. Deria;
- European Region: Sir J. Smith, Chair, European Regional Certification Commission (EURCC), Professor S. Drosdov;
- South-East Asia Region: Professor Natth, Chair, South-East Asia Regional Certification Commission (SEARCC), Dr H. Abednego;
- Western Pacific Region: Dr A. Adams, Chair, Western Pacific Regional Certification Commission (WPRCC), Dr Wang Ke An was unable to attend.

2. Activities of regional certification commissions

The meeting began with a review of the activities of the six regional certification commissions.

The African Regional Commission (ARCC) has not met since the last meeting of the Global Commission in June 1999. Members of the African Commission noted that the Region remained heavily endemic for polio and that significant progress must be achieved in priority countries before it would be appropriate for the Commission to seriously consider regional certification. Progress was noted in the area of containment with a number of network laboratories taking the first steps necessary to contain wild poliovirus stocks. Dr R. Leke and Professor F. Nkrumah, the African Regional members of the Global Commission, attended the recent meeting of the WPRO Certification Commission to familiarize themselves with the process of certification in this Region.

In order to stimulate governments of southern African countries to take the steps necessary to improve acute flaccid paralysis (AFP) surveillance to certification quality, a number of pre-certification visits are being planned. Members of the Regional and Global Commissions will visit these countries to review surveillance data and discuss the requirements of the Commissions with the Minister of Health. The ARCC will next meet in September 2000.

The Regional Commission of the Americas (AMRCC) has not met since the Regional Certification in 1994. The Regional Office for the Americas has stimulated countries to begin the process of laboratory bio-containment of wild poliovirus, but the process by which containment will be verified has not yet been specified.

The Eastern Mediterranean Regional Commission (EMRCC) met for the fourth time in Alexandria, in November, 1999. At the last meeting of the Commission, it noted the expansion and strengthening of AFP surveillance in the Region, the improvement in the immediate reporting of wild polioviruses and the expansion of the regional laboratory network. The quality of national immunization days (NIDs) has been improved and house-to-house immunization has been introduced into high-risk areas. The Commission also reviewed the composition of National Committees, some of which will need to be restructured to be in line with the recommendations of the GCC. Status reports were reviewed from six countries, five of which were satisfactory. The Commission will meet for the fifth time at the end of May 2000.

The European Regional Commission (EURCC) met in Copenhagen in January 2000. There has been good progress in the Region in terms of both eradication and certification activities, and the Mediterranean, Caucasus and Central Asian Republics (MECACAR) programme continues actively. However, several countries within the Region present

problems, due to political issues. Areas within Azerbaijan and Georgia have no contact with their Ministries of Health, the Federal Republic of Yugoslavia is not a member of the United Nations, which has prevented its formal representation in WHO meetings, and Chechnya and parts of Tajikistan are experiencing conflict. Efforts are being made to overcome these problems, but the need for high level political support remains.

In Western Europe, several countries that have long been free of polio have been unable to implement AFP surveillance. The Commission has given much attention to the value of other evidence of poliovirus elimination, notably surveillance of enteroviruses in samples from patients and also environmental surveillance.

The last case of reported polio in the Region was in November 1998, in a boy in south-east Turkey, and it is hoped that Regional Certification will be addressed after November 2001.

There was no meeting of the South-East Asia Regional Commission (SEARCC) during 1999. Of the 10 countries in the Region, the Democratic People's Republic of Korea (DPR) remains of great concern because of its political isolation and previous inability to provide reliable data. India is reporting the largest number of cases, but excellent progress is being achieved. Bhutan, Indonesia, the Maldives, Sri Lanka and Thailand remain free of polio. The Regional Commission will meet next in June 2000.

It has now been more than three years since the last reported case of polio caused by indigenous wild poliovirus in the Western Pacific Region. The Western Pacific Regional Commission (WPRCC) met in March 2000 for a documentation workshop to assist the countries of the Region in preparing their reports for the Commission. The WPRCC is planning to meet again in August 2000 to consider whether the Region can be certified free of indigenous wild polioviruses. The importation of wild poliovirus into China from India in September 1999 was a cause of great concern for the Commission. However, the response of the Chinese government was excellent and it appears that transmission has been interrupted and that the importation can be considered as contained.

3. Supplemental regional data needed prior to global certification

Issue: Which additional information will be required from regional certification commissions prior to global certification, particularly in regions certified more than five years before global certification?

