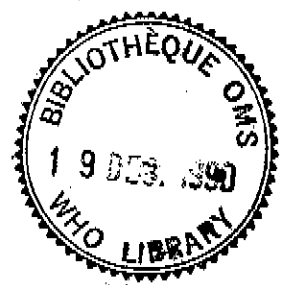


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WHO/EPI/POLIO/90.3  
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DISTR.: LIMITED



**EXPANDED  
PROGRAMME ON  
IMMUNIZATION**



**ERADICATION OF  
POLIOMYELITIS**

**Report of the Third Consultation  
Geneva, 3-6 September 1990**



**World Health Organization**

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## SUMMARY

The Consultative Group is immensely impressed by the progress made in global polio eradication during the past year. Important new initiatives in planning, training and programme coordination have been taken by Headquarters and Regional Office staff. In the Region of the Americas, polio transmission appears to be on the verge of being interrupted; many countries in other Regions have strengthened their programmes and have evidenced increased political commitment. Provided that still serious deficiencies in surveillance, in the quality of vaccines in a few countries and in laboratory diagnostic support services can be addressed, it is reasonable to anticipate interruption of transmission in all or major parts of four Regions and in some countries of the other two Regions by 1995. The tactics employed are evolving through empirical experience and research findings responding to programme needs.

While applauding the achievements, the Consultative Group must nevertheless point out that redoubled efforts will be needed if eradication is to be achieved by the Year 2000 target date. A demonstrable political commitment is not yet apparent in all countries; added resources are required both for programme implementation and research; and indeed important developments, especially in diagnostic tests, improved vaccines and the epidemiological understanding of poliomyelitis are requisite. Research initiatives will need to be fully responsive to programme requirements and closely coordinated with field activities. Preparation of a comprehensive and integrated research plan which takes into account national and international resources and initiatives is a high priority. Needed funds should be justified and presented in a manner so that the document can be used to solicit contributions from donors. It is the Group's belief that these problems can be satisfactorily addressed but the magnitude of the task should not be underestimated.

The potential of the poliomyelitis eradication initiative for strengthening the whole of EPI, especially in surveillance, and other basic health services is apparent from the experience in the Americas. This indeed was an outcome which had been anticipated when global eradication was proposed and agreed. The Consultative Group encourages a continued strengthening and coordination of the effort within and outside the Organization itself.

## MAJOR RECOMMENDATIONS

- i) *Although attainment of high (70% or more) immunization coverage with OPV-3, either by routine services or by mass immunization campaigns, will reduce polio incidence to low levels, additional supplementary policies are usually necessary to achieve interruption of wild poliovirus transmission. Specifically, "mopping-up" operations, in which OPV is administered, ideally on a house-to-house basis, to all children under five in a defined area, have been found to be effective in achieving this interruption in high-risk areas.*
- ii) *To increase immunization coverage to levels high enough to reduce polio incidence, vaccination days may be considered as an epidemiologically sound policy for eradicating wild poliovirus, especially in countries or areas of countries having poor health infrastructures or persisting poliovirus transmission.*
- iii) *Surveillance is the critical strategy for detection of cases of polio and the identification of factors responsible for these cases. Such a strategy will form the basis for sound and epidemiologically correct policies.*
- iv) *For the next 12 months, the use of specific basic surveillance indicators to monitor progress should be promoted at Regional and National levels. These indicators should include those for completeness of reporting, timeliness and completeness of case investigation, and confirming a capacity to identify flaccid paralysis in the population. Feed back to reporting units is an important component of a surveillance system and should be part of the monitoring process.*
- v) *A prompt response to detected outbreaks is necessary and, especially as polio incidence declines, should include four elements:*
  - *initial rapid investigation of cases, including preparation of a line-list of cases, confirmation of diagnosis by the most expert staff available and collection of specimens;*
  - *active surveillance for additional cases;*
  - *immunization conducted ideally on a house-to-house basis in as wide an area as practical; with mopping-up operations conducted later, if appropriate.*
  - *analysis of the outbreak to determine the cause followed by appropriate corrective action based on this analysis*
- vi) *Research activities are critical to evaluate the impact of immunization strategies and must be responsive to the needs of the field. In order to coordinate research on certain topics important to the polio eradication initiative, e.g. in diagnostic test development, vaccine improvement, and operational studies, a liaison post should be created in the WHO secretariat to help coordinate scientific research programmes on polio eradication. These activities will need to be undertaken in the closest collaboration with those responsible for field operations.*

## OBJECTIVE

Participants in the 3rd Consultation on the Eradication of Poliomyelitis concentrated solely on formulating technical policies most likely to lead to the eradication of polio.

It rests with the WHO Secretariat, the EPI Global Advisory Group and responsible national health authorities to incorporate the principles and recommendations included in this report into their EPI plans.

The eradication of poliomyelitis by 2000 will represent a major triumph for both national health authorities and the international agencies, leading to better health care delivery and a wider range of available skilled services.

## GLOSSARY

In this report, the following definitions are used:

**"Coverage"**

The percentage of children who have received a full scheduled course of vaccines before reaching the age of 12 months.

**"Outbreak response"**

The immediate actions to be taken when cases, suspected to be acute polio, are detected.

**"Mopping-up"**

Activities to be undertaken in areas where there is perceived to be a high risk of persisting transmission of wild poliovirus. In general, these actions will involve immunization with trivalent oral poliovaccine (two rounds, at least one month apart, ideally, house-to-house, to all children under five years of age, regardless of immunization status), and usually with other EPI antigens to an appropriate age group, in areas of recent (within three years) reports of polio cases, areas where cases are still occurring and areas of lowest immunization coverage with poliovaccine.

## 1. INTRODUCTION

From 3-6 September 1990, the third Consultation on the Eradication of Poliomyelitis was convened in Geneva. The agenda included a number of key topics, mainly concerning operational issues, such as developing polio immunization policies, improving surveillance for flaccid paralysis, creation of the polio laboratory network and testing for poliovirus in the environment.

The meeting was opened by Dr R.H. Henderson, Assistant Director General, WHO, who welcomed participants on behalf of Dr H. Nakajima, the Director-General. He particularly welcomed the EPI managers from several countries and the WHO Regional Office staff having special responsibilities for polio eradication. He stressed the need for managers of immunization programmes and for Regional Office staff to be involved in the planning and monitoring of policies that they will be responsible for implementing.

Dr Henderson emphasised the importance that WHO attached to the series of Polio Consultations. Reports of the discussions and recommendations of the second Consultation had been widely circulated to concerned staff and had later been discussed at meetings of EPI managers, eventually exerting a strong influence on the development of policies at the Global, Regional and National levels.

Participants reviewed the background documentation prepared for the meeting, considered presentations on the different agenda items and reviewed progress towards polio eradication in each Region and in the countries represented.

Based on their review of progress at different levels, and on experience gained in identifying both successful policies and problems encountered in the initiative, participants were able to define the principles through which polio eradication could most reliably be achieved. The recommendations developed are included in the appropriate section of this report, while those considered to be critically important are detailed on page 1.

## 2. OVERVIEWS

### 2.1 GLOBAL EXPANDED PROGRAMME ON IMMUNIZATION (EPI)

As the decade of the 1990s begins, the EPI has already achieved remarkable success. By mid-1990, 73% of children in developing countries alone are receiving a full course of poliovaccine in their first year of life, 71% receive three doses of DPT, 81% receive BCG and 66% a dose of measles vaccine.

It is estimated that EPI currently prevents 2.6 million deaths each year from measles, neonatal tetanus, and pertussis and prevents 409,000 cases of poliomyelitis. Yet, the continuing occurrence of a further estimated 2.6 million deaths due to these diseases and over 180,000 cases of polio underlines the urgency of continuing to improve EPI target disease reduction efforts.

The 42nd World Health Assembly issued six challenges to be addressed by the EPI during the next decade.

- achieving and sustaining immunization coverage with all antigens;
- controlling the EPI target diseases, including achieving global polio eradication by the year 2000, reduction of measles incidence by 90% by 1995 and elimination of neonatal tetanus by 1995;

- improving surveillance to provide an accurate assessment of progress;
- introducing new or improved vaccines as they become available;
- promoting other primary health care practices appropriate for the delivery system developed for immunization and;
- research and development in support of these goals.

