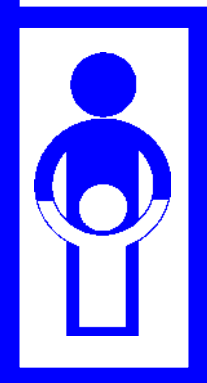


Global eradication of poliomyelitis

Report of the second meeting of the
Global Technical Consultative Group
(TCG), 28 April 1997



**GLOBAL PROGRAMME FOR VACCINES AND IMMUNIZATION
EXPANDED PROGRAMME ON IMMUNIZATION**



World Health Organization
Geneva
1998

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World Health Organization
Global Programme for Vaccines and Immunization
CH-1211 Geneva 27, Switzerland
• Fax: +22 791 4193/4192 • E-mail: gpv@who.ch •

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List of abbreviations

AFP	acute flaccid paralysis
AFRO	Regional Office for Africa
AMRO	Regional Office for the Americas
EMRO	Regional Office for the Eastern Mediterranean
EURO	Regional Office for Europe
GPV	Global Programme for Vaccines and Immunization
IPV	inactivated polio vaccine
LabNet	Global Polio Laboratory Network
NIDS	national immunization days
OPV	oral polio vaccine
SEARO	Regional Office for South-East Asia
TCG	Technical Consultative Group
VAPP	vaccine-associated paralytic polio
WHO	World Health Organization
WPRO	Regional Office for the Western Pacific

1. Introduction

On 28 April 1997, the second meeting of the Technical Consultative Group (TCG) on Global Eradication of Poliomyelitis was convened by the World Health Organization (WHO). The TCG met to review the currently recommended strategies for the global goal of eradication of poliomyelitis by the year 2000.

The meeting was opened by Dr R.H. Henderson, Assistant Director-General, World Health Organization. In welcoming the participants, Dr. Henderson emphasized the importance of the consultation as it facilitated an in-depth discussion of technical aspects of the polio eradication initiative. Dr J.W. Lee, Director of the Global Programme for Vaccines and Immunization (GPV), described the task of the TCG, adding that the agenda before them was a reflection of the progress that had been made since the last meeting of the TCG in 1996. Dr Lee referred to the need to improve surveillance for acute flaccid paralysis (AFP) and the options that might be available for achieving this. The TCG was asked to deliberate on the challenge of furthering certification procedures in both non-endemic and endemic countries. Dr Lee also asked that the TCG provide recommendations on the development of the strategy for the eventual discontinuation of poliomyelitis vaccination once eradication had been achieved.

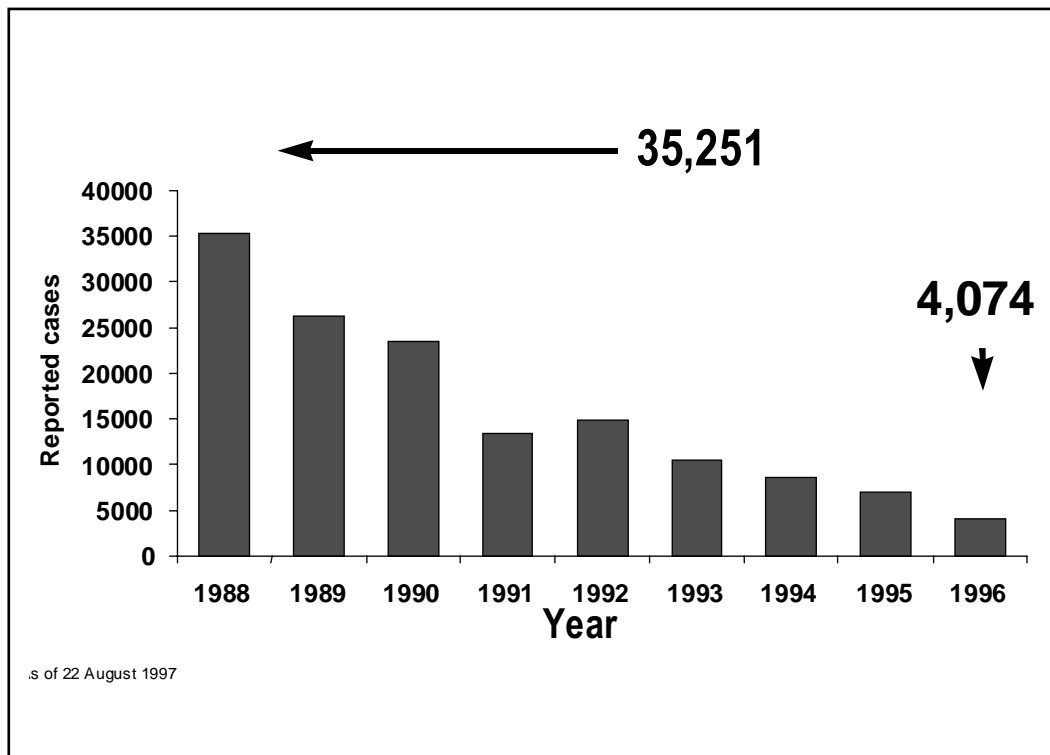
Dr W. Orenstein of the Centers for Disease Control and Prevention of the United States of America served as chairman of the meeting with Dr P. Figueroa of the Ministry of Health, Jamaica, as rapporteur. This report presents an update on the progress and priority activities for the eradication initiative and summarizes the technical deliberations of the second Global Technical Consultative Group (TCG) meeting. The recommendations of the TCG follow each section.

2. The global initiative to eradicate poliomyelitis by the year 2000

2.1 Progress, priorities and resources

The four principal strategies for eradicating polio have been adopted by virtually all countries. These strategies are: achieving and maintaining high routine immunization coverage to reduce disease to low levels; conducting national immunization days (NIDs) in all polio endemic countries to interrupt circulation of wild polioviruses; implementing a system of surveillance for acute flaccid paralysis (AFP) with laboratory investigation to identify the final reservoirs of wild virus; and conducting mopping-up immunization to eliminate the final chains of transmission. Since the last meeting of the TCG in 1996, there were significant achievements in the implementation of these strategies resulting in a further decline in the number of polio cases reported worldwide (Figure 1).

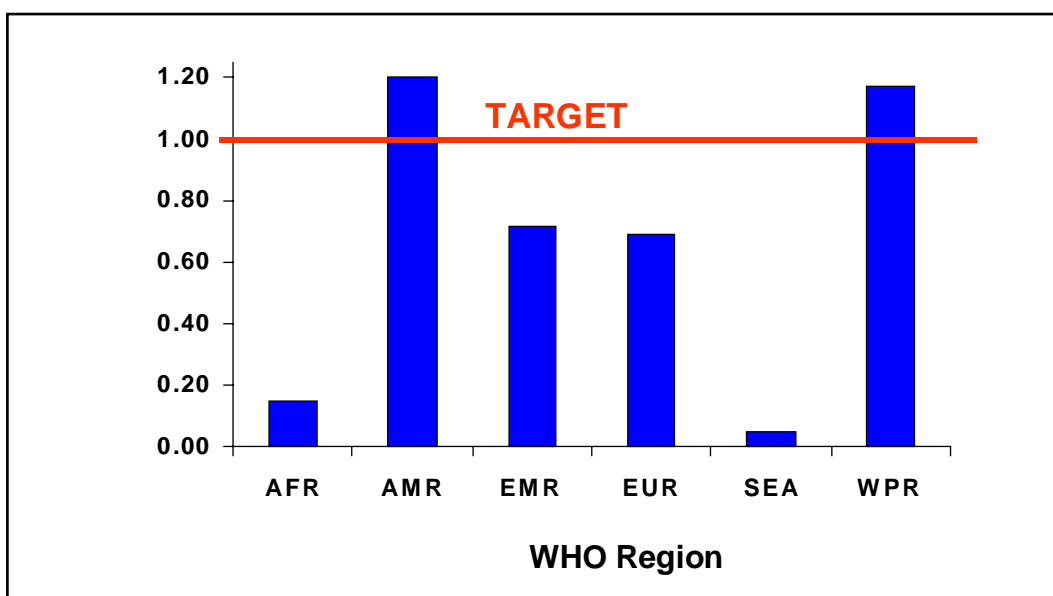
Figure 1: Global annual reported polio cases, 1988-1996



Global routine immunization coverage with three doses of OPV currently stands at 83%. However, the high coverage reported by China, India, Indonesia and several other populous countries obscures the low immunization coverage of many countries. Sixteen countries, 14 of which are in Africa, did not reach even 50% of their children with routine immunization services. The overall immunization trend in Africa has been positive, however, with regional coverage now reaching 58%. In 1996, 82 countries conducted NIDs, 26 for the first time. The cumulative number of countries having ever conducted at least one round of NIDs has reached 92. As of 1996, all endemic countries of Asia had conducted NIDs. Globally, over 400 million children were immunized during NIDs in the past year. Mopping-up immunization campaigns are being planned or implemented in all areas of the Western Pacific Region where remaining chains of wild poliovirus circulation have been identified.

