Special Report

Strategies for the Certification of the Eradication of Wild Poliovirus Transmission in the Americas¹

Because it appears that the last case of poliomyelitis caused by transmission of indigenous wild poliovirus occurred 2 years ago on 23 August 1991 in Peru, the challenge for PAHO is to develop a methodology of certification that will convince the rest of the world that the eradication of poliomyelitis in the Americas has been achieved. To that end, the guidelines set forth here allow for a rigorous and standardized evaluation of the certification process by objective experts. As it was during the campaign to eradicate smallpox, epidemiologic surveillance (of acute flaccid paralysis [AFP] in the case of polio) will be the most important component of the certification process. It must be demonstrated that when cases of AFP occur, they will be identified, reported, and investigated in a timely manner to insure that if wild poliovirus is present, it will be identified.

INTRODUCTION

On 6 July 1990, delegates to the first meeting of the International Certification Commission on Polio Eradication (ICCPE) established preliminary criteria for certifying that countries in the Americas are free of poliomyelitis (1–2). The Commission recognized that it is extraordinarily difficult to demonstrate with certainty that no wild polioviruses are circulating in a given country, let alone in the Region as a whole. The challenge is akin to that experienced in certifying that smallpox had been eradicated, but it is even more difficult, because the ratio of asymptomatic infections to clinical cases is much greater for poliomyelitis than it was for smallpox.

Nonetheless, the basic conditions that were essential to certifying the eradication of smallpox appear to be equally applicable to polio eradication:

- no detection of wild poliovirus over an extended period of time, in the context of a surveillance system that is good enough to detect both cases and the virus, should they be present;
- a thorough country-by-country documentation of program activities and findings; and, finally,
- the judgment by an independent international commission that sufficient evidence is available to support the belief that poliovirus circulation has ceased.

For certification purposes, good surveillance is the most important condition that must be met. Surveillance for polio cases encompasses surveillance for all conditions causing acute flaccid paralysis (AFP) in persons under 15 years of age, as well as for suspected polio cases among older persons. It must be demonstrated that when cases of AFP occur, they will be identified, reported, and investigated in a timely manner to ensure that wild poliovirus will be detected if it is present.

The approach to the certification effort must be rigorous yet practical. Ultimately, the information gathered must be adequate in quantity and quality to constitute convincing evidence before the Commission and the world that transmission of indigenous wild poliovirus has indeed ceased in the Western Hemisphere.

As was the case during the certification of smallpox eradication, the process of certifying polio eradication will evolve, requiring refinement at each step (3–4).

DEFINITION OF POLIOMYELITIS ERADICATION

The evolution of the certification procedures can be understood more readily by reviewing the definition of and the criteria for poliomyelitis eradication as developed by the Directing Council of PAHO in 1985 (5) and the ICCPE in 1990 (1).

The definition of polio eradication (as put forth by the Directing Council) is the interruption of transmission of indigenous wild poliovirus. Such transmission can and usually does occur as inapparent infections. Paralytic cases (one per 100 to one per 1,000 infections) serve as a vital indicator of continuing poliovirus spread; because of this, their detection is critical. At its first meeting in July 1990, members of the ICCPE decided that the Region should be free of any paralytic poliomyelitis due to wild poliovirus infection for at least 3 years before it could be said with reasonable certainty that eradication had been achieved.

The eventual interruption of indigenous wild virus transmission is possible because (1) there is no natural animal reservoir for wild poliovirus, (2) infected persons do not excrete the virus for more than a few weeks, and (3) wild poliovirus does not survive in the environment for prolonged periods of time. Given the large number of inapparent infections that exist for every clinical case of the disease (6–8), measures in addition to case-finding will be needed to detect circulating wild polioviruses. Accordingly, wild poliovirus surveillance will include testing the stools of normal children and sampling and testing community sewage to help rule out transmission after the last culture-confirmed paralytic cases have been reported.

LESSONS LEARNED FROM CERTIFICATION OF SMALLPOX ERADICATION

The smallpox eradication certification process in the Americas provided experience in four significant areas: (1) the amount of time that should elapse from the last case of paralytic disease to the point where one could confidently judge that wild virus has ceased circulating, (2) the comprehensiveness required of the surveillance system, (3) the competence and diligence needed from the official certification committee reviewing national data, and (4) the level of political support that is called for to ensure compliance with the certification criteria.

First, experience during smallpox eradication eventually showed that, with good surveillance, no more than a year was required to confirm that eradication had been achieved. In practice, however, a 2-year interval was observed. Polio presents a more difficult problem owing to
the occurrence of a large number of inapparent infections, so 3 years after the last culture-confirmed case has been provisionally agreed upon as the time period needed for certification of polio eradication.

