Eighteen months – no polio!

Certification of Eradication of Poliomyelitis in the Americas: Update

On December 10, 1992, an ad hoc group of the International Commission for the Certification of Poliomyelitis Eradication (ICCPE) in the Americas, met at PAHO Headquarters in Washington, D.C. to review some of the issues involved in certifying the eradication of wild poliovirus in the Americas. The group (1) reviewed the experience of the program since the last Technical Advisory Group meeting in March 1992 and discussed statistical approaches to the certification process.

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1
Consultation Meeting participants acknowledged the progress the program has achieved. At the time of the meeting more than 64 weeks had passed since the last culture-confirmed polio case was reported in the Americas. Since the last culture-confirmed case was reported from Peru (date of paralysis onset 23 August 1991), the quality of surveillance of acute flaccid paralysis (AFP) has continued to improve there (EPI Newsletter, October, 1992).

Due to the current type 3 poliovirus outbreak in Holland, the countries of the Americas have been placed on alert, and have undertaken special efforts to immunize religious groups that have refused vaccination services in the past. Meeting participants concluded, however, that surveillance in some countries, such as those in the Caribbean, the Southern Cone of South America, the United States, Canada, and Colombia remain less than adequate.

A mathematical model (2) designed to estimate the probability of the occurrence of wild poliovirus transmission over time as of the last reported confirmed case of polio demonstrates that with good AFP surveillance and in the absence of cases of polio, the probability of undetected wild poliovirus continuing after four years of no detection is very low—less than five percent. Although the modeling is still preliminary, this finding underscores the importance of ensuring the quality of surveillance to both eradicate polio and certify its eradication. Accordingly, certification procedures should be closely linked to surveillance of AFP.

The participants agreed that because of seasonal variation in the incidence of polio in the tropics and fluctuating levels of OPV coverage, continuous community surveillance for wild poliovirus would produce more useful information for certification than episodic surveys. To that end, the certification plan will require that stools be taken and processed from at least five contacts of all AFP cases at risk for polio and that the stools all be analyzed through the Polio Laboratory Network. The data base generated by this process over the next 3 to 4 years would then be used by the Certification Commission to determine the likelihood that undetected wild poliovirus could continue to circulate despite the absence of reported polio cases.

Maintaining the AFP surveillance indicators continues to be the backbone of the program. As it did at the first meeting of the ICCPE in July 1990, the Commission recommends that in order for countries to be certified free of polio, they must maintain the following surveillance parameters:

**Surveillance of AFP**

- Weekly negative reporting of AFP should be implemented at all sentinel health units and at least 80% should report weekly;
- All cases of AFP should be investigated by an epidemiologist within 48 hours of being reported;
- Every country should report a minimum rate of 1.0 cases of AFP per 100,000 children under the age of 15 (the background rate of AFP);
- Two stool samples should be taken from 80% of these cases within two weeks after the onset of paralysis;
- The minimum clinical information necessary to assess the quality of the differential diagnosis should be reported for every case of AFP. Only the data reported through the Polio Eradication Surveillance System (PESS) will be used in the certification process.

**Surveillance of wild poliovirus**

- Stool samples from 5 or more contacts of each case should be taken and analyzed for at least 80% of all cases of AFP;
- No wild poliovirus isolated from AFP case or contact stool samples for at least 3 years;
- No wild poliovirus found through surveys of the environment;
- Only results obtained from the laboratories in the PAHO Network in the Americas will be considered valid;
- The presence of ice should be documented each time the transport container is opened, from the moment the stool sample is taken to the time it is received at the laboratory. There should be no history to suggest improper handling of samples during transport;
- For all cases of acute flaccid paralysis that end in death or residual paralysis, or are lost to follow-up and for which two stool specimens were taken within two weeks of paralysis onset and were reported to be negative, the samples should be retested in one additional PAHO Network Laboratory.