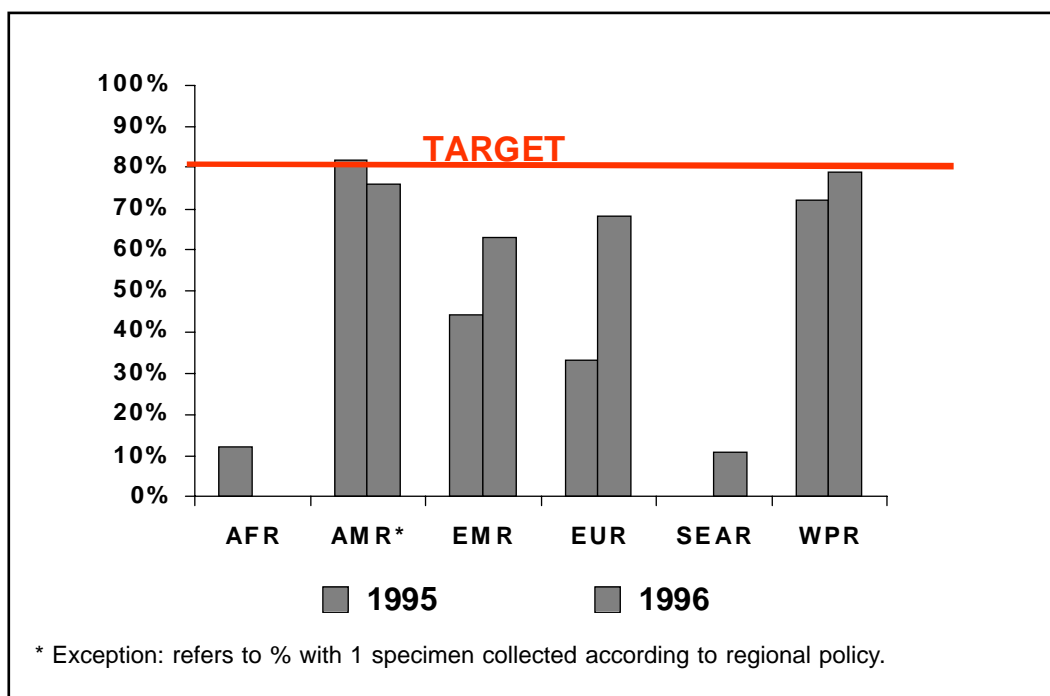
The number of countries conducting AFP surveillance increased from 120 in 1995 to 137 in 1996 (including 11 non-endemic countries in the WHO European Region). AFP surveillance is now conducted in 126 (86%) of the 146 recently or currently endemic countries. From January to December 1996 the global completeness of monthly surveillance reporting was 72% for expected polio reports, but only 52% for AFP. The non-polio AFP rate per 100 000 population aged less than 15 years rose from 0.44 in 1995 to 0.58 in 1996. The AFP rate, however, varied substantially by WHO region (Figure 2).

Figure 2: Non-polio AFP rate per 100 000 children aged less than 15 years, by WHO region, 1996.



The completeness of virologic investigation of AFP cases for 1995 and 1996, by WHO region, is presented in Figure 3. Overall, the percentage of AFP cases with two adequate stool specimens collected increased from 62% in 1995 to 74% in 1996. Information on the adequacy of these specimens, however, was incomplete.

Figure 3: Percent of AFP case with two specimens collected, by WHO region, 1995 and 1996.



Currently, all WHO regions provide routine surveillance feedback to countries as follows: three times annually (EURO), quarterly (AFRO, SEARO), monthly (EMRO) or weekly (AMRO, WPRO). The number of national laboratories in the Global Polio Laboratory Network (LabNet) increased from 65 in 1995 to 67 in 1996, with 16 regional and six specialized reference laboratories. In 1996, WHO began the process of formally accrediting all national laboratories in the WHO LabNet.

The Technical Consultative Group (TCG) was impressed with the global progress toward polio eradication. The initiative is on target with a 90% reduction in reported cases between 1988, the year the initiative began, and 1996. Nevertheless, the TCG was concerned that the implementation of AFP surveillance lagged far behind that of the supplementary immunization strategies. The TCG also worried that many countries were substantially underestimating the resource requirements in their plans for improving AFP surveillance. The TCG noted that the greatest remaining barrier to polio eradication was the implementation of the necessary strategies in strife-torn, war-ravaged countries. Because failure of polio eradication in any one country would mean global failure, increasing resources and efforts must be targeted towards these countries.

RECOMMENDATIONS:

- **Substantial additional efforts and resources, both human and financial, must be urgently directed toward improving surveillance for AFP and strengthening the laboratory network.**
- **Endemic countries which have yet to consistently achieve greater than 80% coverage during NIDs, or in which there is persistent transmission of wild poliovirus after multiple NIDs, should receive the human and financial resources needed to ensure that high quality NIDs are conducted.**
- **The WHO and partner agencies must recognize that a proportionately larger share of the costs of polio eradication in such countries and should substantially increase their efforts to ensure that country plans are fully funded.**
- **Mopping-up is an essential component of the polio eradication strategy but is not a substitute for high quality NIDs or high routine immunization coverage. Mopping-up should be conducted when high quality AFP surveillance demonstrates that transmission is restricted to focal areas.**
- **WHO/HQ should develop guidelines as soon as possible to assist countries in accurately determining their surveillance and laboratory requirements and obtaining the resources needed to enhance surveillance. The guidelines should include numbers and types of staff needed at the national, state and district levels, transport, equipment and logistics requirements and other needs. In developing the guidelines, WHO/HQ should consult with all regions particularly those that have successfully implemented high quality AFP surveillance. The guidelines should be presented at the next TCG.**

3. Acute flaccid paralysis surveillance for global polio eradication

3.1 Global data needs for surveillance

Accurate and timely surveillance data is required at the global level to coordinate many aspects of the eradication initiative. First, timely surveillance information is needed to facilitate a rapid response to areas of interregional wild poliovirus circulation. Secondly, accurate identification of high-risk areas is required to undertake long term planning in the targeting of additional human and financial resources. Thirdly, WHO/HQ must have the capacity to rapidly update WHO Member States, regional offices, key partner agencies, donor organizations and other interested parties on the status of the eradication initiative worldwide. Providing complete information in a timely manner is critical to the credibility of the initiative and the ongoing advocacy for political, financial and technical support.

Four of the five surveillance performance indicators that are the basis for certification are currently monitored at the global level:

- a) Completeness of 'zero' reporting (target: timely receipt of $\geq 80\%$ of expected surveillance reports, including zero reporting when no AFP cases are seen).
- b) Sensitivity of AFP surveillance (target: \geq one case of non-polio AFP detected annually per 100 000 population aged less than 15 years).
- c) Completeness of virologic investigation (target: $\geq 80\%$ of AFP cases have adequate stool specimens collected for enterovirus studies).
- d) Laboratory accreditation (target: all specimens from AFP cases are processed in an accredited laboratory of the Global Polio Laboratory Network).