Preliminary analysis of a mathematical model developed for statistical validation of the eradication of indigenous wild poliovirus in the Americas (Debanne et al., unpublished) indicates that the 3-year period of freedom from paralytic poliomyelitis may need to be extended to 4 years. The provisional results of this study suggest that with good AFP surveillance and no detected culture-confirmed polio cases, the probability that wild poliovirus would continue to circulate undetected for more than 4 years is less than 5%. This probability continues to decrease over time.

Second, the quality of the surveillance system that operated during the smallpox eradication campaign was demonstrated by the comprehensiveness of the reports of rash illness with fever and chicken pox cases once smallpox cases had ceased to occur. These reports were especially helpful in convincing members of certification committees that if smallpox virus had been circulating, it would have been detected and reported. Surveillance for AFP serves this role in the polio program.

For polio, as for smallpox, the shorter the time that has elapsed since the last case, the more sensitive the surveillance program must be. As more time elapses, many hundreds of additional infections are needed to sustain chains of transmission, with higher probabilities that infections will be detected if present. Also as with smallpox, areas of greatest interest are highly populated areas, given that chains of infection are not readily sustained in sparsely populated, remote regions.

Third, as discussed by Fenner et al. (3), the first smallpox eradication certification commission to be established was for South America. It suffered from defects in both composition and performance. The commission for smallpox eradication certification in the Americas had few guidelines and its assessment of the situation was brief and not rigorous. Fortunately, subsequent history demonstrated that smallpox had indeed been eradicated from South America. This lack of rigor will not be the case with polio certification because the epidemiology of polio, i.e., asymptomatic transmission of the virus, presents many more challenges to eradication than did smallpox.

Finally, interest and efforts invested in the earlier certification process varied greatly from country to country. Countries from which smallpox had just been eradicated showed great interest in certification, whereas those countries in which the disease had been eliminated many years before did not consider certification a high priority. In the Americas, governments will have to mobilize adequate numbers of staff to prepare properly for Region-wide certification of polio eradication.

Although details of the process may be modified as certification progresses, the essential features—adequate preparation, detailed documentation of the evidence of at least 3 years of freedom from poliomyelitis, and the independence and authority of the certification team—must remain unchanged throughout.

**CRITERIA FOR CERTIFICATION OF POLIO ERADICATION**

The measures to be taken are set forth below (I):

1. Verification of the absence of virologically confirmed indigenous poliomyelitis cases in the Americas for a
period of at least 3 years under circumstances of adequate surveillance;

2. Verification of the absence of detectable wild polioviruses from communities as determined by testing of stools from normal children and, where appropriate, testing of wastewater from high-risk populations;

3. On-site evaluation by national certification commissions appointed jointly by PAHO and respective member countries, composed of knowledgeable local persons and outside experts. One or two responsible ICCPE members will serve in advisory roles during this process. After the national commission considers that the criteria have been met, the information will be submitted to the full ICCPE for final certification;

4. Establishment of appropriate measures to deal with the potential importation of cases from areas that are not free of polio.

The first two recommendations comprise the foundation for the certification effort and are addressed in detail later in this report. Areas with cases that are classified as "compatible" with polio—a category which indicates a failure in surveillance—will need adequate documentation of special wild poliovirus surveillance and of house-to-house mop-up immunization campaigns. (See below for a full definition of "compatible" and other surveillance classifications of AFP.)

The third recommendation will require on-site evaluation of surveillance criteria and local conditions by the responsible members of the ICCPE.

As pointed out in the fourth recommendation, even after certification, surveillance will need to be continued in the Americas until polio has been eradicated from the rest of the world. As long as other parts of the world remain infected, the risk of importations will continue. However, this does not imply that certification should wait until global eradication has been achieved. As with smallpox, the concept of eradication can apply to entire continents, such as the Americas; but to be certified, each country's surveillance system must be capable of recognizing and containing importations of wild poliovirus when they occur.

**ROLE OF THE ICCPE**

The ICCPE is composed of experts who are critical in their assessments and whose judgment is respected both nationally and internationally. Some of those selected are experts in communicable disease control, others in virology or health management. Some have also had the benefit of serving previously as members of various international smallpox certification commissions. The membership is as follows: Dr. Waldyr Arcoverde, Brazil (later replaced by Dr. Antonio Olinto of Brazil); Dr. Isao Arita, Japan; Dr. Rodrigo Guerrero, Colombia; Dr. Dorothy Horstmann, United States of America; Dr. Jan Kostrewski, Poland; Dr. Maureen Law, Canada; Dr. Elsa Moreno, Argentina; Dr. V. Ramalingaswami, India; Dr. Olikoye Ransome-Kuti, Nigeria; Dr. Frederick Robbins, United States of America (Chairman); Dr. Guillermo Soberón, Mexico; and Sir Kenneth Standard, Jamaica. To prepare for certification of the eradication of poliomyelitis in the Americas, the ICCPE has met twice, the second meeting having taken place in March 1992 in Rio de Janeiro, Brazil (9).