Only the ICCPE will be responsible for certification. As currently envisioned, the procedure will be carried out in two phases and could be implemented by sub-Region. Each country should already have a National Certification Committee made up of experts who will be responsible for organizing the data for review by the ICCPE. In the first phase, groups of countries will be certified by special commissions working with National Commissions (under the guidance of the ICCPE, whose members will make site visits). The special commissions will be responsible for preparing all the documentation necessary for final certification. Phase two will consist in the final review of all data for final certification.

**References**

(1) Dr. Frederick Robbins, Chairman of the ICCPE, Dr. D. A. Henderson, Chairman of the Technical Advisory Group, Dr. Sara Debanne, Case Western Reserve University Medical School, and PAHO/EPI Secretariat.
(2) Dr. Sara Debanne and Douglas Rowland, Case Western Reserve University Medical School.
The Use of BCG Vaccine

Background

Swollen axillary and cervical lymph nodes are a frequent side effect of vaccination with BCG. These should be thought of as a self-limited, natural outcome of vaccination that tends to disappear within 8 to 12 weeks.

Regional supplicative lymphadenitis (SL) is the most typical adverse effect associated with use of BCG. Seventy-five percent of SL cases occur during the first five months after vaccination. This period may be longer, however, and 10 percent of the SL cases occur up to 12 months after the date of vaccination (1). Generally, spontaneous recovery takes no longer than 20 weeks.

The frequency of complications depends on such factors as the bacterial concentration of the vaccine, the age of the child, and whether the inoculation is done properly. Even if a consistent vaccination technique is employed, the frequency of adverse effects may increase or decrease depending on the strain of BCG that is used to produce the vaccine. Under normal conditions, the frequency of SL per 1,000 children vaccinated varies from 0.1 in Denmark to 10 in Brazil and Mexico (1). The frequency in newborns is five times greater than in adolescents (1). Given the large number of variables that influence the incidence of SL, rates from different countries cannot be compared. Each country should therefore maintain records to monitor its own situation.

Several episodes of SL stemming from the use of BCG have been documented in world literature (2). These include cases in St. Lucia and other Caribbean countries in 1982, in Zimbabwe and Zaire in 1986, and in Mozambique in 1987. The studies found that errors in vaccination technique (mainly improper dilution) were the principal cause of SL. The vaccine strain being used had been changed at the same time. Zimbabwe and Zaire had changed from the Glaxo to the Pasteur strain, whereas St. Lucia had changed from the Glaxo to the Connaught strain. In Mozambique, the error was found to be the simultaneous use of the Tokyo, Connaught, and Pasteur strains. A second outbreak was caused by the use of Pasteur strain (2).

The frequency of SL among vaccinated persons in Mozambique was 1.3%, according to case reports kept in the routine reporting system. When an active case search was carried out, however, the reported rate rose to 7.4 percent. In Zimbabwe, 5 percent of those vaccinated with BCG had some form of regional lymphadenitis. In Jamaica, the frequency of SL varied according to the age of the child, from 1.92 percent in children vaccinated at under the age of 6 weeks, to 0.7 percent in those who were older than that (3). On average, 0.9 percent of vaccinated children of all ages had adverse effects.

The World Health Organization and UNICEF have recommended that newborns be given 0.05 ml instead of 0.1 ml of BCG, to reduce the frequency of adverse effects while maintaining tuberculin immunoeconversion. This proposal has not yet been accepted by all of the countries in the Americas. The differences among national vaccination practices have made it difficult for laboratories that produce the vaccine to issue standard instructions for its use. As a result, they have lobbied for the adoption of a universal schedule. A standard schedule does not exist in the Americas because many countries believe that the 0.1 ml dose is more effective in protecting children from the disease.