Background

The Region of the Americas was certified polio-free in 1994, three years following the last indigenous case in 1991. Since 1994, all the countries of the Region except the United States of America and Canada have conducted AFP surveillance. However, the quality of surveillance has declined in some countries, raising concerns that an importation of wild poliovirus could establish indigenous transmission. In addition, no plan for laboratory bio-containment of wild polioviruses existed at the time of certification. The Western Pacific Region (last indigenous polio case: March 1997) and the European Region (last indigenous polio case: November 1998) have initiated the certification process, and will likely be certified well before the remaining WHO regions.

To ensure that all regions are prepared for final review by the Global Commission, regional commissions and WHO regional offices need guidance as to what, if any, additional information will be required.

Discussion

Dr Ciro de Quadros presented an update on the status Region of the Americas. At the time of regional certification, the Global Commission was not in existence and the AMRCC made no plans for reporting to or updating information for a Global Commission. AFP surveillance rates in the Americas declined steadily in the years after certification from a non-polio AFP rate (regional average) of 1.34/100.000 in 1994 to a rate of 0.86 in 1998. However, as a result of the interest in the Global Commission in the question of progress in the Americas, countries improved surveillance rates to 1.22 (regional average) in 1999. There was a similar trend twards increasing the completeness of stool specimen collection, however specific rates were not presented.

The decline in surveillance quality in the Americas was due to a number of factors, including decentralization of the health system, decreasing interest in countries to maintain AFP surveillance for years after regional certification, and a decline in WHO funding for surveillance. The decline of surveillance performance in Brazil contributed particularly to the decline at the regional level. Surveillance quality also continued to be low in Haiti, the Dominican Republic, Argentina, and the Caribbean island countries.

Although the WHO Regional Office of the Americas continues to collect, monitor and publish AFP surveillance data, a number of issues were raised as to how the Region would present data to the Global Commission from now until the date of global certification. The options included reconvening the AMRCC, which has been inactive for six years. The re-established Commission could then present data to the Global Commission. This course would also require the reconstitution of National Certification Committees. An alternative would be to have a subcommittee of the Global Commission meet with the Chairman and other representatives of the AMRCC, supported by the Regional Office, with data presented on an annual basis until the time of global certification. A third alternative would be for the WHO Regional Office to present appropriate updates to the Global Commission.

Discussion of these alternatives indicated that the members of the Global Commission felt that the Region of the Americas represented a special case, since the countries had been certified 6 years ago and because the AMRCC and the National Committees were inactive. Although the final decision on this issue was deferred until the next meeting of the Global Commission, it was decided that Dr de Macedo and Dr Deria would represent the Commission at the next meeting of the AMR Technical Advisory Group in October 2000. In addition, it was decided that the next meeting of the Global Commission would be held in the Region of the Americas, probably in Washington in February 2001, to permit the Chairman of the AMRCC to attend the meeting.

GCC decisions:

1. The GCC decided to address at its next meeting the question of the documentation to be required from WHO regions in the period between regional and global certification, and of how frequently this information would be needed. In doing so it will take into account the report it will receive on the current status of the Region of the Americas, and also a report on forthcoming WPRCC meetings, which may result in polio-free certification of that region.
2. The following list of data items was accepted as a basis for discussion of the status of polio eradication in the Region of the Americas at the next formal meeting of the Global Commission:
   a) immunization coverage;
   b) surveillance indicators;
   c) geographic distribution of AFP cases;
   d) data on ‘polio-compatible’ cases;
   e) reports of the investigation and control of any polio importations;
   f) updates on high risk areas;
   g) laboratory quality control;
   h) plans for and progress toward containment of laboratory stocks of wild virus;
   i) follow-up on previous recommendations of the Global Commission.
3. The WHO Secretariat is requested to prepare a draft document for potential use by WHO regional offices in presenting data to the Global Commission. The draft document will be considered at the next meeting of the Global Commission.
4. The Region of the Americas represents a special case, since it’s Member States were certified six years ago and the Regional Commission and the National Committees are now inactive. The GCC will need to agree on a formal means for reviewing the status of AMR countries since regional certification.

4. Effect of wild poliovirus importations on regional certification

Issue: When, if ever, should a regional certification commission "set the certification clock back to zero" following importation of a wild poliovirus into a polio-free country?