The mode of operation of the ICCPE has been established as follows:

1. For each area of the Americas, one or two ICCPE commissioners will have responsibility for overseeing certification procedures. The seven areas are the Southern Cone countries, Brazil, the Andean countries,
Central America, the countries of the Caribbean, Mexico, and Canada and the United States.

2. Areas will be considered for certification only if all their constituent countries have been free of poliomyelitis for a period of at least 3 years. All countries should now be engaged in the precertification process of collecting and evaluating data from surveillance of AFP and wild poliovirus, as discussed below.

3. National commissions will be organized in each country to review and oversee the precertification activities of intensified surveillance for AFP, active case searches in areas where surveillance is poor, surveillance of wild poliovirus, and immunization campaigns in risk areas, e.g., areas where confirmed and compatible cases have occurred in the past.

4. Each country will prepare a national report to be reviewed by the responsible ICCPE commissioner that will serve to document the interruption of transmission of wild poliovirus.

Once preliminary approval of country reports has been achieved, the ICCPE will meet and review country presentations for a final decision on each area's status. Ultimately, it will be the responsibility of the ICCPE to reach one of two conclusions: either that it is satisfied that transmission has been interrupted, or that it would be satisfied if certain specific additional measures were undertaken.

Certification of eradication is possible only for the Hemisphere as a whole and can only occur when the ICCPE has agreed that transmission has been interrupted in all countries. Because polio eradication is such a tremendous achievement for the countries of the Americas, the process of certification should receive high priority so that all countries can be appropriately recognized for their historic accomplishments.

NATIONAL STRATEGIES FOR CERTIFICATION

Four strategies will be essential for generating country reports that would justify certification by the ICCPE: (1) surveillance of AFP, (2) surveillance of wild poliovirus, (3) active AFP case searches in areas of poor surveillance, such as areas where confirmed or compatible cases occurred in the past or where reports were not received, and (4) documentation of mass immunization campaigns in areas of risk—such as those areas where confirmed or polio-compatible cases have occurred. The final country report must provide accurate documentation of these activities. Simply put, the formula for successful certification is:

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\text{[Adequate AFP Surveillance]} + \text{[Surveillance of Wild Poliovirus]} + \text{[Active Case Searches In Risk Areas]} + \text{[Mop-up Immunization Campaigns In Risk Areas]} = \text{CERTIFICATION}
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Generally, the effectiveness of the reporting system for AFP will determine how prepared a country is to deal with importations of wild poliovirus. Countries will need to document what additional measures have been taken to prevent spread if importations do occur.

Surveillance of AFP and Wild Poliovirus

To achieve poliomyelitis eradication, PAHO has depended upon the following basic program strategies: achievement and maintenance of high immunization levels (which includes supplemental strategies such as national immunization days and mop-up operations), effective surveil-
lance to detect all new cases, and a rapid response to the occurrence of new cases (10-12). Surveillance is the most important component of the overall eradication strategy, because it corroborates that the ultimate goal of the program—zero cases of polio—has been achieved. Moreover, it is an invaluable tool to monitor the impact of the program and permit the assignment of resources to the most needed areas.

Surveillance systems vary from country to country and even within countries. Nevertheless, some common principles have been applied and implemented. At least one reporting source for AFP was identified in each county or district (or comparable small geopolitical unit). Health centers are the primary reporting sources because cases of AFP are commonly encountered there for diagnosis, treatment, or rehabilitation. Each reporting source is required to report to the state, departmental, provincial, or national level every week, whether AFP cases have occurred or not. In turn, state officials report weekly to the national level, and national authorities report weekly by fax or computerized electronic mail to PAHO headquarters (13).

A “suspected” polio case is any case of acute paralysis in a person less than 15 years old for any reason other than trauma, or paralytic illness in a person of any age in whom a diagnosis of poliomyelitis is possible. If the suspected case is determined to have acute “flaccid” paralysis, then the case is reclassified as “probable.” Epidemiologists attempt to investigate every case of AFP within 48 hours after notification, in order to confirm the clinical diagnosis and to obtain laboratory specimens. These epidemiologists have been specially trained by the Expanded Program on Immunization (EPI) and are supervised by the national ministry of health and the PAHO epidemiologist assigned to that particular country. They attend regular meetings at the national level where they are provided with feedback via program evaluations and where they receive continuing medical education.