The use of BCG in the Americas

Before making a recommendation whether or not to use the 0.05 ml dose, PAHO consulted the countries of the Region, with the exception of the U.S. and Canada, on their use of BCG. The current situation in the Region can be summarized as follows: approximately 13 million children are born yearly in the countries surveyed. Ten million of these children live in countries that use a 0.1 ml dose and achieved 80% coverage with it in 1990-1991 without a single recorded incident of SL. Approximately 7 million of the 10 million children live in 6 countries that produce all or part of the vaccine they use. The majority of those countries do not have a system to monitor the adverse effects or the efficacy of the vaccine. All of them maintain registries for tuberculous meningitis but they do not carry out systematic epidemiologic case investigations. Many of the countries surveyed, including those that do not produce the vaccine, are reluctant to change their vaccination schedules because they wish to avoid the operational problems that may be ensue with vaccination personnel that are trained to carry out an established routine. Other countries do not foresee any problems in changing the dose from 0.1 ml to 0.05 ml.

This is the time for each country to weigh the costs of maintaining or changing its schedule, since future vaccine lots purchased from abroad will be issued with instructions for the use of 0.005 ml doses.

In summary, it can be stated that SL resulting from the use of BCG is an expected adverse effect that should be viewed as the price to be paid for the benefit of preventing tuberculosis. Its frequency should be monitored regularly. It is also important to maintain a system to control the quality of the vaccine used in the Region, especially in countries that produce it, and to monitor vaccine efficacy by means of studies.

Given the above, it is advisable that:

1) all countries of the Region maintain, improve, or set up an epidemiologic surveillance system for tuberculous meningitis and miliary tuberculosis in children under the age of five, in addition to conducting case investigations of reported adverse effects resulting from vaccination with BCG.

2) the countries that produce vaccine for national use maintain, improve, or establish a quality control system for the vaccine produced. This will entail sending samples of the lots to be tested systematically in national quality control laboratories and, periodically, in the Pan American Institute for Food Protection and Zoonosis (INPPAZ), the reference laboratory for WHO in the Americas.

3) the countries that purchase BCG vaccine prepare to make the operational changes required to administer the 0.05 ml dose instead of the 0.1 ml dose, in view of the fact...
that all future lots of BCG acquired on the international market will enclose instructions for the use of 0.05 ml doses.

References


General Considerations

Weekly notification of neonatal tetanus (NNT) has been mandatory in Venezuela since 1970. Before that, only mortality data for NNT were available.

Neonatal tetanus was a principal cause of death in the 1970s although the case fatality rate was low compared to other countries. The surveillance system was very sensitive, so false positives are included among the reported cases, according to Halbrohr (1). Geographically, all the states of the country recorded cases of neonatal tetanus.

In 1970, two basic strategies were adopted to reduce the frequency of this disease, as follows:

1. To achieve sanitary childbirth conditions by recruiting and training midwives and hospitalizing deliveries.

2. To vaccinate pregnant women with tetanus toxoid.

Figure 1 shows the trend in this disease by five-year periods. When the 1970-1974 period is compared to 1985-1989, an 87.3% decrease in morbidity and 83.8% reduction in mortality are observed. If the years 1990 and 1991 are included in the analysis, morbidity declines by 94.3% and mortality by 92.9% compared with the first five-year period.

An analysis of NNT cases in the last three years reveals that 46% of all reported cases are from the state of Zulia.

Maps 1, 2 and 3 show the states that have reported cases in the last three years. Map 4 shows the counties that reported cases in 1992.

Epidemiologic characteristics

An epidemiologic investigation of NNT cases yielded the following results for 1990 and 1991.

1. The risk of NNT in Venezuela is 12 times greater in rural areas than in urban areas.

2. Ninety-two% of the mothers of NNT cases had received only one dose of tetanus toxoid or had received none at all.

3. Ninety-three% of the NNT cases occurred as a result of out-of-hospital births. The children who were born in hospitals became infected at home, after being released from the hospital. A study carried out in 1986-1989 revealed that 84.5% of the cases occurred out of the hospital (2).

4. Regarding care during delivery, it was observed that 37% of the cases took place at birth when deliveries were attended by a midwife, 58% when they were attended by unqualified personnel (neighbors, relatives, or the laboring woman herself, and 5% when attended by doctors (hospital births).

5. Fifty% of the mothers were illiterate or had only one year of schooling.

6. The mothers had an average of five children.

7. A striking observation was that almost 50% of all cases between 1989 and 1991 occurred among the indigenous Wayu population that inhabits the Guajira region (in the state of Zulia).