A major concern of the EPI continues to be raising and sustaining levels of immunization, in the hope that coverage will exceed 80% in all countries, and all parts of those countries, by the end of 1990 and reach over 90% by the end of the year 2000.

## 2.2 OVERVIEW: POLIOMYELITIS ERADICATION INITIATIVE

From 1980 to 1985, an average of 42,580 cases of acute polio were reported annually, reducing to an average 29,100 annually in the years 1985 to 1989. By mid-August 1990, 22,687 cases had been officially reported for 1989.

The declining trend in the incidence of reported polio continued in all regions except in the Western Pacific where the number of cases reported by China increased markedly. Data reported by Member States to AFRO are too incomplete to allow conclusions on incidence trends to be drawn.

Low incidence or polio-free areas exist and are further developing in the Americas, Europe, Northern Africa, in the area including the Arabian peninsula, Iran, Iraq, Syria and Jordan, in the Pacific basin and in parts of Southern and Eastern Africa.

All regions have reached polio immunization coverage with three doses of OPV in the first year of life over 70% except for the African Region, which has increased coverage steadily to its present 47%. Caution is needed in interpreting average Regional and National coverage figures, which tend to conceal areas of much lower than average achievement.

Planning for global polio eradication has proceeded well, with plans of action prepared by all regions and 115 countries. Four regions have convened EPI Technical Advisory Groups. In 1989/90, workshops to develop polio eradication activities were held in five regions and in several countries with persisting poliovirus transmission.

The Global Plan of Action for development of the laboratory network has been finalized and Regional Plans of Action will be developed by the end of 1990. A Manual for the Virological Investigation of Poliomyelitis has been prepared and is being distributed. Another manual, describing simple procedures to help reduce disability in polio victims, will shortly be ready for field testing.

Much research work has been conducted, producing important results to help the development of polio eradication policies, notably to support the modification of OPV formulation.

A number of problems which could delay the early achievement of polio eradication have been identified:

- high immunization coverage, even at levels above 90%, does not necessarily guarantee interruption of wild poliovirus transmission, such transmission can persist through the build up of susceptibles, partly immunized and through vaccine failures;
- introduced wild poliovirus can on occasion spread extensively, even in well-immunized populations, emphasising the need for effective continuing surveillance and early control measures;

- low level transmission may persist for years, but, since it may cause only a few cases, it may be difficult to motivate planners to take the corrective measures required;
- factors outside the control of health staff can make it difficult to establish or extend polio free zones. The most intractable problems are war and civil disturbances; and
- adequate funding for essential activities and personnel needed for the initiative is not yet available.

### **2.3 OVERVIEW: POLIO ERADICATION IN THE AMERICAS**

Immunization programmes in the Americas are supported by several international agencies (PAHO, UNICEF, USAID, the Inter-American Development Bank, Rotary International and the Canadian Public Health Association), which together have contributed US\$112 million for the period 1987-1991. The efforts to eradicate polio from the Western Hemisphere, launched in 1985, are included as an EPI target for 1990.

In 1989, immunization coverage in the Region reached an all time high of over 60% for each of the EPI vaccines. The reported incidence of all the EPI target diseases shows a steady decline since the inception of the EPI in 1977.

As efforts to eradicate polio were intensified, the number of probable cases reported from 1986-1989 increased steadily from 500 to 2000, reflecting improved surveillance, while the number of confirmed cases declined dramatically from over 1000 to 130 for the same period of time. Only 24 wild poliovirus isolates were made from the 130 cases confirmed in 1989, suggesting that many reported cases were actually false positives, and that the true incidence of the disease was much lower.

In 1989, cases caused by the wild virus were detected only in the north coast of Brazil (2), Venezuela (1), Colombia (5), Ecuador (3), Peru (1) and North-Western Mexico (13). All cases in Mexico were caused by Type 3 virus, suggesting possible vaccine failure. All other isolates were Type 1 virus.

In 1990 up to week 35, only 4 cases of poliomyelitis due to wild virus have been detected: 2 in Mexico, a continuation of the Type 3 outbreak that started in 1989, and 1 each in Ecuador and Peru, both Type 1. The last case detected had onset in June 1990 in Mexico.

A network of 10 strategically located laboratories are supporting field activities with virus isolation and typing, intra-typic differentiation and characterization.

During each of the last three years, an average of 2000 stool specimens has been examined. 80% of the suspect polio cases have had stool samples collected, 95% of these being collected within 15 days of onset.

It is now believed that transmission has been interrupted in Brazil, the Southern Cone (Argentina, Chile, Uruguay, Paraguay), Bolivia, Central America and Panama, the Caribbean, the United States of America and Canada, with two remaining persistent small foci of transmission, in northwest Mexico and an area bordering Peru and Ecuador.

The goal of final interruption of transmission by the end of 1990 appears to be feasible.

### **2.4 OVERVIEW: POLIO ERADICATION IN THE EUROPEAN REGION**

Eradiation of polio from Europe is included as a Regional Health for All target by the year 2000. The estimated Regional OPV-3 immunization coverage is 86%, and there are only six countries where coverage is less than 90%.

In 1989, 133 cases of polio, including vaccine associated cases, were reported to WHO. The majority of cases were reported by Turkey and the USSR, where major efforts have been made to activate effective polio eradication activities. "Mopping-up" operations are being planned in Turkey, focused on eliminating the high risk of persisting wild poliovirus transmission in certain areas.

Surveillance activities need to be improved in many countries of the Region, especially in terms of prompt reporting of cases to WHO, developing active surveillance and detection of flaccid paralysis, zero reporting by districts, especially in infected countries, as well as surveillance of wild virus in the environment. Criteria for declaring indigenous poliomyelitis eradication from countries of the Region have been proposed.

## **2.5 OVERVIEW: POLIO ERADICATION IN THE AFRICAN REGION**

The Regional Plan of Action for Polio Eradication has been finalized and distributed to Member States of the Region.

Reporting of polio cases remains generally unsatisfactory with reporting completeness estimated at only 3-5%. Cases are reported without any attempt to differentiate wild from vaccine associated polio. Apart from four island countries which have reported zero cases for the past three years, all countries in the Region are believed still to have endemic polio.

The immunization coverage with OPV-3 which was only 18% in 1985, has improved to 47% in 1989, although coverage varies between Sub-Regions.

The Eastern and Southern parts of the Region have better immediate potential to achieve and document polio eradication than the rest of the Region. Meetings of Programme Managers from all Member States to prepare plans of action and activities appropriate for polio eradication are being conducted before March 1991. Some countries, including Zaire, Ghana and Togo, have introduced measures to improve surveillance.

Initial evaluations have been prepared to identify potential laboratories, at least one per Sub-Region, to form the basis of the Regional Polio Laboratory Network. The first training for personnel in these laboratories has been scheduled for 1991 in Ghana.

Some of the constraints encountered have been in communication, poor quality data reporting, and lack of financial support for the initiative. There is a desire on the part of Member States that polio eradication should not become a "vertical" activity.

## **2.6 OVERVIEW: POLIO ERADICATION IN THE EASTERN MEDITERRANEAN REGION**

Since the endorsement of polio eradication by the Regional Committee, in October 1988, regional activities have progressed rapidly.

The main achievements for the initiative are as follows:

- Establishment of a Regional Technical Advisory Group in 1988. The Group has held three meetings and has made recommendations appropriate for levels of achievement and progress in Member States of the Region;
- 16 countries have developed National Plans of Action, and many of these have been updated;
- 18 countries are monitoring immunization coverage and disease incidence by districts and provinces;

- A Regional Manual for Polio Eradication has been produced;
- A Regional Plan of Action for the development of a laboratory network in support of polio eradication was developed in July 1990.

In 1989, the Region reached an average 75% immunization coverage with three doses of OPV for children aged 12 months. Sixteen countries have reached coverage of 80% or over.

In 1989, 2118 cases of polio in 13 countries were reported to WHO. Nine countries reported zero polio cases. Over 90% of these cases were reported from three countries, Egypt, Pakistan and the Republic of Yemen. In four countries, Egypt, Pakistan, Djibouti and the Republic of Yemen, incidence rates were higher than 0.5 per 100,000 population. There are two examples of successful coordination of polio eradication activities between Member States of the Region, firstly, in the Arab countries of the Gulf and, secondly, in the Maghreb countries.

