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THIRD MEETING OF THE EPI TECHNICAL ADVISORY GROUP (TAG) ON POLIO ERADICATION IN THE AMERICAS

BRASILIA, 10-12 SEPTEMBER 1986

FINAL REPORT

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In the eight months since the second meeting of the EPI Technical Advisory Group (TAG) in Mexico, significant progress has been made and several important developments have occurred. Two national vaccination days have been held in Mexico, the two regularly scheduled vaccination days were carried out in Brazil, and several other countries have intensified their activities. PAHO has initiated a weekly bulletin to chart progress. The EPI program managers from the Latin American countries have met and developed plans for the coming biennium. In the fiscal arena, the U.S. Agency for International Development has committed $20.6 million to the hemispheric polio eradication effort, the Interamerican Development Bank is expected to commit approximately $5.5 million, and Rotary International has made major commitments to EPI worldwide ($23 million to date), with a substantial proportion of these commitments being made in the Americas. UNICEF has continued its support, which, so far, amounts to about $17 million. In addition, the evaluation of laboratory capabilities throughout the Region has been completed, a manual of laboratory methods has been developed, and the first international course on laboratory techniques is currently underway in Rio de Janeiro. A field manual for polio surveillance has been developed and is undergoing review, and improved surveillance techniques are being evaluated in two countries. While an excellent foundation for the program is being laid and many national programs are making good progress, unexpected problems have occurred which require immediate attention, most notably, an unanticipated increase in the incidence of poliomyelitis in Brazil.

Against this background, the Third TAG Meeting was held in Brasilia 10-12 September 1986. The meeting was inaugurated by Dr. Roberto Santos, Minister of Health, and Dr. Florentino Garcia Scarponi, PAHO Country Representative. The meeting was chaired by Dr. D. A. Henderson and Dr. Alan Hinman served as rapporteur. A complete list of participants as well as the agenda of the meeting is attached. The following represents a brief summary of the main agenda items and the conclusions and recommendations of the TAG.

PRESENT STATUS OF POLIO IN THE AMERICAS

Through week 35 of 1986, a total of 700 cases of polio had been reported from the Americas, compared with a total of 359 cases reported during the same period of 1985 and an annual total of 488 in 1985. Eight countries have reported polio thus far in 1986: Bolivia, Brazil, Colombia, Guatemala, Haiti, Mexico, Peru, and Venezuela. Only three countries have reported a significant increase in cases during 1986 (Brazil, Colombia, and Guatemala) but the largest increase has been in Brazil, which accounts for 66% of all cases reported in the hemisphere.

Through week 36 of 1986, a total of 724 suspected cases have been notified in Brazil. Of these, 157 are still under study, 319 have been classified as probable cases, 191 have been confirmed, and 57 are believed to be due to other causes. More detailed analysis of cases reported through week 31 indicates that 53.6% of cases have occurred in children less than 2 years of age, and 84.1% in children less than 5 years of age. Of cases from which a poliovirus has been isolated and typed, 71.6% were due to Type 3 and 20.0% to Type 1. This is to be contrasted with the situation in 1985, when Type 3 poliovirus accounted for only 23.7% of cases and Type 1 accounted for 72.4%. No vaccine had been received by 16.5% of cases, 31.7% had received 1 or 2 doses, 36.6% had received 3 or more doses, and 14% had unknown vaccination histories. Cases were concentrated in the northeastern part of the country (see below).

POLIO ERADICATION PROGRAM IN BRAZIL

Because of the high incidence of polio in Brazil, it was decided in 1979 to accelerate the immunization program. In 1980 National Polio Vaccination Days were begun, with two campaigns per year (in June and August) aiming to provide OPV to all children less than 5 years of age (approximately 20 million) regardless of prior vaccination history. Participation in the campaigns was excellent during the first eight cycles (1980-1983) with 95% or more of the expected vaccinations being given. However, in 1984 participation declined to 85-90% and in 1985 to 80-85%. The reasons for the decrease in participation are thought to include:

- decreased logistical support
- with the decreased incidence of polio, a growing perception that the disease is no longer a threat
- lower participation by children who had already received 3 or more doses
- lessened attention to the preparatory phases of each vaccination day
- introduction of other antigens, which complicated operations and necessitated further training.