Before 1990, cases of AFP were “confirmed” as poliomyelitis if there was (a) laboratory confirmation (wild-type poliovirus isolated from stools), (b) epidemiologic linkage to another case of AFP or to a confirmed case of poliomyelitis, (c) residual paralysis 60 days after onset of symptoms, (d) death, or (e) lack of follow-up of a case. Cases of AFP were “discarded” as not being poliomyelitis if they did not meet these criteria. To increase the specificity of the case definition, beginning in 1990, a case of AFP was “confirmed” only if it was associated with wild-type poliovirus isolation. Cases of AFP which could neither be confirmed nor discarded—because two adequate stool specimens had not been collected, the cases had resulted in residual paralysis or death, or there had been no follow-up—were classified as cases “compatible” with poliomyelitis. Specimens were tested for viral isolation in three different laboratories until 1991, when the recommendation was changed to two laboratories.

Special importance is given to collecting two stool specimens within 2 weeks after onset of paralysis because the likelihood of wild-type poliovirus isolation diminishes significantly when stool specimens are collected later (14).

In addition to collecting adequate stools from AFP cases, wild poliovirus surveillance will also include stool surveys of normal children (contact investigations) and sampling and testing of sewage (9, 15-16; Tambini et al., in preparation).

Of the other methodologies available, lameness surveys (17-18) are impractical for most countries because of the large number of persons required for an adequate sample and the difficulties in mak-
ing an accurate etiologic diagnosis long after the onset of illness. Attempts to isolate wild poliovirus from flies is likewise deemed impractical. Poliovirus has been isolated from flies around outbreaks of poliomyelitis, but the flies themselves harbor virus only up to 3 weeks after the last case of the outbreak (19–24). Finally, serosurveys for poliomyelitis neutralizing antibodies are of little value because of the impossibility of discriminating antibodies formed in response to vaccine-related poliovirus from those formed in response to wild-type poliovirus (25).

While surveillance of wastewater for the presence of wild poliovirus is an accepted strategy, it has inherent difficulties. High ambient temperatures and high bacterial content of wastewater in tropical areas promote rapid inactivation of the poliovirus. Given that the predicted survival times of polioviruses under such conditions are short (the half-life for infectivity is <2 days [26]), it is likely that most of the virus detected in wastewater represents what has been excreted from children only a few days before sampling. Its reliability in detecting the existence of wild poliovirus is therefore limited to the brief period during which the virus is circulating in a community. A good AFP surveillance system, meanwhile, is not as time-sensitive, since it detects the presence of wild poliovirus in the community by identifying cases of paralytic poliomyelitis. The importance of high-quality AFP surveillance information, not only for the eradication of wild poliovirus transmission but also for the certification of this accomplishment, cannot be overemphasized.

Accordingly, the ICCPE has recommended that for at least 80% of all cases of AFP, the stools of five contact children be collected and tested in the laboratory. With surveillance of AFP in place, the occurrence of a case of AFP in any given area would make that area a proxy “sentinel site” where stools from normal children would be collected. The program requirement to collect stools from five children who live in the same neighborhood as an index AFP case is already in place, but not all these specimens were processed in the laboratory. The previous requirement to process stools from contacts of only at-risk AFP cases (risk factors being age <6 years and the presence of fever at paralysis onset) would be expanded to contacts of all AFP cases, regardless of the presence of risk factors for confirmed poliomyelitis. This measure would ensure that approximately 10 000 additional stools would be processed each year. Since index cases of AFP that are not caused by wild poliovirus appear more or less at random, the accumulation of this large volume of information over 3–4 years (30 000–40 000 specimens) would be important additional data for the ICCPE to use in deciding about the absence of transmission. The laboratory processing of stools of at least five contacts per AFP case lessens the need for testing and sampling of sewage as a strategy for detecting transmission. However, sewage sampling and testing will be conducted in some selected areas of the Americas (e.g., Buenos Aires; Lima; the northeastern area of Brazil; Mexico City; Canada; and the United States).

With this background, the ICCPE has indicated that every country’s surveillance of AFP and wild poliovirus should meet five key surveillance indicators: (1) at least 80% of the all the health units included in the reporting network should be reporting regularly each week; (2) the rate of AFP cases should be approximately 1.0 case reported per 100 000 population <15 years of age; (3) at least 80% of all AFP cases reported should be investigated within 48 hours of reporting; (4) at least 80% of all AFP cases reported should have two stool specimens taken.
for virus culture within 2 weeks of paralysis onset; and (5) at least 80% of all AFP cases reported should have stool investigations of at least five contacts.