Background

The recent importation of wild poliovirus into China from India raised the question of whether certification of the Western Pacific Region would be delayed. However, an imported wild poliovirus also circulated in Canada in the years between the last indigenous case in Peru and certification by the AMRCC. Although there were no cases of paralysis due to the importation into Canada, the question of how to certify a Region in the face of a recent importation is unclear.

To provide guidance to regional commissions, the GCC was asked to issue a decision on the impact of an importation on certification, taking into account the TCG recommendation on classifying an importation of wild poliovirus as contained or having established poliovirus circulation (see *Global eradication of poliomyelitis. Report of the fifth meeting of the Global Technical Consultative Group for Poliomyelitis Eradication, Geneva, 8-10 May 2000* (WHO/V&B/00.27)), the experiences from smallpox and PAHO, as well as the data from China.

Discussion

Dr Harry Hull reviewed the extensive TCG discussion on the recent importation of wild poliovirus from India into China in late 1999, and the guidelines for the classification of importations presented to the TCG. It was noted first that the situation in China was unique, in that it occurred almost exactly one year prior to the projected date for certification of the Western Pacific Region. Furthermore, there were many importations into polio-free countries during the 1990s resulting in indigenous virus transmission and additional cases within the country. Wild poliovirus importations into the Albania, Bulgaria, China, Iran, Jordan, Malaysia, Netherlands, Russia and Saudi Arabia were documented.

In all these instances, the issue of "resetting the certification clock" did not arise, because wild poliovirus transmission continued in other countries of the Region at the time of the importation. As global eradication approaches, the specific issue of resetting the clock may become irrelevant since both the probability and the absolute number of importations will continue to decrease. However, clear guidance is necessary, and could also be useful in stimulating countries to make information available to WHO rapidly.

The algorithm presented to the TCG and considered by the GCC requires a country to first classify a case of wild poliovirus infection as being due to either imported or indigenous virus based on epidemiological and virological evidence. Investigation of the case would determine the extent of the transmission. If transmission were limited, then the duration of transmission would be considered prior to deciding if the certification clock should be set back. If transmission persisted for one year or through one low transmission season, the virus would then be considered indigenous, requiring that a minimum three years to elapse before eradication could be certified.

The GCC agreed that strong epidemiological and virological evidence would be required before a virus could be regarded as imported. The GCC also felt that evidence of an adequate investigation, high-quality surveillance for polioviruses and an appropriate immunization response would be necessary before transmission could be defined as limited. If such evidence were absent, then the virus would be classified as indigenous. The Commission also felt that absolute criteria, such as the number of cases, number of generations of transmission or extent of geographic spread, could not be specified and that professional judgment would play an important role in evaluating the incident.

GCC decision:

5. The Global Commission decided that, with the caveats stated above, indigenous transmission of an imported wild poliovirus with limited transmission (i.e. confined to a specific geographic area or defined population subgroup) would suspend the process of regional certification for up to one year while the importation is classified as contained or having established circulation. Contained transmission of an imported wild poliovirus has no impact on regional certification. Evidence of prolonged circulation (i.e. longer than one year) will postpone regional certification until three years have elapsed after the last case.

5. Wild poliovirus laboratory containment and global certification

Issue: Should global containment of wild poliovirus laboratory stocks be a precondition of global certification, and how long a period of containment would be needed?

Background

Despite the decision of the third meeting of the GCC in July 1998, the relationship between the certification and containment processes are not clear at the country, regional, and global levels. The 1998 GCC decision (Section 5)[1] clearly states that adequate containment will be a precondition of Global Certification, and that all countries must have completed the first phase of activities described in the Global Action Plan on containment:[2]

"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 II.)

Global Certification will require that Phase II containment activities for wild polioviruses have been implemented world-wide (i.e. destruction or transfer to a high level containment facility in the final version of the Global Plan of Action for the Safe Handling and Maximum Containment of Wild Polioviruses.)"

(Report of the third meeting of the GCC, July, 1998)

Discussion

Confusion has arisen at the regional level because the possibility of regional certification without containment has already been established by precedent (AMRCC), and because containment activities have been initiated too late to allow countries to comply with the requirements before regional certification (WPRCC). However, the WPRCC and

[1] *Global eradication of poliomyelitis. Report of the third meeting of the Global Commission for the certification of the eradication of polio, GenevaI, 9 July 1998* (WHO/EPI/GEN/98.17).