Appropriate Regional polio eradication policies have been developed for two separate geographical areas:

- a) low incidence or polio free areas,
- b) high incidence areas.

The main programme constraint remains the poor levels of surveillance and the difficulties involved in its further development.

## **2.7 OVERVIEW: POLIO ERADICATION IN THE SOUTH-EAST ASIA REGION**

Every country in the Region has prepared a National Plan of Action for poliomyelitis eradication.

A team consisting of staff members from WHO/HQ and the Regional Office visited Bangladesh, Nepal, Sri Lanka and Thailand to discuss with National Authorities the development of the polio eradication initiative, including laboratory surveillance.

An intercountry workshop on polio eradication, integrated with other disease reduction activities, was conducted in New Delhi in March 1990, followed by a national workshop in India in June 1990.

All the countries in the Region have shown increased coverage during the last five years. In 1989, the range of OPV-3 coverage varied from 45% in Myanmar to 99% in the Democratic People's Republic of Korea, giving a Regional average of 66% based on UN population figures. If populations declared by Member States are taken as the denominator, the Regional coverage is 72%. There was a gradually decreasing trend of polio cases in the Region in the period 1981-1986. Reported incidence rates were 29 per million population in 1981 and 13 in 1985, a reduction of 50%. In 1987, incidence rose to 23 per million, decreasing to 18 per million in 1988 and to 11 per million in 1989.

India, Indonesia, Mongolia, Sri Lanka and Thailand have the potential to carry out testing of poliovaccine and isolation of poliovirus. Virus laboratories also exist in Bangladesh and in the Democratic People's Republic of Korea.

It seems probable that Mongolia, the Democratic People's Republic of Korea, Maldives, Sri Lanka and Thailand may be the first to eliminate polio. India, because of its size and being the source of the largest number of cases in the world, has a special place in the Regional and Global Initiative and requires particular attention. Indonesia, Bangladesh, Bhutan, Myanmar and Nepal need improved surveillance. The last three countries also need to further accelerate activities leading to higher vaccination coverage.

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## 2.8 OVERVIEW: POLIO ERADICATION IN THE WESTERN PACIFIC REGION

The Western Pacific Region consists of 35 countries and has a population of 1.5 billion, of which 1.2 billion live in China.

Six countries are still endemic for polio. Only recently, have EPI activities reached a satisfactory level, with most countries achieving high immunization coverage.

The incidence of polio, although markedly increasing in 1989, has declined in recent years but much remains to be done if the 1995 target of zero polio is to be achieved.

To control the EPI diseases, it is proposed to convene a Task Force whose terms of reference will be to raise additional funds to help meet the polio and neonatal tetanus targets, increase social mobilisation and monitor progress.

It is hoped that countries endemic for polio will create similar National task forces, establishing targets for all districts and provinces.

By the end of 1995, it should be routine for all polio cases to be investigated and classified and for immunization coverage to be monitored on a district level basis.

Laos and Cambodia still have very low immunization coverage with EPI vaccines and poor health system infrastructures, and will find it difficult to conduct nation-wide National Vaccination Days. Small provincial vaccination days, however, may be possible. Cold chain improvements are also needed in Cambodia and Laos.

In several countries, especially in urban areas, a strategy to minimize missed opportunities is being conducted.

Surveillance indicators are not being used. It is hoped that weekly reporting can be universally established by 1992.

In 1991, it is hoped to train a corps of Regional epidemiologists and to conduct meetings of EPI managers.

In reviewing Regional priorities the possibility of early polio eradication in the Philippines and Papua New Guinea, which, as islands, should have a very low chance of re-infection, will be considered.

## 3. IMMUNIZATION POLICIES

### 3.1 BACKGROUND

Since poliovaccines were first introduced in the 1950s and 1960s, much experience has been gained on their impact in eliminating clinical polio.

Initially, most industrialized countries made the vaccines widely available to a receptive population, with the result that very high immunization coverage was achieved within a short period of time. Polio incidence then dropped dramatically, but normally persisted at a low level for several years. Frequently, small epidemics later occurred, following which, either because of increased immunization activity or because most susceptibles had been infected, zero clinical cases due to the wild poliovirus were reported.

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The development of EPI in the 1970s brought the benefits of immunization to most developing countries, with services being offered from fixed, outreach or mobile clinics and given to children at scheduled ages. Mass campaigns were generally discouraged, although EPI accelerations in the late 1980s included national vaccination days, weeks or months.

Experience has shown that the incidence of polio in countries achieving high immunization coverage through EPI has fallen markedly. However, it has rarely been possible to demonstrate the disappearance of clinical polio or the interruption of transmission of the wild virus based solely on high immunization coverage achieved through routine services on the recommended EPI schedule.

### 3.2 POLICY OPTIONS

Immunization strategies are based on four main types of activities:

- services based on fixed health facilities, outreach and mobile clinics;
- National Vaccination Days or pulses of immunization;
- administration of vaccine around cases;
- selective administration of OPV in areas perceived to be at high risk of continuing wild virus transmission (mopping-up).\*

Each type of activity has certain advantages. Services based on fixed health clinics have a relatively high potential for further developing primary health care, and for maintaining a reliable cold chain, training, and supervision. All EPI vaccines can easily be provided. High immunization coverage, especially in the highest risk groups, will most readily be achieved by vaccination days or by mopping-up policies. Both fixed health clinic policies and mass immunization strategies can effectively reduce polio incidence. Data from the Americas suggest that the latter will do so more rapidly, reliably, and with a greater chance of the early achievement of zero polio.

### 3.3 EXPERIENCE IN THE AMERICAS

In the Americas, the policies and strategic approaches for immunization have relied on a mixture of different systems including delivery through fixed health facilities, outreach mobile units, and national, regional or local vaccination days, usually implemented twice a year, four to six weeks apart. Policies have emphasized that all strategic approaches should contribute to the overall development of the health infrastructure, with national vaccination days as a complement to vaccine delivery through the other approaches, especially for polio-endemic countries. During the organization of national vaccination the opportunity has been taken to deliver other EPI antigens, including TT for women of child-bearing age.

In addition, in polio endemic countries, supplementary mopping-up operations have been added, especially in the peri-urban and under-served areas. These operations are presently providing immunization against polio in areas of persistent transmission. The vaccine is usually given on a house-to-house basis, to all children under five years of age. Initially, in 1988, the first mopping-up operations were targeted at areas where cases of poliomyelitis had been notified in the previous three years. In 1989, these activities were carried out in 10 countries, covering 898 districts with two rounds of immunization and with health staff visiting more than 2.8 million

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\*Definition of mopping-up in Glossary.

In the Americas, mopping-up operations were carried out in 2-3% of the total districts in the Region.

households. Through these activities, 4.9 million children were vaccinated, 3.6 million below the age of five years. In 1989 and also in 1990 mopping-up operations were systematically organized whenever a probable case of poliomyelitis was detected. In 1990, through two immunization rounds, 200 municipalities in the Andean Region were covered, vaccinating more than 700,000 children. Each of these activities is closely monitored at the country level and generally organized with voluntary participation of all the resources available from the community.

Cost estimates have been calculated. Excluding vaccines, the cost of vaccinating one child against polio in mopping-up operations has averaged US\$0.15. These activities were made possible through a grant to PAHO of US\$1.2 million from Rotary International.