Several steps have been taken to increase participation, including:

- designation of national and state level polio eradication coordinators
- special immunization days in the Northeast
- increased training of staff
- relocation of vaccination posts
- consultation/evaluation in the Northeast
- improvements in social marketing and health education

Before 1986 most health education messages were directed primarily at participation in campaigns. Now, efforts at social mobilization focus also on the concept of polio eradication as well as participation in campaigns. The mass media, schools (both public and private), and religious organizations are all involved in these efforts. Problems of inadequate coordination at the local level are being addressed by inter-sectoral seminars, and special seminars are being held in areas

with large numbers of cases or low participation rates. There has also been a strong move to assure uniformity of approach.

The current plan of action includes:

- formation of Executive Commissions at national and state levels
- community education/mobilization
- surveillance (case investigation, completion of pending investigations, training, information systems, information dissemination, and active search for cases)
- vaccination activities (routine vaccination, campaigns, "bloqueos," and coverage surveys)
- development of the laboratory network.

Coverage in the two 1986 cycles has improved somewhat over 1985, with 88% participation in the June campaign and 81% in the August campaign.

An additional component of the program in Brazil has been a pilot program of active search for cases through hospitals and health care settings likely to see cases of acute paralytic illness. In the state of Rio de Janeiro, appropriate ICDA codes were identified which might represent polio cases and hospitals were asked to identify individuals who would be responsible for reporting each week whether any cases diagnosed under these codes had been seen. Of 25 suspected cases reported thus far in 1986 in the state, 19 came from the hospital system; 8 cases have been confirmed as polio. In São Paulo, an intensive investigation is underway to detect the cause of all acute neurological illnesses which might possibly be polio. This involves testing for 23 different possible etiological agents.

Exciting data were presented from Bahia regarding the operation of the surveillance system in that state. Some of the indicators being followed included: proportion of cases with complete information, length of time required to complete an investigation, and rapidity with which investigations were carried out. In addition, useful analyses of coverage have been carried out to determine the number of "municipios" with coverage of at least 80% in each cycle in 1986.

TYPE 3 POLIO IN NORTHEASTERN BRAZIL

In February 1986 an outbreak of paralytic poliomyelitis began in the Northeastern Region of Brazil. By June 30, a total of 107 confirmed cases and 166 probable cases had been reported. Of 71 cases with laboratory confirmation, 56 (80%) were caused by Type 3 poliovirus, which was a change from the pattern observed during the past four years. Investigations revealed that 36% of confirmed cases had received at least three doses of OPV. Estimates of vaccine efficacy suggested that efficacy in infants and one-year-old children was lower than expected, although precise calculation of efficacy was not possible due to lack of exact information on the proportion of children in each age group who had received specified numbers of doses of vaccine. Serologic studies of

cases indicated that the mean titer of antibodies to Type 3 virus was lower than that to Types 1 and 2, possibly although not conclusively indicating a lower than desired effectiveness of the Type 3 component of the vaccine. Studies of bulk and finished vaccine titers at FIOCRUZ also indicated the possibility that the virus titer in the Type 3 component might be low, although other studies of FIOCRUZ and the PAHO reference laboratory did not confirm this.

Because of the current outbreak due to Type 3, it was decided to hold a special vaccination campaign in the Northeast and this was accomplished in April. However, the campaign did not stop the spread of cases, again suggesting there might be lower than normal efficacy, either as a result of insufficient Type 3 virus at the time of production or because of deficiencies in the cold chain. To gain further understanding of the serologic responses of children to different formulations of the Type 3 vaccine, special studies are now underway in Recife to evaluate the serologic responses to three different preparations of Type 3 OPV (monovalent, trivalent, and trivalent with twice the present titer of Type 3) to determine whether monovalent Type 3 vaccine or trivalent vaccine with an increased titer of Type 3 is required to provide an adequate serological response. The study involves 734 children aged 2 months to 5 years divided equally into the three vaccine groups. Most of the children have received some OPV previously (more than one-half have received one or two doses and approximately one-third have received three or four doses).

POLIO ERADICATION PROGRAM IN MEXICO

The two national immunization days (in January and April) were apparent successes with vaccinations in the second cycle reported to be equivalent to 95.3% of the target population. Rapid coverage surveys carried out in several states in the week following the second cycle suggested that the actual coverage was probably on the order of 80-85%. The technique of rapid coverage assessment was thought to be quite useful and will be continued. These surveys also provided valuable information on the reasons why some children did not participate. Key among these was that the child was ill on the day of the campaign. Since this should not have prevented participation, this knowledge is important in planning health education topics for the next cycle.