The current status of AFP surveillance performance indicators, as reported to WHO/HQ, was presented to the TCG (Figures 2 and 3) following which the constraints to the timely collection of this information was discussed. The TCG was informed that there were still substantial delays in the collection, collation and forwarding of surveillance data at the peripheral, national and regional levels. In addition, the information which was forwarded to the next level was often incomplete.

It was suggested that the standardization and streamlining of AFP surveillance information could substantially facilitate the goal of a global surveillance system that was timely and accurate. The TCG reviewed a proposal for a set of critical core data on AFP surveillance that would be forwarded to WHO/HQ on a routine basis (Table 2). In summary, wild poliovirus circulation would be reported immediately to

all levels; AFP cases and clinically/virologically confirmed polio cases would be reported weekly. In addition, sub-national (e.g. province/state level) data would be reported on a quarterly basis to ensure that important local trends in surveillance results and performance could be identified.

Table 1. Proposal for the submission of AFP surveillance data to WHO/HQ.

Frequency of reporting	Data required
Immediate	- Wild polioviruses, by district of paralysis onset, from all polio-free countries.
Weekly	- Number of AFP cases and number of AFP with two adequate stool specimens; total number of confirmed polio cases and number of polio cases confirmed virologically.
Quarterly	- By province/state: number of AFP cases and number of AFP cases with two adequate stool specimens; total number of confirmed polio cases and number of polio cases confirmed virologically.

The TCG was also informed that at present there was no single database of the wild polioviruses that had been isolated worldwide. The TCG noted that absence of such a global database compromised efforts to share information between laboratories and efficiently track chains of wild poliovirus transmission.

RECOMMENDATIONS:

- **By the end of 1997 all countries should be providing a weekly AFP report to regional offices.**
- **Details of any wild poliovirus isolated from any area should be immediately reported to regional offices. Also, details of any wild poliovirus isolated from a previously polio-free area should be immediately reported to WHO/HQ.**
- **On a weekly basis, each regional office should report to WHO/HQ aggregate data on the number of AFP cases, confirmed polio cases, wild poliovirus isolates, and AFP cases with two adequate stool specimens (see Table 2.)**
- **On a quarterly basis, each regional office should report the same data to WHO/HQ, by sub-national administrative level (e.g. province, state).**
- **WHO/HQ should maintain a wild poliovirus database with information on sequenced wild polioviruses. The elements of this database should be established in consultation with the Global Polio Laboratory Network.**
- **The specialized laboratories should make the sequencing information widely available to the Polio Laboratory Network.**

-
- **RECOMMENDATION: Regional reference laboratories should be providing updated information to WHO regional offices on at least a monthly basis.**

3.2 Collection of stool specimens from AFP cases

At the 1996 TCG, AMRO presented an analysis on the utility of collecting a second stool specimen from all AFP cases. The data demonstrated that the collection of the second specimen did not increase the sensitivity of the AFP system to identify wild poliovirus infected geographic areas in the Americas. However, a mathematical model presented at that meeting suggested that this finding might not be immediately generalizable to other WHO regions due to differences in both the prevalence of wild poliovirus and the strength of the laboratory network. Following these presentations, the TCG had recommended that each WHO region should conduct a standard analysis of the additional sensitivity gained and the programme costs of routine collection of the second stool specimen from each AFP case.

An analysis was presented of sensitivity gained by collecting a second stool specimen using data from the Western Pacific and the African Region. The analysis from the Western Pacific focused on the last endemic foci from 1993 to 1996 and only on cases from whom adequate stool specimens had been collected. The results showed that the second stool specimen increased the probability of detecting wild poliovirus infected individuals and areas by at least 20%. The data from the African Region was comprised of an analysis of paired stool specimens from 281 cases of AFP during the period 1991 to 1997. The results showed that 70 cases with wild poliovirus were positive in both the first and the second specimens. Two cases had positive isolation on the second specimen only. Further analysis of nine cases that were part of an outbreak in Bangui, Central African Republic, in 1994 showed that of nine cases analysed, six had wild poliovirus type 1 isolated. Two of these cases would have been missed had the second specimen not been collected. Both of these cases occurred at the tail end of the epidemic. The TCG advised that regions continue to analyse and present this data to the TCG on an on-going basis.

RECOMMENDATIONS

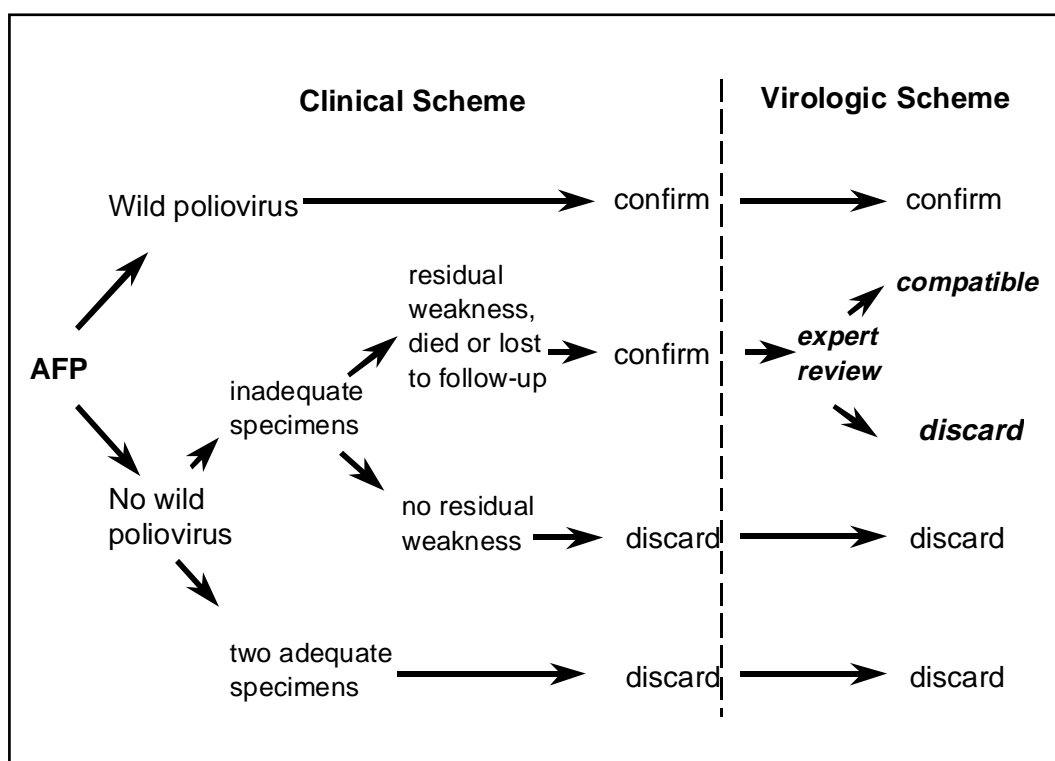
- **The gold standard for evaluating AFP cases is the collection and processing of two adequate stool specimens at a WHO-accredited laboratory.**
- **In regions where the elimination of indigenous wild poliovirus has been certified and data demonstrate that there is no added value of a second specimen, only one specimen is necessary. At the present time, this applies only to the Region of the Americas.**
- **In analysing this data, each region should evaluate the number of infected districts that would be missed had a second specimen not been collected and processed.**

3.3 Classification of AFP cases

In 1996, the TCG reviewed and revised the WHO-recommended scheme for classifying AFP cases as confirmed poliomyelitis. The WHO-recommended case classification included a clinical classification scheme to be used in countries which had only recently introduced AFP surveillance and a virological classification scheme for countries with high quality AFP surveillance. The TCG also set performance criteria for shifting from the clinical to the virological classification system.