### 3.4 CONCLUSIONS ON IMMUNIZATION POLICIES

- i) Immunization with presently available poliovaccines, whether administered through "routine" methods or in vaccination days, is highly effective in reducing rapidly the incidence of acute polio. Interruption of wild poliovirus transmission does not appear to occur immediately, however, even when high immunization coverage is reached using routine methods. Supplementary policies targeted at ensuring full OPV coverage in areas where wild virus transmission is persisting are usually needed to finally eradicate the wild poliovirus. The key element of this success appears to be displacement of the wild virus by short-term simultaneous administration of the vaccine virus to all possibly susceptible children.
- ii) The policy of using national vaccination days or other special immunization activities to achieve high coverage rapidly in polio-infected countries was based on the observation that such strategies have effectively been utilized in the past in almost all countries, industrialized or developing, that succeeded in interrupting transmission. Examples from Cuba, Brazil, Costa Rica, Chile, Malaysia, England and Wales, Czechoslovakia, and Japan illustrate this point. It is possible that, while mass immunization was clearly important in eliminating poliovirus in industrialized countries, it may be essential to achieve polio eradication in developing countries with poor hygiene and sanitation.
- iii) Vaccination Days have proved very effective in reducing polio incidence or interrupting transmission of poliovirus. In these days TOPV is given in any area within a very short period, at least twice a year, one month apart to all children aged under 5 years of age. To be effective, vaccination days require strong Government commitment, ensuring the involvement of non-health sectors, such as education, religious groups, etc. There is a potential drawback in that National Vaccination Days may repeatedly reach mainly the population that has already been reached.
- iv) Evidence based on other viral diseases, including smallpox, and experience in tracking polioviruses of particular sequences in the Americas suggest that the disease may prove to be more focal than previously thought. It is possible that, especially in the season of low incidence, transmission may be sustained only under certain circumstances, for instance in crowded urban areas or in areas of poor hygiene. If this is true, policies based on mass immunization of identified high risk areas at times of low incidence may produce high benefit results in terms of interruption of transmission.
- iv) Experience in many countries, the Americas, Israel, Oman, Saudi Arabia, suggest that the principles involved in the "mopping-up" strategy are relevant and appropriate to achieve control of the spread of polioviruses in epidemic situations and rapidly lead to effective eradication.

### 3.5 Recommendations

- i) *Managers of EPI should modify existing plans of action for polio eradication to include policies which, based on experience, have proved effective.*
- ii) *Policies aimed at polio eradication should be targeted at protection of the community through displacement of the wild virus as well as further increasing individual protection. Countries with well established immunization services should aim rapidly to reach at least 70% coverage through routine services or vaccination days, but, at that level, should also focus on identifying high risk areas and reaching 100% coverage in those areas in which mopping-up operations are being conducted.*
- iii) *Immunization policies should be targeted at securing the earliest and most complete reduction of acute polio cases. In countries with poor health infrastructure or persistent poliovirus transmission, the use of vaccination days should be considered as an effective, epidemiologically sound policy of reducing polio incidence, as well as that of the other EPI diseases.*
- iv) *Countries should develop surveillance as the critical strategy through which all cases of polio should be detected and the factors responsible identified and analysed. Such a strategy should allow for study of the epidemiology of the disease, forming the basis for sound and epidemiologically correct immunization strategies.*
- v) *The basis for immunization in most circumstances remains services operating from fixed health clinics and their outreach activities. Additional policies may be needed to supplement those services if polio eradication is to be achieved. In particular, the use of extensive, thorough, but local "mopping-up" has proved to be effective in stopping wild poliovirus transmission in certain situations where well defined indications exist. These indications include:*
  - *areas where polio cases are still occurring;*
  - *areas where any polio case has occurred in the past three years;*
  - *areas where the epidemiology of polio suggests a high risk of wild virus transmission persisting (urban slums, newly developed peri-urban areas, areas of poor hygiene);*
  - *areas where polio immunization coverage is significantly below national or local averages.*
- vi) *Countries which have reduced the incidence of polio to low levels through high immunization coverage should include mopping-up in their available strategies. "Mopping-up" should be based on careful management. Maps of polio incidence covering several years are essential to identify polio "hot-spots" where cases of polio have regularly occurred in successive seasons. These areas should be the focus for intensive immunization, ensuring that coverage is maintained at high levels. This immunization should be to all susceptible children; usually all those aged 0-5 years, regardless of their previous immunization status, who should receive a dose of TOPV ideally on a house-to-house basis. The use of other EPI vaccines and repeated immunization rounds after 4-6 weeks are recommended, but should be based on local need and potential.*

*vii) Research should be conducted to determine the epidemiology and spread of wild and vaccine poliovirus, to identify risk factors of polio transmission in any area/country, to evaluate the impact of different immunization strategies, and to define the length of time poliovirus may persist in the environment without overt cases of poliomyelitis.*

## 4. SURVEILLANCE AND OUTBREAK CONTROL

### 4.1 BACKGROUND

The report of the second Consultation (1989) provided specific recommendations for strengthening surveillance, based on lessons learned regarding surveillance from the Region of the Americas. The third Consultation again reviewed progress in developing this strategy and following discussions, formulated recommendations for surveillance activities within the next 12 months.

It was considered that in spite of changes introduced in the Americas, the case definitions for suspect, confirmed and discarded cases of poliomyelitis that appear in the Polio Manual (Manual for Managers of Immunization Programmes, EPI/POLIO/89.1) continue to be applicable in the global eradication initiative.

In the Americas, the creation of special national case classification committees composed of neurologists, virologists and epidemiologists to examine and classify data on probable poliomyelitis cases has been a stimulus to the eradication effort.

Where possible, and provided that at least a monthly system exists, reporting of polio should aim to reinforce a country's routine disease reporting, rather than creating a parallel system of a different frequency. However, to ensure a rapid response to a suspect case of poliomyelitis, disease reporting should be modified to include immediate reporting of poliomyelitis, especially in countries in an advanced stage of poliomyelitis eradication. This reporting would be done through the most rapid means possible as with other immediately notifiable disease, such as cholera. As soon as possible, countries and WHO Regions should aim to monitor the incidence of polio through weekly reporting of cases.

Case investigation of poliomyelitis becomes increasingly important as areas/countries or areas within countries progress towards poliomyelitis eradication. The emergence of computer software for generating and analysing line listings of poliomyelitis cases such as the Poliomyelitis Eradication Surveillance System (PESS) software developed in the Americas holds great promise that each case of poliomyelitis can be brought to the attention of those responsible for eradication at various levels.

One possible social mobilization technique, aimed at promoting community-based active surveillance is the use of monetary rewards for reporting a case of poliomyelitis confirmed to be caused by the wild virus. The usefulness of these rewards in identifying new cases and in raising public awareness of the poliomyelitis eradication initiative should be assessed in the Americas and in China.

There is now a need, especially in countries poised for more aggressive poliomyelitis eradication activities, to ensure that training in surveillance, suitably adapted to the conditions at each level, is conducted at national, state/provincial, and district levels, combined, as appropriate, with other EPI topics.

## 4.2 EXPERIENCE IN THE AMERICAS

In the Americas, establishment of a surveillance system for poliomyelitis has been a gradual experience starting from basic concepts which evolved as more information became available and its flow improved.

The major elements in the establishment of surveillance have been:

- Preparation of a Field Guide to standardize the most important elements of the programme: case definition, reporting, investigation, surveillance criteria.
- This field guide was the basis of a training course organized at the Regional level and following distribution of the guide, the course then replicated for each country and at the sub-national level within some of the large countries.
- Organization of a Technical Advisory Group (TAG), sub-regional and national meetings, which have been fundamental in facilitating follow-up, guiding the technical progress of the programme, as well as stimulating communication between countries.
- Shift in reporting from probable cases of polio to cases of acute flaccid paralysis which has helped "polio free" countries to set up a surveillance system required to assure that no polio cases are occurring.
- As an effort of highest priority, organization of a weekly notification system involving more than 15,000 reporting units throughout the Region, to ensure that no cases of acute flaccid paralysis remain unreported. The monitoring of acute flaccid paralysis rates per 100,000 children aged less than 15 years, by country and within countries has proved to be a good indicator of the development of the surveillance system.
- Placing greater emphasis on surveillance of wild poliovirus through the constant monitoring of stool samples and laboratory results.
- Development of a standardized data base system (Polio Eradication Surveillance System, PESS) with electronic data transfer from countries to the Regional Office.
- Involvement of neuropaediatricians, paediatricians and electrophysiologists, in national case classification committees, subregional technical meetings and prospective studies of acute flaccid paralysis, to secure the cooperation of clinicians in improving reporting and follow-up of cases.
- In some isolated areas with a poor health infrastructure, organizing extensive active searches for cases. These consist of lameness surveys in countries where no cases of polio had been identified for more than 10 years.
- Remuneration of US\$100 for each confirmed case of polio.
- Improvement in the flow of communication through a weekly Bulletin as well as Regional and national newsletters.