Important changes have taken place in the surveillance system in Mexico. A surveillance manual has been developed and distributed to state epidemiologists. All suspected cases are being investigated (usually within 24 hours) by trained epidemiologists from the central level. Although 1986 began with a large number of reported cases of polio, there has been a striking drop-off in incidence since the second campaign and, for the first time, there are now weeks in which no cases are reported.

POLIO ERADICATION PROGRAMS IN OTHER COUNTRIES

Brief reports were received of the programs in Colombia, Ecuador, and Peru. These reports highlighted some of the problems being faced both with surveillance and with vaccination coverage.

PARALYSIS ASSOCIATED WITH ORAL POLIO VACCINE

Information was presented about the experience with vaccine-associated polio in the United States. In the 12-year period 1973-1984, 105 (76%) of the 138 poliomyelitis cases reported were considered to be vaccine-associated: 35 occurred in recipients of OPV, 50 were in contacts of OPV recipients, 14 were in immune-deficient individuals, and 6 were in individuals with no history of receipt of, or contact with, OPV but from whom vaccine-like viruses were isolated. The overall frequency of vaccine-associated paralysis was 1 case per 2.6 million doses of OPV distributed. However, the relative frequency of paralysis varied according to the dose in series--the frequency associated with the first dose was 1 case per 520,000 doses whereas for subsequent doses it was 1 case per 12.3 million doses.

Data are not currently available from other countries in the Americas but these rates are compatible with those found in the international study coordinated by WHO for the period 1970-1979. As paralysis due to wild poliovirus becomes less and less frequent in the Region, it can be anticipated that a higher proportion will be vaccine-associated. While this serves to emphasize the importance of prompt and thorough investigation of every case of poliomyelitis, it should be recognized that available experience suggests that no more than 10-20 vaccine-associated cases will occur annually in Latin America.

CONCLUSIONS AND RECOMMENDATIONS

The TAG notes with pleasure the striking progress that has been made since the last meeting. This is particularly evident in Brazil and Mexico. The Group also wishes to express its appreciation for the rapid and generous support of bilateral and international agencies (e.g. USAID, UNICEF) and voluntary agencies such as Rotary International. This support has been a key factor in the progress achieved to date. In the face of all the external support being provided, it is essential for countries to begin now to plan for the continuation of efforts once the period of external funding has come to an end. Notwithstanding the progress to date, several problems remain which threaten the success of the program. Some of these are addressed below, by category.

1. National management

The intersectoral nature of the program, its national (and international) scope, and the multiplicity of external funding sources make it essential that an individual or small group be designated at the national level and given the responsibility for coordinating the program. This individual or group should also have the authority to affect policy.

2. Operational issues

Vaccination coverage should more regularly be analyzed at the level of the "municipio" (or smaller) and special efforts should be planned to increase coverage in areas where coverage is lower than 80%. This might include special vaccination cycles. Because of the problems in using

available population data to estimate coverage, other techniques, such as the rapid coverage surveys being used in Mexico, should be considered to obtain accurate data.

The occurrence of cases in areas where there have been repeated vaccination cycles (such as in Northeastern Brazil) raises questions about the adequacy of the cold chain. A special study of its adequacy would appear to be warranted. In all countries, however, continued attention to the appropriate conservation of vaccines from the manufacturer to the vaccine recipient is essential because of OPV's extreme sensitivity to heat.

Although the inclusion of other antigens in programs which have previously been exclusively directed at polio introduces operational complexities, the TAG continues to feel that efforts should be made to include other EPI antigens in the campaigns.

3. Surveillance

Considerable progress has been made in developing surveillance manuals and a beginning has made in the development of national surveillance systems. Nonetheless, surveillance issues continue to pose the most critical problems. The TAG notes that in some countries the number of suspected cases notified is equal to, or greater than, the number of probable or confirmed cases. The SUSPECTED case categorization should be very temporary. Within 48 hours of initial notification, every SUSPECTED case should either be categorized as a PROBABLE case or dropped as due to some other cause. Similarly, PROBABLE cases should be finally classified within 10 weeks of notification as either CONFIRMED polio or NOT POLIO.