During the 1997 meeting, the TCG was presented with data and experience from the African Region on the use of the new case classification system. The TCG was informed that confusion was arising because of inconsistencies between the clinical and virological classification schemes. Under the clinical classification system, for example, some AFP cases would be classified as 'confirmed poliomyelitis' even if adequate stool specimens tested negative for wild poliovirus in an accredited laboratory of the Global Polio Laboratory Network. In contrast, under the virological system such cases would be discarded as non-polio AFP, regardless as to the clinical outcome. Furthermore, the apparent differences in the two classification schemes was complicating the necessary training when it was appropriate to switch from a clinical to a virologic scheme. Therefore, a proposed modification of the WHO clinical classification system, to discard cases that tested negative for wild poliovirus in a WHO accredited laboratory, was reviewed by the TCG (Figure 4).

Figure 4: Modified classification system for AFP cases*



* NOTE: countries should shift to the virologic classification scheme only after: (a) the national non-polio AFP rate is equal to or greater than 1/100 000 population aged less than 15 years; (b) two adequate stool specimens are being collected from at least 60% of AFP cases; and (c) all specimens are being processed in a WHO-accredited laboratory.

RECOMMENDATIONS:

- The WHO case classification system should be modified to allow the discarding of AFP cases which have had two adequate stool specimens test negative for wild poliovirus in a WHO accredited laboratory.
- Until the national AFP surveillance system meets the performance criteria established by the 1996 TCG, countries should continue to confirm all AFP cases which have residual weakness at 60 day follow-up, died, or are lost to follow-up, unless two adequate stool specimens test negative for wild poliovirus in a WHO-accredited laboratory.
- When the national AFP surveillance system meets the performance criteria established by the 1996 TCG, an expert committee should determine whether such cases (i.e. those with the combination of inadequate stool specimens and residual weakness at 60 day follow-up, death, or loss to follow-up) should be discarded as non-polio AFP or classified as 'polio-compatible'.

3.4 Diagnosis and classification of vaccine associated paralytic poliomyelitis (VAPP) in endemic countries

Paralytic poliomyelitis is a clinical syndrome usually caused by wild poliovirus but which may also be the result of other, non-polio, enteroviruses, or rarely vaccine-related polioviruses. In the absence of a definitive test, vaccine associated paralytic poliomyelitis (VAPP) is a diagnosis of exclusion, that includes the absence of any epidemiologic link to a wild poliovirus confirmed case or outbreak. A review of the global literature on VAPP showed that the risk of the condition in developing countries, including countries conducting mass oral polio vaccine (OPV) immunization campaigns for polio eradication (NIDs), was comparable to that observed in industrialized countries. After controlling for study differences in methodology of reporting and case classification, the risk of VAPP was found to be both extremely low and virtually the same everywhere.

In polio endemic countries, diagnosing VAPP without properly ruling out wild poliovirus infection as the cause of the paralysis could substantially compromise the sensitivity of AFP surveillance and could limit the capacity to identify reservoirs of wild poliovirus transmission. The TCG was informed that in some instances AFP cases were classified as VAPP simply on the basis of vaccine virus isolation in the stool. The TCG noted the experience with such cases and expressed concern that cases of wild poliovirus infection were being mis-classified as VAPP because of the lack of stringent diagnostic criteria. Such mis-diagnoses could lead to delays in detection of wild poliovirus in endemic countries.

A proposal for a standard VAPP case definition was presented to the TCG. The TCG reviewed the proposal for a standard VAPP definition, but recognizing the legal, operational and epidemiologic implications, preferred that WHO established and promoted guidelines for VAPP diagnosis, rather than a case definition. The TCG stated, however, that a standard WHO case definition should be available for countries which chose to use it.

RECOMMENDATIONS:

- A working group should be established to develop a case definition for VAPP that would ensure that disease due to wild poliovirus would not be missed.
- Guiding principles for the diagnosis of VAPP must include: paralytic poliomyelitis with residual paralysis at 60 days after onset; adequate stool specimens test negative for wild poliovirus in a WHO-accredited laboratory but positive for vaccine virus; the case is evaluated by an expert committee which considers additional data such as exposure history and potential epidemiological links to confirmed poliomyelitis cases.
- Since the objective of the polio initiative is to eradicate wild poliovirus, under the WHO AFP classification system (Figure 4), VAPP cases should not be counted as 'confirmed due to wild poliovirus'.

3.5 The role of community surveillance

An effective surveillance system for polio eradication depends on the rapid detection and investigation of AFP cases. At present, health facility based surveillance is the primary source for detection of AFP cases. However, the utility of community-based detection methods has been discussed for areas where there is poor access and low utilization of health services. The TCG was presented with community-based surveillance experiences in Bangladesh, in Africa and in the Guinea Worm Eradication Programme.

AFP surveillance in Bangladesh includes three components: active weekly surveillance in all major hospitals, immediate reporting of any suspected AFP cases from all health facilities and immediate reporting of all cases from the community. Community-based activities included identification and sensitization of: (1) key informants from the community who report target conditions (AFP, neonatal tetanus and measles) directly to the health department or through field workers, and (2) primary or secondary school students who report suspected cases through their teachers. Regular communication was to be established between the key informants and their supervisors.

Once an endemic village is identified in the Guinea Worm Eradication Programme, one or more residents of the village are designated to provide monthly reports of cases. These village based reporters are trained and supervised to conduct household visits within the village each month, record the cases and report them to outreach health workers or directly to the primary health care post. UNICEF presented a proposal to implement and evaluate the role and feasibility of community surveillance in a number of African countries. The proposal included evaluation of: (a) community active participation, social mobilization and use of village level workers, (b) integration of community-based surveillance with other programmes, and (c) targeting of activities in hard-to-reach areas and populations.

The TCG noted that 'community-based surveillance' included a wide and disparate group of activities ranging from social mobilization to increase awareness to the use of village-level health workers for case detection. The TCG noted the suggestion that such systems were at risk of being both unsustainable and inefficient for a rare disease or condition such as AFP. In closing the discussion the TCG stated the necessity of establishing a health facility based reporting and investigation system in a country prior to expanding to community-based surveillance activities.

RECOMMENDATIONS:

- **The highest priority for AFP surveillance should be the immediate reporting of AFP cases from all health facilities and ensuring a mechanism for the prompt investigation and response to each case report. In addition to immediate case reporting, all health facilities should file weekly zero reports.**
- **In many countries or areas within countries, such surveillance should be supplemented with other strategies to improve the timely detection of AFP cases.**
- **Advantage should be taken of NIDs, mass media and other communication channels to sensitize the community to report all AFP cases.**
- **In areas with poor access to health facilities or low utilization rates, the use of innovative activities (e.g. 'key informant' reporting or 'market searches') should be explored as a means of improving the detection of AFP cases. Such community-based activities should be integrated with surveillance of other diseases of public health importance (e.g. neonatal tetanus).**

3.6 Active search for AFP cases during 'mopping-up' activities

An essential component of the polio eradication strategy is house-to-house mopping-up immunization campaigns covering large geographic areas surrounding high-risk or known wild poliovirus infected areas. In addition to delivering supplementary OPV doses, an active search for AFP cases is currently recommended during 'mopping-up' activities in all areas with poor surveillance.

The TCG reviewed the experience with active AFP searches during mopping-up activities in Latin America during the period from 1989 to 1992. These campaigns were conducted in the then endemic countries of Bolivia, Columbia, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Peru and Venezuela. During the campaigns, 5894 counties were covered and the number of households visited during the two rounds was 12.84 million. A total of 22.65 million children were immunized, representing 80% coverage of the target population in these areas. An active search for AFP cases was conducted in all areas with a history of polio cases, silent areas, areas with no AFP cases and areas with reported AFP rates of <1/100 000 population aged less than 15 years. During the active searches, interviews were conducted at the household level for (a) knowledge of the polio eradication programme, (b) vaccination status of children aged less than 5 years, (c) knowledge of children with signs of limping or paralysis. Interviews were also conducted with community leaders and local authorities. The results were presented for El Salvador and Peru.