### 4.3 Recommendations

- i) *National and Regional Plans of Action for Polio Eradication should be reviewed and updated to include surveillance activities related to these recommendations.*

- ii) *The same case definition as recommended in the Manual for Managers of Immunization of polio should continue to be used as the basis for surveillance of cases of acute flaccid paralysis.*

*As the incidence of reported acute polio reaches low levels, Expert Review Committees, including paediatricians, neurologists and epidemiologists, should be convened, especially at the national level and in major subdivisions of countries with low or zero polio incidence, to confirm the clinical diagnosis of suspect polio cases and later to classify the case according to the causative virus.*

- iii) *All countries should aim for weekly reporting of polio cases, as well as immediate reporting to the level where action will be taken as soon as cases are detected.*

*Achieving improved reporting should be phased, initially making existing systems, including those with monthly reporting, more complete and efficient.*

*Regional Offices should request all Member States to send monthly or, whenever possible, weekly telegrams of polio incidence. Monthly reports of cases should be sent from Regional Offices to Headquarters. Where incoming reports are incomplete, either at the National or Regional Office level, provisional data, or reports received to date, should still be despatched on time.*

*Monitoring of polio incidence should be by district and should include zero reporting where no cases have been detected. Additional techniques such as examination of hospital records, special surveys and active case searching should be considered as possible activities to supplement the routine surveillance system.*

- iv) *Computer software should be adapted from PESS or other available software to assist in the promotion and preparation of line listing of all polio cases. Global EPI should make such software available to all countries.*

- v) *In the next 12 months, all Regional Offices should promote the use of basic surveillance indicators in all National EPI, using the results to monitor progress and to form the basis for annual reporting to the programme manager's meetings, other Regional meetings and to the Global level.*

*The main indicators to be adopted should include:*

- *District reporting completeness - A list of reporting sites and the number/ratio to population in each geo-political subdivision should be prepared.*

*The surveillance indicator should be the percentage reporting within one week of the date of the expected report.*

- *Reporting sensitivity - The percentage of all detected suspect cases reported within one week of onset of paralysis. An effective programme should be achieving 80% effectiveness in this indicator.*

*The percentage of cases in which a faecal specimen has been collected within 15 days of onset of paralysis. Again an effective programme should achieve 80% with this indicator.*

*Based on experience in the Americas, an effective surveillance system should detect at least one case of flaccid paralysis due to non-polio causes for every 100,000 children aged less than 15 years.*

*vi) Feedback to reporting centres, in the form of a newsletter or surveillance report, should be initiated.*

## 5. OUTBREAK RESPONSE

### 5.1 BACKGROUND

Surveillance should be an integral part of all national programmes of immunization, collecting data on the occurrence of cases and the epidemiology of the disease in each country. These data should form the basis for the development of policies on immunization and on continuing surveillance.

It is necessary, in addition to collecting, collating and analysing these data, to have clear established guidelines on the response to be initiated when cases are reported. Such a response is necessary for three reasons:

- to establish activities that will control polio outbreaks and help eradicate poliovirus;
- to demonstrate to staff reporting cases that the information provided by them is necessary to initiate appropriate action;
- to motivate health staff and the public to further develop surveillance.

In all countries, an outbreak response is appropriate, but the extent of the response will vary according to the status of polio eradication, including the reported incidence of the disease.

At the least, when cases are reported, an outbreak investigation should be conducted and all children in a defined at-risk age living in the village/ward should receive two doses of vaccine at one month intervals. Surveillance should be intensified in surrounding areas and the factors likely to be responsible for the occurrence of the cases should be identified. These factors should later be corrected.

In polio-free areas should importations occur or in areas of low incidence, in addition to these activities, extensive immunization, which may be nation-wide, should be given to an epidemiologically appropriate age range of children. As the number of detected cases declines, it becomes essential to strengthen surveillance and ensure that all cases are detected, investigated and contained.

It is necessary to include clear policy guidelines on outbreak response in all immunization plans of action and include training on this response in EPI courses for health staff.

### 5.2 Recommendations

*i) All national EPI and polio eradication Plans of Action should be reviewed and updated to include guidelines on action in response to the detection of suspect polio cases.*

*ii) The minimum response has four elements:*

- *All cases should be investigated and suspect cases line listed. In all countries reporting less than 50 cases nationally or in major geographical subdivisions, an expert review committee should confirm the clinical diagnosis and, where suitable laboratory facilities exist, faecal specimens should be collected to test for poliovirus isolation.*
- *Surveillance for further cases should be conducted over an extensive area.*
- *Immunization should be given to all children of the appropriate age group at risk, irrespective of their immunization status, ideally on a house-to-house basis (two doses, one month apart). The area to be covered with immunization will vary according to the status of polio eradication in the country or area. Where zero or few cases are occurring, it should be as extensive as possible. Even in countries with a high polio incidence, immunization should be completed in the affected village or ward in urban areas.*
- *Identification of the likely reasons for the outbreak should be determined. If the reasons include low immunization coverage or vaccine failure for whatever reason, "mopping-up" operations over as extensive an area as possible should be conducted.*

## 6. COUNTRY EXPERIENCE IN IMMUNIZATION SERVICES, SURVEILLANCE AND OUTBREAK CONTROL

### 6.1 THE USSR

In accordance with the resolution of the 42nd World Health Assembly, May 1989, the Ministry of Health of the USSR elaborated a plan for eradication of poliomyelitis for the period 1989-1995. This plan was put into action in July 1989.

According to this plan, all territories (Republics) in the USSR were classified into three groups. Appropriate measures were planned for these Republics according to the poliomyelitis situation:

Group A Republics where no polio cases had been recorded for over three years - Estonia, Latvia, Lithuania. For these Republics, activities included monitoring of every case of flaccid paralysis and ensuring high immunity among all children.

Group B Republics where sporadic polio cases were being recorded - RSFSR, Ukraine, Kazakhstan, Byelorussia, Georgia, Moldova, Kirghizia, Armenia. In territories recording polio cases, intensive immunization programmes are being carried out.

Group C Republics with continuing polio morbidity - Azerbaijan, Uzbekistan, Turkmenia, Tadzhikistan. After appropriate surveillance, mass campaigns were carried out with further surveillance and appropriate immunization.

The responsibilities for elaborating and carrying out poliomyelitis control are delegated by the Ministry of Health of the USSR, to the Ministries of Health of the Republics.

Since adoption of the USSR plan for poliomyelitis eradication, certain measures have already been undertaken. In the Republics, groups of specialists have been appointed to work in the polio programmes. Special seminars and workshops were carried out in association with members of the managerial and consultative groups of the Ministry of Health of the USSR.

Surveillance for poliomyelitis in all territories includes clinical and laboratory diagnostic work based on detection of cases of flaccid paralysis and use of the standard case definition, reporting firstly to district level, then to regional or Republic level, then to the Ministry of Health of the USSR, epidemiological surveillance; evaluation of all data, planning immunization, evaluation of its results, serological studies of levels of immunity, environmental virology. During the past year, molecular epidemiology has also been introduced into surveillance practice.

According to the results of surveillance for Republics of Group C, mass vaccination campaigns were recommended and carried out using trivalent oral poliovaccine. In Uzbekistan, because of the known prevalence of polio cases caused by Type 3 virus, an immunization campaign with monovalent Type 3 OPV was carried out.

In 1989 poliomyelitis incidence in the USSR slightly decreased (91 cases in comparison to 174, 176 and 165 cases respectively in the three previous years). Nevertheless, the incidence in Group C Republics (Uzbekistan, Kazakhstan and Azerbaijan) remains significant, totalling 61 cases in 1989.

## 6.2 CHINA

China, responding to the WPRO and the 41st World Health Assembly resolutions on polio eradication, has established a goal to eradicate polio by 1995, and has developed a National Plan of Action.

Although average coverage with OPV-3 at the provincial level is high, it remains very low in some counties where polio is still endemic. Actions have been undertaken to improve immunization coverage, mainly by sustaining routine immunization services, evaluating coverage by county, conducting immunization campaigns, providing vehicles and cold chain equipment to high priority areas.

Between 1981 and 1988 there was a successive decrease in polio cases. This trend, however, was reversed when 4,628 cases were detected in 1989. More than 2,000 suspect cases have been reported up to June, 1990.

Active surveillance of acute flaccid paralysis and investigation of cases which remain key components of the eradication strategy, received additional impetus and support through the lessons learned from several large outbreaks in 1989.