All investigations should be carried out by specially trained epidemiologists from the state (in large countries such as Brazil) or national level. Every effort should be made to obtain both acute AND convalescent sera as well as stool specimens in order to increase the likelihood of confirming the case. Efforts should also be made to determine WHY the case occurred--vaccine failure, unvaccinated child (and if unvaccinated, why?), etc.--as a guide for remedial efforts.

Surveillance systems will undoubtedly vary from country to country and even within countries. Nonetheless, some common principles should be followed. At least one reporting source should be identified in each "municipio" (or comparable small geo-political unit) and should report to the state (or national) level each week, whether polio cases have been seen or not. Participation of the reporting source should be monitored as one form of evaluation of the surveillance system. Other indicators of the adequacy of the surveillance system should be developed and used, including the interval between case onset and notification, interval between notification and investigation, proportion of cases with complete information, length of time to complete the investigation, proportion of reporting sources reporting each week, etc.

All countries reporting few or no cases should augment their detection system by identifying all hospitals and rehabilitation centers where cases are apt to be seen and by asking them to report each week all

cases of febrile paralytic disease, Guillain-Barré syndrome and transverse myelitis. This will undoubtedly require repeated visits by program surveillance officers to establish the system. All such cases should be investigated by specially trained epidemiologists and laboratory specimens should be obtained and tested promptly. Other efforts to confirm the absence of polio might include lameness surveys in areas which have gone several years without reported cases.

4. Laboratory support

Improvements in laboratory support and development of a comprehensive laboratory network are urgently needed. The TAG notes the considerable progress that has already been made in the evaluation of national laboratories, the development of laboratory manuals, and the training of laboratory personnel. As a next step, the TAG feels it appropriate for PAHO to designate a limited number of laboratories (5-6) to receive immediate support which would allow them to function as international resources. Based on the evaluations carried out, the TAG suggests that the laboratories of Argentina, Brazil (FIOCRUZ), Colombia, Guatemala, Mexico, and Trinidad (CAREC) might be appropriate selections for the first stage of development.

For purposes of polio eradication, the primary diagnostic information needed from the laboratory is whether the causative agent is poliovirus or not. It is not necessary to pursue further a possible non-polio etiology. In a few areas, however, where capacity already exists, it will be of interest to carry out the more complex and expensive tests necessary to identify the non-poliovirus etiologic agent on at least a sample of cases. The decision to carry out this additional effort should be made in the full awareness of the costs and labor involved.

In some countries, the close coordination necessary between the laboratory and the epidemiologists/program managers has not yet been developed. The laboratory plays a critical role in surveillance, which itself is key to the success of the program. Every effort should be made to ensure that laboratory, epidemiologic, and operational personnel work closely and effectively together, perhaps to the extent of including representatives of each activity in case or outbreak investigations.

5. Research

Both basic and operational research will be required in the eradication program. The most pressing needs seem to be in the area of operational research targeted to solve existing problems--e.g. cold chain system, vaccine non-acceptance, most effective surveillance tools in a particular area. Additionally, consideration should be given to an evaluation of coverage by individual year of age to determine whether 3- and 4-year-old children are participating in vaccination days to the same extent as infants and younger children, and whether inclusion of 3- and 4-year-olds in the target population affects estimates of coverage in the population most at risk. More basic tools are also needed, such as a rapid test to differentiate wild from vaccine virus. The TAG believes PAHO should coordinate development of a formal research agenda and then seek to ensure the research is carried out.

6. Brazil

The Type 3 outbreak in the Northeast is puzzling and apparently could be due either to selective failure of the Type 3 component of OPV or to overall failure of OPV (e.g. because of cold chain problems) in an environment where Type 3 poliovirus happened to be circulating. The steps that have been taken to address the current problem are appropriate and the studies now underway should be completed as soon as possible. Further approaches which might be taken to help identify the causes of the problem include a careful evaluation of the cold chain, assessment of coverage at the local level by means of surveys to determine if low coverage may exist in affected areas, and further analysis of available data to see if there is any apparent difference in clinical efficacy of the Type 1 and Type 3 components. If there is any indication of problems with the cold chain, the use of temperature indicators to accompany vaccine should be considered.

7. Next TAG meeting

The next TAG meeting was tentatively set for late April 1987, in Guatemala. Primary agenda items should include presentations on the current status of activities in the Central American countries, updates from Brazil and Mexico, discussion of Type 3 poliovirus and vaccine, and consideration of a research agenda.