[2] *WHO global action plan for laboratory containment of wild poliovirus* (WHO/V&B/99.32).

EURCC have expressed their intent to call for documented evidence of progress towards global containment requirements before their respective regions will be certified polio-free. Progress is now being made in implementing containment activities in the Region of the Americas. Broad consensus among clinicians, researchers, vaccine producers, and public heath professionals exists regarding the feasibility of the goals of containment and the appropriateness of containment strategies.

GCC decisions:

6. The Global Commission re-emphasizes its endorsement of the *WHO global action plan for laboratory containment of wild polioviruses*, January 2000 and its recommendations of the Third GCC Meeting, 1998 as follows:

a) Regional certification as polio-free requires each country to submit satisfactory documentation to the Regional Commission for the Certification of Polio Eradication (RCC) that:

- a national survey of all laboratories that may possess wild poliovirus infectious or potentially infectious materials has been conducted and a national inventory has been developed;
- all laboratories have been requested to dispose of such materials that are no longer needed;
- laboratories electing to retain such materials have been instructed to institute enhanced biosafety level 2 (BSL-2/polio) procedures and have been listed on the national inventory;
- nations have established implementation plans for the post-global eradication phase.

b) Global certification of eradication requires that each RCC submit satisfactory documentation to the GCC that all laboratories in its Region possessing wild poliovirus infectious or potentially infectious materials have either:

- implemented high containment (BSL-3/polio) procedures; or
- transferred such materials to WHO-designated repositories or rendered such materials non-infectious or destroyed them under appropriate conditions.

6. Enterovirus surveillance data and certification

Issue: Are the proposed guidelines for the use of enterovirus surveillance sufficient as evidence for certification of polio-free status in selected industrialized countries?

Background

A number of countries in the Region of the Americas, Europe and Western Pacific regions that have been polio-free for >10 years and have advanced sanitation, immunization, health care, and surveillance systems will not submit routine AFP surveillance data as a basis for certification (e.g. United States of America, France, Japan). Several countries are planning to submit data derived from a combination of strong ongoing surveillance for suspect polio and enterovirus surveillance efforts through public health laboratory networks as primary evidence for the absence of circulating wild poliovirus. Preliminary review of these data by the WHO European Regional Certification Commission indicates a significant variability in the quantity and quality of such "enterovirus data." A draft recommendation for parameters for enterovirus surveillance will be presented to the European Regional Commission's working meeting in early 2001. Given the implications for other regions, this issue will also need to be formally reviewed by the GCC.

Discussion

Dr Mark Pallansch presented an analysis of the sensitivity of enterovirus surveillance to detect wild poliovirus transmission and demonstrate the absence of wild poliovirus in a population. He noted that the analysis is still in progress and anticipates that it will be finalized by the October 2000 meeting of the EURCC.

Dr Pallansch began his presentation by noting that no surveillance system is 100% sensitive and that the goal is to assess the efficacy of enterovirus surveillance in comparison to AFP surveillance, the gold standard for certification. Any surveillance system comprises a number of components and the sensitivity of each component of the surveillance system contributes to the overall sensitivity of the system. For AFP surveillance, benchmarks have been established to permit the evaluation of each component of the surveillance system. The most important of these are the standard surveillance indicators – non-polio AFP rate, percentage of AFP cases with adequate stool specimens, and laboratory accreditation.

No such benchmarks are available at present for non-polio enterovirus surveillance. However, Dr Pallansch's analysis of the sensitivity of the components of enterovirus surveillance indicated that potential standards could be set that would permit non-polio enterovirus surveillance to be almost equivalent to AFP surveillance in overall sensitivity to detect wild poliovirus.

Criteria that would increase the probability of an existing poliovirus being found through enterovirus surveillance include:

- the diagnosis/condition triggering the collection of specimens (neurological conditions being more valuable than non-neurological diagnoses);
- specimen collection from children;
- use of stool specimens as opposed to cerebro-spinal fluid (CSF) or throat swabs; and
- wide geographic distribution of origin of specimens analysed.

Also of value would be the demonstration of the isolation of non-polio enteroviruses, specific virus typing and intratypic differentiation of all polioviruses found, and the isolation rate from specific categories of specimens (meningitis cases in children, for example). Although it was unlikely that a specific number of specimens per population unit could be specified through this analysis, the degree of enrichment of the specimens collected would be valuable in assessing the validity of enterovirus surveillance data. Dr Pallansch specifically noted that the length of the surveillance period enhances the sensitivity of the system. Thus, under certain conditions, continuing non-polio enterovirus surveillance for several years without finding wild poliovirus may be equivalent to several years of AFP data. A similar analysis was also presented for environmental sampling.