Plan of Action

These results were important for implementing the Plan to Eliminate Neonatal Tetanus (2). The counties at risk were identified using indicators recommended by PAHO, that is, those with cases in the years 1989, 1990, and 1991. A study carried out by PAHO in Venezuela identified the counties with the highest percentage of Unsatisfied Basic Needs, or UBN, a set of poverty indicators including housing, sanitation, school attendance, and relationships between income and family size. These were cross tabulated the data with epidemiologic data on NNT.

The analysis revealed that the highest incidence occurred in counties with 90% or more of UBN (Figure 2).
resulting recommendation was that after vaccinating women in the counties that had cases of NNT, vaccination activities would be started in counties in which there were no cases but where the percent of UBN was 90% or greater. The strategy was supported by the Child Foundation, headed by the First Lady of Venezuela, and the Ministry of Health and Social Welfare, which are the leading institutions in the Program to Eliminate Neonatal Tetanus.

The plan, which was started in April 1992, identified 48 counties at risk. Given that the vast majority of cases of NNT occur out of hospital, emphasis was placed in identifying the women of childbearing age who were at greatest risk, i.e., those who were unvaccinated and those who did not have access to hospital delivery services. Based on the available data, only 7% of the births in Venezuela occur outside a hospital (the figure varies from 0.5% to 30%, depending on the state involved) and the number of high-risk women was estimated at 65,000.

In 1992, 26 cases were recorded, 21 of which occurred in 18 counties at risk and 5 of which occurred in counties that had not been classified at risk. In other words, 87% of the cases occurred in counties at risk and 13% occurred in new counties. A door-to-door vaccination campaign was initiated in all the high-risk counties that reported cases in 1992. As a result of the campaign, 21% of women of childbearing age in the at-risk areas received one dose and 75% received two or more doses of tetanus toxoid.

Source: This article was prepared by Drs. Adella Betancourt de M., EPI/MSAS Coordinator in Venezuela, and Airton Fischman, EPI/PAHO Consultant in Venezuela.

References


(3) Boletín Epidemiológico Semanal, MSAS/Ven, 41 (47):3512.
Global EPI Progress Reviewed

The Global Advisory Group of the WHO Expanded Program on Immunization held its 15th meeting in Jakarta, Indonesia from 12 to 16 October 1992. The Group reviewed progress in the African, American, Eastern Mediterranean, European, Southeast Asian, and Western Pacific regions of WHO. It then focused discussions on the following areas of interest:

* Integrated and sustainable approaches to achieving and maintaining high coverage rates, measles control, the elimination of neonatal tetanus and the eradication of polio

* Research and development efforts in the production of new vaccines

* Special issues in disease control, including the selection and use of surveillance indicators and using immunization contacts to combat vitamin deficiency disorders

* Logistics and cold chain updates

The 1991 global immunization coverage was 85% for BCG, 78% for measles, 81% for three doses of OPV, and 79% for three doses of DPT. Coverage for tetanus toxoid for pregnant women in developing countries was 42%. These levels were estimated to be equivalent to averting 2.9 million deaths each year due to measles, neonatal tetanus and pertussis. However, 2.1 million such preventable deaths still occurred.

The Group reaffirmed that immunization are among the most cost-effective of all health services and should remain a top health and development priority. Nonetheless, the 1991 figures indicate that the world-wide economic crisis has led to stagnation or slippage of coverage, especially in the African region. The Group expressed concern about this because it may suggest that "the sustainability of past accomplishments is being threatened, and progress is being blunted in reaching the 'hard to reach' populations who bear a disproportionate burden from vaccine preventable diseases, as well as other conditions preventable by primary health care."

Immunization campaigns as a means to eliminate measles, such as those being conducted in some countries in the Region of the Americas, as well as other approaches, should be evaluated as possible future strategies for the eventual global eradication of measles.