China has adopted a standard polio case definition. Attempts have been made to improve case notification, special sites being selected to supplement routine reporting. In some areas a reward is being offered to health workers for reporting polio cases. Feedback in the form of a newsletter has been provided.

County or prefecture-based OPV immunization campaigns and containment immunization have been widely used, with the following requirements:

- early investigation and containment;
- immunization coverage over a wide geographical area;

- all children up to four years of age receive vaccine;
- the quality of containment immunizations is guaranteed.

### 6.3 GUATEMALA

Prior to the 1970s, immunization in Guatemala could be obtained only by request. With the start of the Polio Eradication Initiative in 1985, the country initiated National Vaccination Days. This strategy acted as a complement to other immunization strategies such as the routine immunization programme and the "canalization" strategy in which, along with other health interventions, vaccine is offered during house-to-house visits. Since 1988, financial resources for accelerated vaccination programmes and "mopping-up" operations have been decentralized to the operational level, so that activities can be programmed on the basis of local needs.

Between 1985 and 1989, Guatemala experienced a sharp increase in immunization coverage and for the first time, in 1989, officially passed the 60% barrier for OPV-3 coverage in children < 1 year of age, with only 31% of all municipalities having OPV-3 coverage below 50%. As a result of these renewed efforts, the number of polio cases has declined and it is expected that the country will succeed in achieving the goal of universal immunization of children under the age of five. Since Guatemala committed itself to eliminating the circulation of wild poliovirus, the surveillance programme for acute flaccid paralysis cases has improved considerably.

The establishment of a network of 246 health services reporting the presence or absence of acute flaccid paralysis on a weekly basis, has resulted in an increased number of reported cases. The acute flaccid paralysis rate per 100,000 children below 15 years of age has reached 1.5. Other epidemiological parameters used to evaluate the programme have shown similar improvement. These include the interval between onset of paralysis and notification (>90% of cases reported in the first two weeks of paralysis), the interval between onset and taking of stool samples (>90% of cases with samples taken in the first two weeks after onset), and the interval between notification and beginning of control measures (>90% of cases with control measures started < 72 hours after notification).

The announcement by the Minister of Health of the \$100 reward for information regarding any case of acute flaccid paralysis, subsequently confirmed as polio, has improved reporting compared with the same period last year.

Although more cases of acute flaccid paralysis are being investigated, fewer polio cases have been confirmed. There has been no isolation of wild poliovirus since December 1987. If the programme maintains its present efforts, it is expected that Guatemala will succeed in the goal of interrupting transmission of wild poliovirus.

### 6.4 IRAN

Polio immunization in Iran started in 1966 with OPV administration to children aged less than five years living in urban areas, and was subsequently extended to rural areas. It continues as an integral part of the National EPI.

Nationally, OPV-3 coverage of over 80% has been achieved in children aged under one year. There is a disparity in coverage between different provinces, between urban and rural areas, and finally between different types of service delivery system, e.g. PHC and mobile teams. A plan of action has been prepared in collaboration with provincial health authorities. Areas inadequately reached with immunization services have been defined.

Since 1974, the country has produced its own oral poliovaccine from the original Sabin seed and now is self-sufficient.

OPV is given at birth and in two boosters after the routine three doses, which are started at six weeks of life and subsequently given at six weekly intervals.

Surveillance of poliomyelitis is a part of general disease surveillance and poliomyelitis is a notifiable disease which is subject to the Compulsory Notification Act.

According to the National Plan of Action for polio eradication, the country has been divided into six regions each supported by an epidemiologist and laboratory facilities. There is a National Reference Laboratory in Teheran capable of isolating and typing polioviruses and also conducting vaccine potency testing.

All reported suspect cases are investigated immediately and containment measures are started without waiting for laboratory results, extending the area of immunization if the case proves positive.

Polio-free zones have been identified and are detailed by district. Of 214 districts in the country, more than 80% are reported to have been polio-free for five years. In 1989 cases were reported from only six districts.

## 6.5 INDIA

In India, the immunization programme delivering OPV has extended from 30 districts in 1985-1986 to more than 435 districts in 1989-1990. OPV-3 coverage in 1990 is reported to be 81%. There is however, a large variation in coverage between States.

The cold chain is monitored by vaccine potency testing. In 1990, more than 90% of the samples tested proved to have satisfactory potency. The number of samples tested is progressively increasing.

India plans to establish laboratories on a tiered system, to include a National Laboratory, as well as Regional and State Laboratories.

Future strategies include aiming to achieve 100% immunization coverage, especially in areas identified as having high disease incidence, or those where presently there is low immunization coverage. Area-specific strategies are to be developed. Laboratory development will proceed, along with indigenous production of cold chain equipment and vaccines. It is intended that all Child Survival Programmes will be integrated.

## 6.6 SRI LANKA

Sri Lanka has a relatively long history of immunization, with smallpox vaccination being carried out towards the end of the last century. Polio immunization commenced in Sri Lanka in 1962 following the largest outbreak of polio which the country had so far experienced. The Expanded Programme on Immunization was inaugurated in 1978 and island-wide coverage was achieved in 1979. Initially five antigens were used in the EPI, measles vaccine being introduced only in August 1984. Immunizations are carried out through regular fixed MCH clinics where other services, in addition to immunization, are also available. Immunizations are also carried out in hospitals and by private practitioners, to whom vaccines are provided free of charge. Immunization coverage for all antigens including poliovaccine is over 80%.

Following the WHO/UNICEF review of the EPI in 1981, the immunization schedule was changed to unify the interval between the three doses of OPV. This has helped, in part, to reduce drop-out rates to below 5%. The motivation of the peripheral health workers and high degree of motivation of the mothers will ensure that the high levels of coverage presently being achieved will not only be sustained but will even improve in the future.

Cold chain monitors are presently being used up to the level of distribution of vaccines from the centre to medical institutions. This will soon be extended to more peripheral levels. Poliovaccine potency testing is now being carried out in the Virology Department of the Medical Research Institute.

Poliomyelitis is one of the 20 notifiable diseases listed under the Quarantine and Prevention of Diseases Ordinance. The WHO definition of a suspect case of polio is used in Sri Lanka. A suspect case of polio must be notified either by telegram or telephone to the area Medical Officer of Health (MOH) and the Epidemiologist within 24 hours. The MOH informs the Epidemiologist weekly of all notified cases through a return of communicable diseases. These returns are analyzed in the Epidemiology Unit and feedback is provided to all MOH and hospital doctors of the situation of all notified diseases in the region. In addition, a quarterly epidemiological bulletin is published by the Epidemiological Unit.

The incidence of polio has shown a marked decline in recent years. A feature of the epidemiology of polio in Sri Lanka has been the six year cyclical pattern of outbreaks. However, the expected outbreak in 1986 did not occur and only nine cases were reported. In 1990, six virologically positive cases have so far been reported. Unusual features about these cases are that they have all been in older (6-12 years) children, and they had all received a full course of immunization in infancy. Two of these cases also gave a history of polio, several years previously.

Laboratory surveillance is being carried out by the Virology Department of the Medical Research Institute. Poliovirus type 1 had been the predominant type identified in Sri Lanka. Genetic marker studies are also being carried out.

When a suspect case is reported the following actions are taken without delay:

- A dose of TOPV is given to every child below a predetermined age in the entire village or in the ward of the town where the case occurred;
- all children who have been partially immunized or not immunized at all are followed up until their immunization course is completed;
- a house-to-house search is carried out to detect any other cases of flaccid paralysis in the affected area.

## **7. SPECIMEN COLLECTION AND TRANSPORT: UPDATE**

Specimen collection kits and transport containers which are capable of maintaining specimens in good condition for up to four days have been developed and will be available for field study this autumn. Components of the kit include rectal straws, which are known to yield 0.5 to 2.0 grams of faeces, in addition to conventional specimen pots. Chemical indicators are attached to each set of specimens to monitor the reverse cold chain. These materials will be evaluated in the field during the next 12 months.

Although the rectal straws will be useful in those cases where it is difficult to get a stool specimen, or for special surveys or case contact specimens, the current policy in the Americas of examining specimens in three laboratories puts constraints on the routine use of this method for stool collection. These constraints on the amount of specimen must be balanced against the advantages of the rectal straws in ease of collection and ability to ship more specimens in a given container volume.