Dr Oblapenko presented an analysis of the plans of European countries for presenting data to the EURCC. Seven countries (Denmark, France, Iceland, the Netherlands, Norway, Sweden and the United Kingdom) would present mainly enterovirus surveillance data to the Commission. One country, Finland, would present mainly environmental data. Central and southern European countries, including Germany, Italy, Spain and the Baltics would present AFP data plus enterovirus surveillance data. All recently endemic countries and the countries of the Balkans would present AFP surveillance data.

GCC decision:

7. In considering the analysis presented and the inability of a number of non-endemic countries to establish a new AFP surveillance system, the GCC decided that non-polio enterovirus surveillance data could be accepted as an important component of the data presented to regional commissions by countries that have been non-endemic for an extended period. However, enterovirus surveillance is only one component of a comprehensive analysis of the status of polio in a country (including routine infectious disease surveillance for suspect polio cases).

Evaluation of enterovirus surveillance data will need to take account such factors as:

- age of individuals sample;
- diagnoses/conditions for which samples were take;
- type of the specimen (i.e. throat swab, stool sample);
- geographic distribution of specimen;
- referral of all non-typable enteroviruses to a WHO- accredited laboratory to exclude the presence of polioviruses in the sample; and,
- referral of all polioviruses for intratypic differentiation to a WHO-accredited laboratory.

Information should also be presented on the quality of the laboratories contributing enterovirus surveillance data and the organization of national enterovirus surveillance.

7. Other agenda items

The Global Commission also considered the following items that were not on the prepared agenda.

a) At the request of the Chairman of the WPRCC, the GCC *decided that regional commissions would be initially certifying that all of the countries of the region have interrupted transmission of indigenous wild polioviruses.*

b) In a discussion of the problem of certifying politically isolated countries, GCC noted that it was an independent body and may need to seek to establish direct links with these countries when the WHO Secretariat is unable to do so.

c) The GCC noted the value of attending the full meetings of the TCG and expressed their desire to be present during the entirety of future TCG meetings.

d) The GCC also noted the need to have full, separate, annual meetings in the future.

e) The next meeting of the GCC is tentatively set for February 2001 in the Region of the Americas. The following agenda items and questions are to be considered:

- update on the status of the Region of the Americas, including clarification of the manner in which the Region of the Americas will continue to provide update information to the GCC;
- report on Certification in the Western Pacific Region;
- what process should be employed for final certification in the Region of the Americas?
- what documentation will the GCC require from Regional Certification Committees after they are certified?
- what should be the format and frequency of reports presented to the GCC?
- how can the Global Commission help to promote surveillance and immunization in the years after regional certification?
- how can the GCC contribute in countries where progress has been particularly difficult?

f) The GCC expressed a desire for improved communication with the WHO Secretariat. They noted that despite a prior request, members were still not receiving all reports published by WHO, including the Weekly Epidemiological Record/ Morbidity and Mortality Weekly Record reports, Polio News, press releases, scientific articles and the annual summary. They felt strongly that providing such information would not be difficult and was vital to the work of the GCC.

g) Due to the continuing illness of the Chairman of the Global Commission, Sir Joseph Smith would speak for the GCC.

h) The GCC expressed its desire that background papers should be prepared for all discussion items at future meetings. These papers and other appropriate documents should be circulated well in advance of all future meetings to permit the members to be fully prepared for the meeting.

i) At all future meetings, copies of all prior reports of the GCC should be available for review during deliberations.

j) Future GCC meetings should include a report on the actions taken in response to its prior decisions.

The Chairman, Dr Jan Kostrzewski, was unable to attend the fifth meeting of the GCC due to illness; GCC members sent their best wishes to Dr Kostrzewski, wishing him a speedy recovery.

The Commission recorded its warm thanks to Dr Harry Hull, as this was the last of its meetings he would attend before returning to work in the United States. Dr Hull had made an enormous contribution to global polio eradication and its certification, and had been of invaluable help to the GCC in its work. The GCC offered Dr Hull its very best wishes for continuing success in his new post.

Annex 1:
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