The TCG noted that in retrospect the comprehensive searches did not find many unreported AFP cases or additional areas with wild poliovirus circulation. However, the active searches provided an opportunity to validate the performance of the national surveillance systems and demonstrated that the existing surveillance methods were appropriate. The experience with active searches had demonstrated that it was more efficient to pass the information on to appropriate health authorities for later follow-up and investigation than try to investigate the cases at the time of the 'mopping-up' itself.

In the discussion that followed it was noted that the AFP cases reported during 'mopping-up' activities were often found to be non-AFP cases when they were eventually traced during the follow-up activities. The TCG also noted that there was limited capacity to resolve whether cases with onset more than two months before the active search were indeed polio.

RECOMMENDATIONS:

- **During house-to-house visits for 'mopping-up', an active search for AFP cases should be considered in all areas with poor surveillance. Consideration may also be given to expanding the active case searches to other areas to validate the performance of the surveillance system.**
- **The highest priority when conducting AFP searches is to identify cases with onset of paralysis within the two months prior to the search.**
- **Searching for AFP cases with onset of paralysis more than two months prior to the search may be useful in validating the quality of the surveillance system.**

4. Detection of wild poliovirus and the polio laboratory network

The Global Polio Laboratory Network is an essential component of the eradication initiative. The purpose of the Network is three fold; to detect the circulation of wild poliovirus in communities; to guide OPV immunization activities for interrupting transmission of wild poliovirus; and to facilitate the eventual certification of wild poliovirus eradication. For wild poliovirus surveillance to be effective there must be a high rate of AFP case detection, efficient stool specimen collection and transport, competent enterovirus laboratories, and excellent data flow and communication.

4.1 Proficiency of the Global Polio Laboratory Network

An update of the activities of the Global Polio Laboratory Network and the recommendations from the 1996 Network meeting were presented to the TCG. During the period 1994-1996 100 proficiency tests were completed by the 67 national laboratories in the Network. The proficiency panels were prepared by the National Institute of Public Health and Environmental Protection (RIVM) in Bilthoven, Netherlands, and consisted of five stool samples containing 0,1,2 or 3 poliovirus serotypes and/or non-polio enteroviruses. For national laboratories, the passing score on a proficiency test is 80%. Correct results were obtained for 332 (66%) of the 500 total samples. Of the samples containing one poliovirus type, 90% were correctly identified; of the samples containing two poliovirus types, 71% were identified correctly; of the samples containing three poliovirus types, 33% were correctly identified.

Of the 168 samples (34%) with incorrect results, 26% were caused by errors in virus isolation or typing, and 8% by virus contamination of negative samples or cross contamination of virus-containing samples. Samples containing poliovirus, without regard to how many or what type, were identified with a sensitivity and specificity of 92% and 91%, respectively. All regional reference laboratories scored 100% on the most recent panels designed to test proficiency in distinguishing wild from vaccine-derived polioviruses.

Despite the generally good proficiency results, the TCG noted its concern over the substantial delays in many Network laboratories in completing the processing of specimens and reporting of results on both proficiency panels and AFP case specimens.

RECOMMENDATIONS:

- The timely submission and processing of adequate stool specimens and rapid reporting of results should be recognized as es-

essential for effective wild poliovirus surveillance.

- **The system of specimen referral, testing and subsequent reporting of wild poliovirus isolates to WHO should be accelerated. Performance standards should be established for every stage, obstacles to implementation identified and corrective action taken.**

4.2 Laboratory accreditation

The goal for the Global Polio Laboratory Network is for every country to have rapid access to a competent accredited laboratory for the processing and analysis of stool specimens from AFP cases. To ensure this, a draft schema for accreditation of Network laboratories was presented to the TCG. The six criteria proposed as the basis of the accreditation procedure are as follows:

- a) Timeliness of reporting;
- b) Number of specimens tested (minimum of 150 per year);
- c) Non-polio enterovirus isolation rate from stool specimens of AFP cases (at least 10%);
- d) Accuracy of poliovirus identification;
- e) Score on an annual proficiency test; and
- f) Score from an annual on-site review of laboratory operating procedures and practices.

A laboratory that received less than 80% (10% for non-polio enterovirus isolation) on any one of the six criteria would be placed on provisional status until passing scores were achieved. Accreditation would provide documentation that the Global Polio Laboratory Network has the capability and capacity to detect, correctly identify, and promptly report wild polioviruses that may be present in clinical specimens or environmental samples.

The TCG reviewed the proposed checklist for the annual accreditation of individual Network laboratories and discussed the role of non-Network laboratories that perform virologic procedures other than those recommended by WHO.

RECOMMENDATIONS:

- **The TCG endorses the draft schema for accreditation of Polio Network Laboratories. The accreditation schema should be implemented by WHO as soon as possible and revised as appropriate.**
- **Recognizing that many non-Network laboratories may process specimens using methods other than those recommended by WHO, these laboratories would be required to provide documentation that such procedures when used in their countries are equivalent in specificity and sensitivity to WHO poliovirus procedures.**
- **All network laboratories should have been through the accreditation process within the next 12 months (i.e. by April 1998) and a report submitted to the next TCG.**

4.3 Laboratory containment of poliovirus stocks

With the on-going success of the polio eradication initiative, it is anticipated that wild poliovirus transmission could cease worldwide within 3-4 years. However, wild poliovirus stocks and diagnostic specimens containing wild polioviruses could still be present in laboratories all over the world. These poliovirus stocks would form a formidable threat to the ultimate success of the initiative unless strict guidelines for their safe handling and containment were established and implemented. The TCG was presented with two recent case reports of laboratory 'escapes' of wild polioviruses into the community which demonstrated the importance of eventual containment of laboratory stocks.

The first case occurred in 1992 and was detected during the type 3 poliomyelitis outbreak in the Netherlands. A poliovirus type 1 was isolated from a fully inactivated polio vaccine (IPV) vaccinated 18 month old boy who had been hospitalized with fever, vomiting, diarrhoea and symptoms of endocarditis. Molecular analysis of the virus revealed that it was identical to the Mahoney strain of poliovirus type 1. Furthermore, the father of the boy worked at a vaccine production facility where the Mahoney strain was used in the manufacture of inactivated polio vaccine. The father remembered having been exposed to high doses of the virus during an accident several weeks prior to the boy's illness. Stool samples from family contacts taken several months later were all virus negative.

The second case occurred in 1993 when a wild poliovirus type 3 was isolated from a fully IPV immunized 5-year old boy who had gastroenteritis shortly after visiting a large recreational park in France. *Salmonella paratyphi* was isolated from the patient as well as wild poliovirus type 3. Molecular analysis showed the isolate to be identical to the Saukett prototype virus. The Saukett prototype strain was not present in the laboratory that carried out the original isolation. Moreover, laboratory contamination was excluded by re-isolation of the virus from the original stool specimen by a second laboratory. Stool specimens from close contacts of the patient were negative. Environmental samples taken near the house and the school of the patient were also negative for poliovirus. Although the origin of the virus is still unknown, the molecular data strongly suggests that the strain probably originated from a laboratory. A similar virus had been found two years earlier in France.

The TCG was alarmed by the documented wild poliovirus infections in the community that were traced to laboratory virus stocks. The TCG noted that inadvertent release of a wild poliovirus from a laboratory could threaten the ultimate success of the polio eradication initiative. These examples stressed the importance of safe handling and eventual laboratory containment of poliovirus stocks.

RECOMMENDATIONS:

- As a matter of urgency, the WHO should convene a meeting of experts to develop a strategy for the containment of laboratory stocks of polioviruses.
- The conclusions and recommendations of the containment meeting should be presented at the next TCG.