Experience in the Americas has shown that the identification and documentation accompanying the specimens is critical. The specimen collection kits will have a unique identification number formatted onto the label.

## **8. DEVELOPMENT OF THE GLOBAL LABORATORY NETWORK**

### **8.1 LABORATORY NETWORK**

The Plan of Action for the Global Laboratory Network has been finalized after receiving comments from the Regions. It calls for a three tiered system of laboratories. Specialized Reference Laboratories will provide standard reagents, perform certain special tests, provide training, and do research and development on new diagnostic methods. So far, four laboratories have been established by formal agreement, and have begun to develop and distribute standard reagents.

Regional Reference Laboratories will coordinate Regional needs for isolation and testing of specimens from cases, including quality control and training of laboratories in their Regions. They will also serve as referral laboratories for isolation, typing, and further characterization of specimens from National Laboratories within their Region. Regional Laboratory Plans of Action will be developed in all Regions by the end of 1990, with certification of Regional Reference Laboratories to begin within the next few months.

National Laboratories will be established from among diagnostic virology laboratories already functioning within the Region. The principle defined in the Americas, of beginning with a small number of excellent laboratories and assuring coordination and communication between them, will be followed.

Training courses have been held at the global level and in one Region on the basic laboratory diagnosis of polio. Two more basic diagnostic courses plus a global workshop on Polymerase Chain Reaction (PCR) testing are scheduled to be held in next few months. A laboratory manual, "The Virological Investigation of Poliomyelitis," has been developed, tested, and is now ready for distribution.

Despite a slow start, progress is now being made on development of the Global Laboratory Network, which will be greatly facilitated by the addition to the EPI staff in Geneva of a laboratory coordinator. Funding may be a primary obstacle, as the network will need approximately US\$ 1.2 million per year until eradication of wild poliovirus is achieved and certified.

The development of the Global Laboratory Network has been modeled on the network in the Americas which is now functioning well. The steps in its development will include the basic points found to be important in the Americas, including training, evaluation, quality control, supply of reagents and human resources, development of a laboratory manual, meetings, research, and the goal of transfer of technology as new diagnostic methods, particularly PCR, are developed. The lessons from the Americas, especially the obstacles met and now successfully overcome, will be used to benefit development of the Global network.

### **8.2 DIAGNOSTIC TESTS**

Experience with the Regional Laboratory Network in the Americas has shown the need for diagnostic tests which are not only specific and sensitive, but are also inexpensive, reliable, rapid, able to be standardized, and amenable to transfer to laboratories lacking sophisticated equipment and highly trained technical staff.

The general types of tests available are cell-culture-based (isolation or immunofluorescence) and non-cell-culture-based (ELISA, agglutination, PCR). The standard for comparison is the classical isolation and typing of virus, following which sequence information on the isolate can be obtained. This method is limited by its complexity and by the fact that several weeks or months are required for results to be available. The immunofluorescence technique can cut the time needed for a cell-culture method, and is particularly good for viral mixtures.

Non-cell-culture techniques need further investigation. ELISA or variations of agglutination techniques have the advantages of simplicity and may be useful as rapid screening tests. The PCR technique may prove to be the test of choice in the future, but at present it remains a research method.

Much work needs to be done to develop diagnostic tests. Interest of appropriate researchers in relevant topics must be stimulated, possibly by facilitating publication of results.

A capture ELISA for detecting poliomyelitis IgM specific antibody to diagnose poliovirus infection has been developed in China. The method has no cross reaction with other virus antigens, and can be blocked by the same type of poliovirus antigen. In comparing the rate of positive response between virus isolation and the IgM antibody detection test, the latter was found to be more sensitive. From 52 suspect poliomyelitis cases, the positive rate of virus isolation was 44.2% and the IgM detection rate was 76.9%.

The capture ELISA was also useful for typing of poliovirus infection. The test is simple, cheap and suitable for early and rapid diagnosis. In China, more than 200 laboratory workers have been trained and can do the test in many provinces and counties.

Use of the IgM test has also been studied at the National Institute of Public Health and Environmental Protection, Bilthoven. Dose-response curves indicate a dependence of response on the age of the child. Studies on sera from a polio outbreak in the Netherlands showed a positive IgM response in a case as well as in contacts of that case. More research is needed on the test, using sequentially collected sera from well-defined populations including vaccinees and prospectively, from cases of polio, as well as matched stool specimens. Moreover, the operational aspects of getting a test to the field, including manufacture and field testing of a kit, need attention.

The IgM test and another non-standard test method, the microplate method, were evaluated by participants at a recent regional laboratory training course held in Beijing. The participants felt that the IgM test shows promise, though standardization is needed, and more data should be assembled on specificity and sensitivity of the test, interference by concurrent enterovirus infections, and kinetics of the IgM response.

The microplate method is a variant of the isolation technique which allows simultaneous isolation using small volumes of faecal extracts in several cell types. The test in its current form was not felt to be usable owing to specimen toxicity.

## 9. VACCINES

### 9.1 POTENTIAL USE OF NEW POLIOVACCINES

A meeting held in Geneva in March 1990, assembling experts in manufacture and licensing of poliovaccines as well as research scientists, considered what criteria could be developed for licensing a new poliovaccine. Aspects discussed included the vaccine strains used, the laboratory characterization of the product, the manufacturing process, and the conduct of human trials. It was felt that only derivatives of the Sabin strains should be considered, and the lack of

neurovirulence and genetic stability of the new vaccine must be at least as good as the current Sabin vaccines before human trials would proceed. Furthermore, vaccines must meet WHO production requirements. The highest priority would be for an oral poliovaccine of improved immunogenicity.

## **9.2 ORAL POLIOVACCINES CURRENTLY IN USE**

Despite recommendations by the Consultative Group on Poliomyelitis Eradication and the EPI Global Advisory Group at previous meetings, only five of the current 18 producers of OPV are known to be producing vaccine in accord with WHO Requirements. Three additional producers are located in countries whose National Control Authorities certify vaccines for UNICEF supply, and thus are deemed competent to assure compliance with WHO Requirements. Five producers are known not to be producing vaccines in accord with these requirements, and the quality of the remaining vaccines is not presently known. Further activities are clearly required if all vaccines used are to meet WHO requirements.

The history of development and distribution of the Sabin vaccine strains underlines the problems with the Type 3 seed virus. Several variants are currently in use. Preliminary data suggest that these strains may differ in their immunogenicity, indicating a need for determination of the seroresponse to vaccines prepared from different type 3 poliovaccine seeds.

## **9.3 GAMBIA AND BRAZIL CLINICAL TRIALS OF ALTERNATIVE FORMULATIONS OF OPV**

The preliminary results of a randomized trial of alternative formulations of OPV in Brazil and the Gambia were presented. The trial, sponsored by WHO, PAHO, USAID, and several other organizations, was conducted over a three-year period, and involved over 2000 children.

Preliminary results from the trial showed that increasing the titer of the type 1 component to approximately 2,000,000 infectious units per dose was associated with a 10-15% increase in seroconversion after four doses in both countries; a doubling of the type 3 component was also associated with an improvement in seroconversion rates after two doses (Gambia only), but there were not significant differences after four doses. Regardless of formulation, an incremental increase in seroconversion to all three types was noted following each successive dose (including the dose administered at birth), suggesting the potential utility of adding additional doses to the primary series.

Because of the disappointing results for seroconversion to the type 3 component, and because of the possibility that the potency of that component was still on the ascending part of the dose-response curve, the possibility of further formulation studies was discussed.

## **9.4 REPORTS OF THE EPI RESEARCH AND DEVELOPMENT GROUP MEETINGS**

In accordance with the plan of action approved by the Forty-second World Health Assembly, the EPI Research and Development Group has set several priorities for polio-specific research. These include operational studies on immunization strategies, optimization of the TOPV formulation and development of diagnostic tests. The procedures through which research studies are evaluated and funded by WHO were reviewed. Several recently initiated studies were described, including an evaluation of combined schedules using TOPV and e-IPV, a study on interval between TOPV doses, and a study evaluating the impact of a dose of either e-IPV or TOPV given at six or nine months (at the same time as measles vaccine) to children who have previously received a full course of TOPV.