Active Case Searches in Areas of Poor Surveillance

A country's report should contain an account of active case searches in selected areas, using standardized methodologies. In particular, it should include identification of risk areas, the questionnaire employed, and analysis of the data collected.

Mop-up Immunization Campaigns Directed at Areas of Risk

The ICCPE recognizes two important concerns regarding certification of polio eradication in the countries. Some countries as a whole may meet all five of the AFP surveillance indicators described above; but within the country, smaller units, such as states, provinces, or districts, may not and thus will remain areas of concern. A second worry pertains to the so-called high-risk compatible cases which occurred within the last 4 years. A PAHO investigation revealed that among AFP cases, the ones most likely to be polio were those among children less than 6 years of age who experienced fever at the onset of paralysis (14, 27). Special mop-up immunization campaigns in areas where such cases occurred are important. Accordingly, spot maps of these high-risk compatible cases have been prepared. Reports (to be incorporated in the certification document) should be prepared describing the number of children under 5 years of age targeted for immunization, number or percentage immunized with OPV, and number of households visited.

Other certification strategies that should be highlighted in a country's final report include establishing a "rumor register," carrying out publicity campaigns, and setting up a system for rewards. The reward system established by PAHO in 1988 has not been readily accepted in all countries because some national health authorities fear that it would set a precedent with regard to the reporting of other diseases. In fact, no evidence of this has been found. Indeed, the smallpox experience demonstrated that rewards were an important adjuvant to other surveillance efforts. The smallpox rewards were initially small but were gradually increased to a high of US$ 1 000 offered by WHO in 1978. At present the polio reward offered by PAHO/WHO is US$ 100. Serious consideration should be given to increasing this reward, particularly in view of the approximately 2 years that have elapsed since the last culture-confirmed polio case in the Americas was reported in Junín, Peru, on 23 August 1991. Ecuador has already raised the reward to US$ 1 000.

Finally, border locations and areas with civil disorder, heavy migration, and refugee populations should receive special attention.

Surveillance of AFP will spearhead PAHO's efforts to certify that indigenous wild poliovirus transmission has been eradicated from the Americas. To that end, all countries must demonstrate that when cases of AFP occur, they will be identified, reported, and investigated in a timely manner to ensure that wild poliovirus will be recognized if it is present. Until global eradication is gained, much work still needs to be done to maintain the apparent polio-free status that has been achieved in the Western Hemisphere.

REFERENCES


26. Hurst CJ, Benton WH, McClellan KA. Thermal and water source effects upon


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**ANNOUNCEMENT**

**1994 Award in Honor of Fred L. Soper (1893–1976) for Publications in the Field of Inter-American Health**

This is a call for submission of nominations for the 1994 award in honor of Fred L. Soper, former Director (from 1947 to 1958) of the Pan American Health Organization, Regional Office of the World Health Organization for the Americas. In addition to his service with PAHO/WHO, Dr. Soper played a major role in the fight against yellow fever and other infectious diseases in Brazil, as part of his work with the Rockefeller Foundation in the 1920s and 1930s, and in the control of typhus in North Africa and Italy during the Second World War. He was one of the truly major figures in inter-American health in this century.

The award is presented annually to the author or authors of an original scientific contribution containing new information on, or insights into, the broad field of public health, with special relevance to Latin America, the Caribbean, or both. This work may be a report, an analysis of new data (experimental or observational), or a new approach to analyzing available data. Preference is given to studies involving more than one discipline and to papers related to infectious disease, a life-long concern of Dr. Soper.

Only papers published during calendar year 1993 in Latin American scientific journals listed in the Index Medicus or in the official journals of the Pan American Health Organization are eligible for consideration for the 1994 award. Furthermore, the award is limited to works by authors whose principal affiliation is with teaching, research, or service institutions located in the countries of Latin America and the Caribbean (including the Centers of the Pan American Health Organization).

The Award Fund is administered by the Pan American Health and Education Foundation (PAHEF), which receives voluntary contributions designated for the purpose and holds them in a separate fund. The award consists of a certificate and a monetary prize of US$ 400.00. Each year’s winner(s) are nominated by an Award Committee, composed of representatives designated by PAHO and by PAHEF; final selection is made by the Board of Trustees of PAHEF.

Papers meeting the above criteria and submitted by or on behalf of their authors may be considered for the Fred L. Soper Award. All submissions must be received by 31 March 1994 at the following address:

Executive Secretary
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Washington, D.C. 20037
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