5. Supplementary surveillance for wild poliovirus

AFP surveillance is the international standard for surveillance for wild polioviruses in the Global Polio Eradication Initiative. In some industrialized countries which have been polio-free for many years, however, and where routine AFP surveillance may not be practical, the use of supplementary surveillance methods has been proposed for documenting the absence of wild polioviruses. In 1996, the TCG recommended further investigation of the utility of these methods but stated that research for such methods should not divert funding from the implementation of the basic surveillance strategies.

5.1 Environmental surveillance

In 1996, the TCG noted that ICCPE of the Americas considered but did not adopt the use of environmental surveillance was considered but not used in certifying the interruption of wild poliovirus transmission in the Region of the Americas. However, the role of environmental surveillance in the final stages of certification of global eradication (i.e. following regional certification) remains to be fully defined. It has been suggested that environmental sampling has the potential to effectively monitor poliovirus circulation in large communities. In areas of relatively insensitive AFP surveillance, it has been proposed that targeted environmental surveillance in high-risk communities might directly detect the circulation of wild poliovirus.

The TCG reviewed the experience with environmental surveillance in both endemic and non-endemic countries. In summary, it was reported that environmental surveillance had:

- a) Detected wild poliovirus circulation in high-risk communities in Colombia;
- b) Led to the detection of importations of wild poliovirus in non-endemic countries such as Israel, Russia, Estonia and the Netherlands;
- c) Been used for monitoring the extent of spread of wild poliovirus in epidemics (Finland, the Netherlands);
- d) Detected wild poliovirus in communities lacking sewage systems (South Africa, Congo);
- e) Detected wild poliovirus in populations where OPV was widely used (Colombia, Estonia, Israel and Italy).

The TCG reviewed the report of the February 1997 meeting of the Working Group on Environmental Surveillance. The Working Group noted that implementing environmental surveillance could result in findings that are difficult to interpret (e.g. differentiation of indigenous circulation from importations). The group therefore recommended a baseline study in areas where wild virus was still known to be circulating to evaluate environmental sampling against the results of AFP surveillance over time. Because of the urgency to obtain field experience with environmental sampling in polio endemic countries, the Working Group selected one method for concentration and purification of viruses and recommended that this method be tested in at least three Network Laboratories. The Group will reconvene in January 1998 to carry out an interim review of the study results, exchange experiences in testing the selected procedure in different laboratories, and consider other collaborative studies.

RECOMMENDATION: The TCG welcomes the report of the Working Group on Environmental Surveillance for Wild Polioviruses. Upon completion of the baseline study the results should be presented to the TCG.

5.2 Aseptic meningitis surveillance

In 1996, the TCG had recommended an evaluation of the effectiveness and programmatic implications of aseptic meningitis surveillance as a strategy for wild poliovirus surveillance and, potentially, certification of polio eradication in industrialized countries. A review of the role of aseptic meningitis as a supplementary surveillance method in industrialized countries was presented. In summary, the rationale for considering aseptic meningitis surveillance for the detection of polioviruses was based on the relatively high incidence of aseptic meningitis as compared to paralytic disease in poliovirus infections. Therefore, theoretically a surveillance system for aseptic meningitis could have a high sensitivity for detecting wild polioviruses through sentinel surveillance at tertiary care hospitals. However, several disadvantages and limitations were noted including: (1) aseptic meningitis surveillance would usually require the establishment of a new system (especially for the collection of stool as opposed to CSF specimens); (2) there are uncertainties as to the sensitivity of aseptic meningitis surveillance due to insufficient information on both the proportion of poliovirus infections that result in aseptic meningitis and the proportion of aseptic meningitis cases that present to health care providers; and (3) the highest-risk group for aseptic meningitis is also the group that would be most likely to receive OPV and excrete vaccine-related polioviruses.

A review of meningitis and paralytic poliomyelitis cases during endemic and epidemic periods in the USA between 1955 and 1960 was presented. In the pre-vaccine era, the proportion of wild poliovirus infections that resulted in aseptic meningitis ranged from 0.2% (in outbreaks) to 3.7% (in population based studies), compared to 0.5% for paralytic poliomyelitis. The proportion of acute meningitis cases presenting to health facilities was found to be age dependent. Investigations of non-polio enterovirus outbreaks revealed that only 10-20% of aseptic meningitis patients actually sought medical attention.

The TCG was concerned that aseptic meningitis surveillance would not result in a higher sensitivity than AFP surveillance, even if reporting was complete for those who sought care. The TCG also noted that operationally it would be easier for countries to establish AFP surveillance unless an aseptic meningitis surveillance system was already in place.

RECOMMENDATIONS:

- **Data from existing aseptic meningitis surveillance systems may be used as supplementary evidence that wild poliovirus transmission has been interrupted.**
- **Countries should not establish aseptic meningitis surveillance systems as a basis for certification of the elimination of indigenous wild polioviruses. Such surveillance is not a substitute for AFP surveillance and offers little, if any, additional benefit.**

5.3 The role of public health and other laboratory networks

Many countries have networks of diagnostic virus laboratories that are routinely conducting enterovirus culture and typing. These laboratories may be formally organized and linked or may constitute an informal network of academic and hospital laboratories. The potential role of these networks in demonstrating the absence of wild poliovirus circulation was presented to the TCG. The advantages to fully exploiting such networks included: sampling of older individuals than those usually targeted by AFP surveillance; the possibility of increasing the sensitivity to detect polioviruses through the high number of specimens processed; and the capacity to exploit an existing surveillance mechanism. It was recognized, however, that a mechanism for verifying the quality of results from these laboratories would be required as they would not have been accredited as part of the Global Polio Laboratory Network.

The TCG agreed that a network of public health laboratories could provide valuable supplementary information on poliovirus circulation in a community through the virologic analysis of routine diagnostic specimens. To assist in the certification of the absence of poliovirus circulation, it would be necessary to have the peripheral laboratories systematically submit samples to a WHO-accredited laboratory for intratypic differentiation. The referral process could have indirect benefits for the eradication initiative through the wide involvement of the diagnostic virologists. However, the workload of the accredited laboratories could be markedly increased. Provided that adequate quality controls were in place, the TCG stated that results from such a network might be used as supplemental data for the certification process.

RECOMMENDATION: Surveillance for wild poliovirus through established laboratory networks within countries may be a valuable supplementary surveillance mechanism provided there is adequate quality control by a WHO-accredited laboratory. This should include: retyping of all poliovirus isolates by a WHO-accredited laboratory; re-screening for poliovirus in selected NPEV isolates and non-typable enteroviruses and genotyping of all wild polioviruses.

6. Certification of polio eradication

Among the principles for certifying polio eradication will be the documentation of effective surveillance for acute flaccid paralysis (AFP) and wild polioviruses. However, as noted in the previous section the Global Commission for the Certification of the Eradication of Poliomyelitis has recognized that in countries where polio has been eradicated for many years, it may prove impossible to establish satisfactory AFP surveillance. As a result, a number of supplementary surveillance strategies have been proposed for certification of eradication in some industrialized countries. While these strategies may contribute to the data required to document that a country is polio-free, they will constitute only a part of the total information that will be needed. To clarify the types of information that will be required in such settings, the TCG reviewed and endorsed a proposed framework for demonstrating adequate surveillance for the certification of eradication in industrialized countries.

The framework stressed that in the absence of routine AFP surveillance, an industrialized country would need to demonstrate the following: (a) high quality surveillance for suspected poliomyelitis cases; (b) high quality surveillance for wild poliovirus, including the appropriate virologic analysis of specimens from all suspected polio cases and/or AFP cases, and (c) that all virologic results either came from or were confirmed by a laboratory which was accredited as part of the Global Polio Laboratory Network.