Despite these threatened setbacks, the virtual eradication of poliomyelitis from the Americas was cited as an example of what can be done when efforts are joined toward such an achievable goal. The Group underlined the need to invest additional resources now in the campaigns to eradicate poliomyelitis, eliminate neonatal tetanus, and reduce measles, or the goals will not be achieved.


Preparing a Cold Box for Vaccine Transport

Attention!

* Bacterial vaccines and toxoids such as DPT, TT, DT, and Dt, should never be frozen.

* Cold packs removed from the freezer of cold storage equipment and placed in the cold box immediately, may freeze these vaccines.

* To avoid this, do the following:

1. Cold packs taken from the freezer may be very cold (-5° C to -30° C).

2. Leave cold packs at room temperature for a few minutes until water, or "sweat," appears on the surface of the packs.

3. Place the packs that are "sweating" in the cold box. They are at 0° C.

4. Now you can safely put in the bacterial vaccines and toxoids.

Drawing: Victor Gómez
## Reported Cases of EPI Diseases

Number of reported cases of measles, poliomyelitis, tetanus, diphtheria, and whooping cough, from 1 January 1992 to date of last report, and the same epidemiological period in 1991, by country.

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- Data not available.
Poliomyelitis in The Netherlands: Update

The outbreak in the Netherlands of poliomyelitis among unvaccinated persons who are members of religious groups that generally do not accept vaccination is continuing (1). From September 17 through December 5, 1992, 54 cases of poliomyelitis were reported to the Netherlands' Office of the Chief Medical Officer of Health. Of the 54 patients, 41 (76%) had paralytic manifestations of this illness; one neonate died, and 12 patients had aseptic meningitis. Fifty-one (94%) of these cases have been laboratory confirmed: 40 patients had wild poliovirus type 3 isolated from stool, and 11 had IgM-specific antibody to poliovirus type 3 suggestive of recent infection. All of the reported cases have occurred among unvaccinated (n=53) or inadequately vaccinated (n=1) persons belonging to a religious denomination that routinely does not accept vaccination. Patients ranged in age from <1 month to 56 years (mean age: 18.9 years). Of the 12 provinces in the Netherlands, seven have reported cases of poliomyelitis; the most severely affected provinces are South Holland and Gelderland.

Editorial Note: The poliomyelitis epidemic in the Netherlands continues despite control measures initiated by the Dutch health authorities, including offering oral poliovirus vaccine to all previously unvaccinated persons aged <41 years and offering one dose of enhanced-potency inactivated poliovirus vaccine to persons who are completely vaccinated. Based on the ratio of cases of asymptomatic infection to paralytic disease for persons infected with poliovirus type 3 (at least 1000:1) (2), an estimated 54,000 persons in the Netherlands may have been infected with wild poliovirus type 3 during this outbreak. Therefore, the risk for infection may be greater than previously assumed for unvaccinated or inadequately vaccinated travelers to the Netherlands. In addition, the potential for spread of this poliovirus to other countries by asymptomatically infected travelers from the Netherlands—even if not directly linked to a clinical case—also may be higher than previously assumed.

To prevent transmission of imported polioviruses and cases of paralytic disease, increased efforts are necessary to vaccinate all unvaccinated or inadequately vaccinated persons (3,4). Public health agencies and health-care providers should intensify outreach, especially to unvaccinated persons in these religious communities who do not routinely accept vaccination.

The risk for acquiring poliomyelitis while in the Netherlands is considered small because of the excellent sanitation in the country and because transmission of the poliovirus has been limited primarily to unvaccinated religious groups. Nonetheless, the polio immunity of travelers to the Netherlands should be evaluated, and persons with inadequate protection should complete a primary vaccination series with three doses of poliovirus vaccine before departure. For travelers with a completed primary series of poliovirus vaccine, it may be prudent to obtain one dose of poliovirus vaccine before departure, especially if extensive travel in the Netherlands or contact with persons in the affected religious groups is anticipated.


References

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References to commercial products and the publication of signed articles in this Newsletter do not constitute endorsement by PAHO/WHO, nor do they necessarily represent the policy of the Organization.

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