The Research and Development Group considers many of the same basic issues being presented to the Consultative Group for the Eradication of Poliomyelitis. A suggestion was made that all EPI issues and strategies related to the control of measles, elimination of neonatal tetanus, and the

eradication of poliomyelitis might usefully be considered by one consolidated consultative group in the future. This group might meet concurrently with the Research and Development Group to allow for interaction, exchange of ideas and discussion of priorities for research in their areas of interest.

## 9.5 REPORT ON THE PROGRAMME FOR VACCINE DEVELOPMENT STEERING COMMITTEE ON POLIO/HEPATITIS

The priorities for research for this group included improved diagnostic methods, improved thermostability of OPV, and approaches to developing a new Sabin vaccine which would be more antigenic as well as less neurovirulent. For the first two priorities, no proposals are presently funded by the Programme for Vaccine Development, although efforts will be made to encourage more and better proposals in the future.

### 9.6 Recommendations

- i) *In order to coordinate research in laboratory test development, vaccine improvement and operational studies with the requirements and priorities of the field, a post should be created in EPI/WHO to serve as a liaison between the field coordinators and the scientific research programme. That person should provide an in-depth understanding of field situations, strategies and priorities to the Research and Development coordinator in EPI. This may at times necessitate the convening of meetings to stimulate interest, define direction and coordinate particular areas of polio research with field priorities and to identify laboratories interested in carrying out such research. These meetings should include laboratory and field-based experts.*
- ii) *Efforts should be made to reactivate a draft resolution to the World Health Assembly specifying that all OPV used in the Polio Eradication Initiative meet WHO Requirements. Resources within WHO can then be used to ensure the use of vaccines of acceptable standards.*
- iii) *Research should pursue the issue of development of improved TOPV, particularly with regard to improved thermostability. This may necessitate assembling a meeting to discuss approaches to stabilization and establishing an integrated research effort in this area.*
- iv) *Evidence from controlled studies suggests that the formulation of 2,000,000, 100,000, and 600,000 infectious units per dose for types 1, 2 and 3, respectively, will give better type 1 seroconversion. WHO should work with OPV manufacturers to overcome the barriers to supplying vaccines of this formulation.*
- v) *Alternative delivery strategies should be implemented, aimed at maximizing the chances for protection of the individual and of the community against polio and to interrupt the transmission of wild poliovirus, especially in view of limitations in the immunogenicity of the current OPV, particularly for type 3.*
- vi) *The possibility of trials to investigate the utility of different formulations as well as the response to vaccines using different type 3 seeds should be examined.*

## 10. POLIOVIRUS IN THE ENVIRONMENT

### 10.1 REPORT OF THE CONSULTATION ON THE CREATION OF A BANK OF WILD VIRUS STRAINS

Four participants were convened for this meeting to develop a plan for a wild virus strain bank, to collect circulating poliovirus strains and to exchange information on the antigenic structures of these strains. The estimated costs for such a bank would be about US\$ 25,000, required for sequencing and specimen shipping.

This kind of research was felt by the members of the Consultative Group to be integrated and responsive to the needs of the field.

### 10.2 MONITORING OF POLIOVIRUS IN THE ENVIRONMENT

Methods of collection, concentration, and identification and quantitation of viruses in the environment differ depending on the type of system which is being sampled, as well as the type of virus. Different methods for each of these steps have advantages and disadvantages. Recent work sampling sewage in Sao Paolo, Brazil and quantitating poliovirus by the plaque method showed a number of poliovirus isolates, all of which were vaccine-like. This method of quantitation, though giving useful results, is labour-intensive and time-consuming.

PCR has been used to detect wild poliovirus in sewage samples which had been artificially spiked. The method was capable of detecting less than 200 plaque forming units in five litres of water, but could be made more sensitive by altering the staining technique used.

Although the methodology used shows much potential, it is still very much in the research phase. Consideration must be given to the sites for sampling, the frequency, and the sensitivity needed to assure absence of circulating wild poliovirus. These questions are part of the research agenda for the Americas, but will need to be considered very soon at the global level, particularly for the European Region.

#### *10.3 Recommendations*

*Reasonable protocols for monitoring of the environment for wild poliovirus, particularly in Europe and the Americas, with emphasis on the sensitivity, frequency, and numbers of locations needed, should be developed.*

## 11. MANUAL FOR COMMUNITY-BASED REHABILITATION

A manual for community-based rehabilitation has been developed and will be ready for distribution by the end of 1990. It is intended to be used with the support of rehabilitation specialists at the local level in training of family and community workers in the use of community-based rehabilitation techniques to help the child stricken with poliomyelitis.

The manual is divided into five sections, including one on how to recognize the disease, and chapters on how to care for the child in the acute and convalescent phases. Production of splints from readily available materials is illustrated, as well as specific exercises and movements which can help prevent deformities. It has many illustrations specific to each of these topics, and its use should be part of each outbreak investigation.

Because the techniques are designed to prevent deformities, it has often been found that parents and field workers become discouraged due to lack of improvement in the child's condition. Thus, the manual is not intended to be distributed directly to parents, but to be used for training, with proper and adequate supervision. It was felt that unless rehabilitation is built into the polio eradication initiative, the range of activities is incomplete.

## 12. FUNDING OF POLIO ERADICATION

Financial resources are essential if global polio eradication is to succeed. The total required is at least \$12 million per year, although if larger financial resources were available, much more support could be given to Regions and countries with greater need.

It is planned that a central HQ unit of five professionals supported by fund raising staff, should assist polio eradication activities at the Regional Offices where two staff, a medical officer and a laboratory specialist should be located. At least 16 long-term staff will be required at the national level, with an additional 90 person months of consultants per year.

One hundred and twenty training courses costing US\$ 600,000 are planned for each year. The laboratory network will require US\$ 1.2 million per year and essential research activities, US\$ 3 million per year.

Information services will need US\$ 314,000 per year and it will be necessary to maintain a reserve of poliovaccine and an outbreak control capacity costing US\$ 1 million annually.

Fund raising for EPI in the 1990s is targeted at six main EPI objectives:

- achieving and sustaining full coverage;
- achieving disease reduction, elimination and eradication targets;
- improving surveillance;
- introducing new vaccines;
- promoting other PHC interventions;
- research and development.

To meet these objectives, the budget for global immunization services will need to be substantially increased with the supply of extra budgetary funds, presently US\$16 million per year, being tripled. Various sources of funds, Government, non-governmental organizations, funds and trusts will be approached to identify support.

In raising funds, the fact that immunization is the most cost-effective procedure in medicine, and the easiest to apply, must be emphasised.

## 13. CERTIFICATION OF POLIO ERADICATION

PAHO convened a Commission in July 1990 to consider how polio eradication might be certified.

The Commission established a number of criteria for surveillance of flaccid paralysis:

- the number of units submitting weekly reports;

- percentage of case investigations carried out within 48 hours of detection;
- adequacy of specimen collection, shipping and testing;
- rates of flaccid paralysis.

It defined surveillance indicators for wild poliovirus:

- through the absence of detected wild poliovirus in suspect cases;
- through environmental studies;
- results from the laboratory network;
- results from other laboratories.

In January, a Technical Advisory Group meeting will be conducted to plan for the Commission's field work, leading to possible national commissions.

At least three years will elapse after the last known case before the Commission will certify polio eradication in the Region.

Mathematical models of polio may prove useful to help determine the likely longest period that poliovirus could circulate without being detected.

It was suggested that eradication should be considered by geographical areas, with countries cooperating across borders to confirm the absence of cases and to conduct common policies, including surveillance and environmental monitoring.

## 14. PROVOCATION POLIO

Some multiple pharmaceuticals, including penicillin and vitamins, injected into an infected child, have been implicated in provoking polio, as have trauma and operations, notably tonsillectomy. The role of DPT in provoking acute polio has been exaggerated. Very few cases of polio occur in the first six months of life, possibly reflecting trans-placental immunity.

### *14.1 Recommendations*

- DPT and other immunizations should be continued even in the presence of endemic poliovirus transmission, but other non-essential injections or those for which oral alternatives are available must be discouraged. Non urgent operations such as tonsillectomy should be deferred if polio cases are occurring in the area.*
- Immunization against polio should be completed as early in life as possible to reduce the risk of provocation polio.*

*Therefore, existing policies for primary health care, emphasizing early completion of primary immunization services and minimization of non-essential operations and injections, should be emphasized.*

## ANNEX 1

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