RECOMMENDATIONS:

- **The international standard for polio eradication remains routine surveillance for all cases of AFP with full clinical, epidemiological and virological investigation.**
- **Industrialized countries which have been polio-free for prolonged periods and in which it is not practical to establish routine AFP surveillance should ensure that the documentation submitted for certification demonstrates the adequacy of surveillance in three general areas:**
 - **surveillance for individuals with suspected poliomyelitis,**
 - **surveillance for wild polioviruses, and**
 - **laboratory competence to isolate and identify polioviruses.**

7. Stopping polio immunization after eradication of wild poliovirus

The rapid progress toward polio eradication has now begun to focus attention on the potential strategies for stopping immunization against polio once eradication has been achieved. A decision tree analysis was presented to the TCG to identify the key issues and information that will be required to develop the best strategy for eventually stopping immunization. The decision tree was based on the following scenario: (1) supplementary immunization activities accelerate and result in global coverage of all poliovirus endemic areas by the year 1999; (2) poliovirus surveillance continues to improve and effective global surveillance is achieved by the year 2000; (3) the last wild type 2 poliovirus is detected in 1997, the last wild type 3 poliovirus in 1999 and the last wild type 1 poliovirus in the year 2000; and (4) the Global Certification Commission meets in 2003 and declares the global eradication of wild polioviruses.

The decision tree for stopping immunization chronologically linked the decisions regarding changes in vaccination strategies to the status of the global certification process and the containment of laboratory stocks of poliovirus. Two key issues raised by the decision tree were discussed by the TCG. First, whether Sabin-like virus strains would continue to circulate after OPV immunization was discontinued and secondly, if the scientific evidence indicated that there was no risk of continued circulation of Sabin-like strains, what would be the options for discontinuing OPV vaccination.

7.1 Circulation of Sabin-like virus strains

There is no long-term carrier state of poliovirus in immunocompetent persons. However, persistence of Sabin-like poliovirus excretion in immunocompromised persons has been documented in a number of reports in the literature. Recent molecular sequencing studies of a poliovirus isolate from an immunodeficient patient with common variable hypogammaglobulinemia and onset of paralysis in 1981 suggested that a Sabin-like virus may have replicated in this individual for nearly seven years. While the TCG recognized the potential for prolonged excretion in such cases, it did not believe that this would compromise the ultimate goal of stopping polio immunization. However, the report did demonstrate the gaps in the scientific knowledge on persistence and circulation of Sabin-like polioviruses.

7.2 Options for discontinuing OPV vaccination

Three principal options for stopping OPV immunization were presented to the TCG: (1) cease the use of trivalent OPV at once worldwide; (2) switch from OPV to only IPV immunization; (3) sequentially drop poliovirus types from the OPV formulation as the respective wild poliovirus types are eradicated. This last option could potentially be achieved by either changing the existing OPV formulation or switching to monovalent P1 and P3 polio vaccines. The most appropriate strategy for discontinuing polio vaccination would primarily depend on the risk of continued circulation of Sabin-like poliovirus strains after OPV vaccination was discontinued.

The TCG was informed that the available data suggested that a global IPV strategy would be neither necessary nor desirable. If such a strategy was eventually deemed necessary, however, IPV producers would require substantial lead time to undertake the investments required to expand IPV production to meet the global demand. It was noted that manufacturers would also require guarantees of future purchase orders.

A review was presented on the feasibility and utility of sequentially dropping poliovirus types from the trivalent OPV formulation (eg. creating a "II-less" OPV). This data demonstrated that the development, production and licensing of such a vaccine would probably not be feasible within the timeframe of global polio eradication.

The TCG concluded that the available evidence continued to indicate that polio immunization could eventually be stopped after wild poliovirus has been eradicated.

RECOMMENDATIONS:

- **Additional scientific studies should be conducted to assure that vaccine viruses will not continue to circulate and cause outbreaks of disease after immunization has been stopped.**
- **A detailed strategy for stopping immunization must be clearly defined because immunization must be stopped if the world is to realize the full benefits of polio eradication.**
- **By the end of 1997 a working group should be established to define the appropriate studies needed to: determine the circulation of vaccine viruses in countries which rely solely on mass immunization campaigns to deliver OPV; determine the frequency and duration of vaccine virus shedding in immunocompromised persons including HIV infected persons.**
- **Based on the findings of these studies, the working group should develop a proposal for stopping immunization and present the proposed strategy to the TCG.**

Annex 1:

List of participants

Dr W. Orenstein, Centers for Disease Control and Prevention,
National Immunization Program, 1600 Clifton Road, Atlanta, Georgia 30333,
United States of America (**Chairman**)

Dr P. Figueroa, Department of Epidemiology, Ministry of Health, Kingston,
Jamaica (**Rapporteur**)

Dr I. Arita, Agency for Cooperation in International Health, 4-11-1 Higashi-
machi, Kumamoto City 862, Japan

Dr N. Begg, Public Health Laboratory Service, 61 Colindale Avenue,
London NW9 5EQ, United Kingdom

Dr R. Nath Basu, A73 Yojna-Vihar, New Delhi 110092, India

Professor F.K. Nkrumah, Noguchi Memorial Institute for Medical Research
(NMIMR), University of Ghana, P.O. Box 25, Legon, Ghana

Dr M. Suleiman Ali Jaffer, Ministry of Health, P.O. Box 393, Muscat,
Sultanate of Oman

Technical Advisers

Dr S. Cochi, Centers for Disease Control and Prevention, National Immunization
Program, 1600 Clifton Road, Atlanta, Georgia 30333, United States of America

Dr W. Dowdle, The Task Force for Child Survival and Development,
The Carter Center, 750 Commerce Drive, Suite 400, Decatur, Georgia 30030,
United States of America

Dr T. Hovi, National Public Health Institute, Mannerheimintie 166,
SF-00300 Helsinki, Finland

Dr E. Ruiz-Tiben, Global 2000, The Carter Centre, Atlanta, Georgia 30030, USA

Dr D. Salisbury, Department of Health, Wellington House, 135-155 Waterloo
Road, London SE1 8UG, United Kingdom

Dr R. Sutter, Centers for Disease Control and Prevention,
National Immunization Program, 1600 Clifton Road, Atlanta, Georgia 30333,
United States of America

Dr A. M. Van Loon, Research Laboratory for Infectious Diseases (RIVM),
Antonie Van Leeuwenhoeklaan 9, P.O. Box 1, 3720-BA Bilthoven, The Netherlands

Dr D. Wood, National Institute of Biological Standards and Control, Blanche
Lane, South Mimms, Potters Bar, Hertfordshire EN6 8QG, United Kingdom

Dr Jane Zucker, Program Officer, Immunization, UNICEF Health Section,
New York, USA

Participants

Dr H. van der Avoort, Laboratory of Virology, RIVM,
Antonie Van Leeuwenhoeklaan 9, Box 1, 3720-BA Bilthoven, The Netherlands

Dr K.J. Bart, Associate Director for Scientific and Medical Affairs,
Department of Health & Human Services, Rockville, USA

Dr Y. Chiba, International Medical Centre, JICA, Shinjuku Maynos Tower Bldg,
8th Floor, 1-1, Yoyogi, 2-chome, Shibuya-ku, Tokyo 151, Japan

Dr R. Crainic, Institute Pasteur, 28 rue du Docteur Roux, F-75724 Paris, Cedex
15, France

Dr P. Crooy, Director, Scientific Affairs, Public, Corporate & Government Af-
fairs, Smith-Kline Beecham Biologicals, Rue de l'Institut 89, 1330 Rixensart,
Belgium

Mr M. Diamond, Humanitarian Programs Manager, The Rotary Foundation,
1560 Sherman Avenue, Evanston, Illinois 60201, USA

Dr H. Gary, Centers for Disease Control and Prevention,
National Immunization Program, 1600 Clifton Road, Atlanta,
Georgia 30333, United States of America

Ms Anne-Renée Heningburg, Centers for Disease Control and Prevention,
National Immunization Program, 1600 Clifton Road, Atlanta, Georgia 30333,
USA

Dr A.R. Hinman, Coordinator, CDC/World Bank Collaboration on Immuniza-
tion, The Task Force for Child Survival and Development, One Copenhill, At-
lanta, Georgia 30307, USA

Mr B. Keegan, Centers for Disease Control and Prevention, National Immuniza-
tion Programme, 1600 Clifton Road, Atlanta, Georgia 30333, USA

Dr O. Kew, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, Georgia 30333, United States of America

Ms. Ellyn Ogden, Polio Eradication Coordinator, USAID, 320 Twenty-first Street NW, Washington D.C. 20523, USA

Dr M. Pallansch, Centers for Disease Control and Prevention, Center for Infectious Diseases, 1600 Clifton Road, Atlanta, Georgia 30333, United States of America

Ms Carol Pandak, Supervisor, PolioPlus Volunteer Support, The Rotary Foundation, 1560 Sherman Avenue, Evanston, Illinois 60201, USA

Dr Hervé Periès, Regional Project Officer, UNICEF West and Central Africa Regional Office, Abidjan, Côte d'Ivoire

Mr R. Saboo, Chairman, The Rotary Foundation, 1560 Sherman Avenue, Evanston, Illinois 60201, USA

Mr W. Sergeant, Chairman, International PolioPlus Committee, The Rotary Foundation, 1560 Sherman Avenue, Evanston, Illinois 60201, USA

Dr R. Steinglass, Immunization Coordinator, BASICS, 1600 Wilson Blvd., Arlington, VA 22209, USA

Dr P. Strebel, Centers for Disease Control and Prevention, National Immunization Program, Atlanta, Georgia 30333, USA

Dr N. Takeda, National Institute of Infectious Diseases (NIH), Tuyama 1-23-1, Shinjuku-ku, Tokyo 162, Japan

Dr M. Trostle, Public Health Advisor, USAID, 320 Twenty-first Street NW, Washington, DC 20523, USA

Dr Iyorlumun Uhaa, Regional Health Adviser, UNICEF East and Southern Africa Regional Office, Nairobi, Kenya

Dr K. Watanabe, Director, Research & Programming Division, Japan International Cooperation Agency, Tokyo, Japan

Members of the Global Commission for Certification of the Eradication of Poliomyelitis

Dr Hadi M. Abednego, Director General, CDC & EH, Ministry of Health, Jalan Percetakan Negara 29, P.O. Box 223, Jakarta 10560, Indonesia

Professor A. Adams, National Centre for Epidemiology and Population Health, The Australian National University, Canberra ACT 0200, Australia

Dr Abdul Rahman Abdullah Al-Awadi, Executive Secretary, Regional Organization for the Protection of the Marine Environment (ROPME), P.O. Box 26388, Safat 13124, Kuwait

Dr Abdullah Deria, 28 Claudia Place, Augustus Road, London SW19 6ES, United Kingdom

Professor S. G. Drozdov, Director, Institute of Poliomyelitis and Viral Encephalitis of the Academy of Medical Science of the Russian Federation, Moscow 142782, Russian Federation

Professor J. Kostrzewski, Department of Epidemiology, National Institute of Hygiene, 24 Chocimska Street, 00-791 Warsaw, Poland

Dr Rose Leke, Department of Immunology and Microbiology, Faculty of Medicine, University of Yaoundé, Cameroon.

Dr C. de Macedo, SMDB Conjunto 01 Casa 05, Lago Sul, Brasilia, DF 71680-010, Brazil

Prof Natth Bhamarapavati, Center for Vaccine Development, Institute of Sciences & Technology for Development, Mahidol University at Salaya, Nakhonchaisri, Nakhonpathom 7310, Thailand

Professor F.K. Nkrumah, Noguchi Memorial Institute for Medical Research (NMIMR), University of Ghana, P.O. Box 25, Legon, Ghana

Dr F.C. Robbins, Department of Epidemiology and Biostatistics, School of Medicine, Case Western Reserve University, 10900 Euclid Avenue, Cleveland, Ohio 44106-4945, USA (Unable to attend)

Sir J. Smith, 95 Lofting Road, Islington, London, GB-N1 1JF (Unable to attend)

Dr Wang Ke-An, Vice President, Chinese Academy of Preventive Medicine (CAPM), 27 Nanwei Road, Beijing 100050, People's Republic of China

WHO regional offices

AFRO

Dr J. M. Okwo-Bele, EPI, AFRO

Dr A. Lobanov, EPI, AFRO

Dr M. Otten, EPI, AFRO

Ms Melinda Mailhot, EPI, AFRO

Dr D. Nshimirimana, WHO, Yaoundé, Cameroon

Dr J.M. Tapsoba, WHO, Abidjan, Côte d'Ivoire

Dr B. Morinière, WHO, Addis Ababa, Ethiopia

Dr Celia Woodfill, WHO, Accra, Ghana

Dr D. Klaucke, WHO, Nairobi, Kenya

Dr R. Biellik, WHO, Harare, Zimbabwe

Dr O. Tomori, WHO, Harare, Zimbabwe

AMRO

Dr C. de Quadros, Director, SVI, AMRO

Dr Ana-Cristina Nogueira, EPI, AMRO

Dr B. Hersh, EPI, AMRO

Dr C. Silveira, EPI, AMRO

EMRO

Dr M. H. Wahdan, Deputy Regional Director, EMRO

Dr B. Sadrizadeh, Director, ICD, EMRO

Dr T. Gaafar, EPI, EMRO

Dr R. Aslanian, EPI, EMRO

Dr H. Jafari, EPI, EMRO

Dr J. Boshel, EPI, EMRO

Dr Fatem Kamel, EPI, EMRO

Dr E. Durry, WHO, Sana'a, Yemen

EURO

Dr Colette Roure, EPI, EURO

Dr G. Oblapenko, EPI, EURO

Dr S. Wassilak, EPI, EURO

Dr S. Deshevoj, WHO, Almaty, Kazakhstan

SEARO

Dr I. Mochny, EPI, SEARO
Dr J. Andrus, EPI, SEARO
Dr D. Caussy, EPI, SEARO
Dr Jean Smith, EPI, SEARO
Dr G. Hlady, EPI, SEARO
Dr Ana-Maria Henao-Restrepo, EPI/SEARO
Dr D. Sniadack, WHO, Dhaka, Bangladesh
Dr S. Rosenthal, WHO, Jakarta, Indonesia
Dr J. Luna, WHO, Kathmandu, Nepal

WPRO

Dr J. Bilous, EPI, WPRO
Mr. C. Maher, EPI, WPRO
Mr R. Sanders, EPI, WPRO
Mr D. Basset, WHO, Phnom Penh, Cambodia
Mr A. Schnur, WHO, Beijing, China
Dr Jessie Wing, WHO, Beijing, China

CVI Secretariat

Dr R. Widdus
Dr M. Miller

Secretariat, WHO Headquarters

Dr R. Henderson, ADG
Dr J.W. Lee, Director, GPV
Mr P. Evans, Chief, VSQ
Dr P.-H. Lambert, Chief, VRD
Dr B. Melgaard, Chief, EPI
Dr B. Aylward, EPI
Ms Amie Batson, VSQ
Mr A. Burton, EPI
Dr Maureen Birmingham, EPI
Dr J. Clements, EPI
Mr H. Everts, EPI
Dr F. Gasse, EPI
Ms Rachael Horner, EPI
Dr Barbara Hull, EPI

Dr H. Hull, EPI
Dr M. Kane, EPI
Dr J. Lloyd, EPI
Dr Julie Milstien, VSQ
Mr B. Mahoney, EPI
Ms Maryanne Neill, EPI
Dr B. Nkowane, EPI
Dr J.M. Olivé, EPI
Dr Y. Pervikov, VRD
Dr P.J.A. Ranque, DRA/CTD
Dr Susan Robertson, VRD
Dr M. Ryan, EPI
Dr R. Tangermann, EPI
Mr M. Zaffran, EPI

