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Report of the Expanded Programme on Immunization
 Global Advisory Group meeting, 9-13 November 1987, Washington, D.C.

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1. INTRODUCTION

The Global Advisory Group of the Expanded Programme on Immunization (EPI) consists of 12 members. All WHO Regions are represented, six members being drawn from panels nominated by the Regional Offices and six members being selected either "at large" or from regional panels to provide geographical and technical balance. Representatives of collaborating agencies and donor sources are invited to Global Advisory Group Meetings as observers, and their views are considered in preparing the report.

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The tenth meeting of the EPI Global Advisory Group took place from 9-13 November 1987 in Washington, D.C. in the Regional Office for the Americas. The Officers for the Group were:

Chairman: Professor L. Kaprio (Finland)
Vice-Chairman: Dr J.P.Risi (Brazil)
Rapporteur: Dr Mambu-Ma-Disu (Zaire)

Annexes 1-3 contain a list of participants, a list of documents used during the meeting and the terms of reference of the Global Advisory Group.

The meeting was opened by Dr Robert Knouss, Deputy Director, Pan American Health Organization, who welcomed the participants on behalf of Dr Carlyle Guerra de Macedo, the Director.

Dr Knouss noted that all nations of the world are now accelerating their immunization programmes in order to achieve the goal of universal immunization by 1990, a milestone toward achieving the overall goal of health for all by the year 2000. The nations of the American Hemisphere have also set the goal of interrupting the transmission of wild polio virus by 1990.

The success of the EPI in the Americas is demonstrating that neither technical problems nor different stages of national development pose major threats to the achievement of the EPI goals. The most critical factors for success are the political commitment of the respective governments and the coordination of the various international agencies who are supporting immunization and other child survival initiatives.

An example of the excellent coordination now being achieved among these international agencies is the Joint Statement on EPI Policy and Strategic Approaches in the Americas which has recently been signed by PAHO, UNICEF, USAID, the InterAmerican Development Bank and Rotary International, the organizations constituting the EPI Interagency Coordinating Committee. The strategy uses polio eradication as an opening wedge for the full development of immunization services and disease surveillance. These services, in turn, strengthen institutional capacity for the sustained delivery of other primary health care services.

Operations research is another factor critical for the success of the EPI. Problems of training, implementation, monitoring and evaluation particular to each national programme must be identified and solved, using the experiences and the ideas of health workers engaged in day to day programme implementation at peripheral level. It will play a continuing role in programme evolution, particularly as the arsenal of new vaccines promised by the biotechnology revolution becomes available for wide scale public health use.

Dr Knouss, on behalf of himself and Dr Macedo, wished the meeting all success. They looked forward to receiving the Global Advisory Group's conclusions and recommendations, which would further guide the actions of the EPI in the Americas.

In assuming the Chair, Dr Kaprio thanked Dr Knouss for the hospitality of the Regional Office in hosting the meeting. He extended a special welcome to the new members of the Group: Dr Salah Hassan Al-Kandari (who was unable to attend) and Professor V.I. Pokrovski. He also welcomed the observers representing national development agencies, UN agencies and non-governmental organizations, noting that it was their partnership in supporting the efforts of national programmes which is making the EPI such a success.

The Group began its work with reviews of progress at global and regional level and concluded with discussions of selected technical issues of global relevance.

2. CONCLUSIONS AND RECOMMENDATIONS

After its review and discussion of the items on the agenda, the EPI Global Advisory Group adopted the following conclusions and recommendations:

2.1 Overall programme status

Due to the efforts of national governments, non-governmental organizations and support from the international community, the Expanded Programme on Immunization is achieving remarkable success. Coverage for a third dose of DPT or polio vaccines in infants are at a 50% level in developing countries (Annex 4: Table 1; Figure 1) where immunization programmes are now preventing over a million deaths a year from measles, pertussis and neonatal tetanus and over 188 000 cases of poliomyelitis (Annex 4: Table 2). Although significant progress has been achieved, it must be recognized that over three million deaths preventable by immunization still occur annually.

Continued acceleration of the EPI is needed to meet the goal of Universal Childhood Immunization by 1990. This should be pursued according to the guidance provided by the World Health Assembly in 1982 (Resolution WHA35.31) and in 1986 (Resolution WHA39.30) and according to the recommendations made by the Global Advisory Group, particularly those made in 1986.

Many developing countries will need external support well into the 21st century to sustain their immunization programmes. United Nations agencies, international development agencies, non-governmental organizations and other donors should plan to continue their support to national, regional and global levels of the programme for the foreseeable future, recognizing the critical role immunization is serving in reducing childhood mortality and disability, as well as its role as a building block for the primary health care infrastructure.

Improved coordination of outside donors in support of national immunization programmes would be useful in most countries. Excellent coordination is occurring within most countries of the Americas, where effective inter-agency coordinating committees have been established at country and at regional level under the leadership of PAHO. These groups have elaborated detailed financial plans, outlining the commitments of the national governments and outside groups over a 5 year period and are following programme performance at country level through quarterly and annual meetings, making necessary adjustments of plans and funding. The formation of such committees is recommended in all Regions and in all countries receiving outside support for immunization; where such committees already exist, they should receive the support of all agencies involved. This coordination benefits both the receiving countries and the donor agencies. It promotes effective use of available resources and provides the individual donors with both accountability and visibility, helping to assure their continuing support.

The primary objective of immunization is to reduce mortality and morbidity. Countries and Regions are encouraged to set specific disease reduction targets to be met during the period 1990-1995 (during which immunization coverage rates achieved in 1990 and beyond will have their impact on disease incidence) and to develop surveillance systems adequate to measure that impact. Sentinel surveillance should be encouraged during the period in which routine surveillance is being strengthened. Reports from each Region concerning the setting of disease reduction targets are requested for the next meeting of the Global Advisory Group in 1988.

In strengthening surveillance, primary emphasis should be placed on poliomyelitis, measles and neonatal tetanus. Together, they serve as indicators for a wide spectrum of programme activities. Poliomyelitis should come under rapid control where immunization services attain moderate levels of coverage. Measles will only be well controlled in the best immunization programmes. The control

of neonatal tetanus is best accomplished by strengthening primary health care services so as to assure clean deliveries and hygienic post delivery care and immunization of women of childbearing age.

2.2 Poliomyelitis eradication

The poliomyelitis eradication initiative in the Americas is commended. The commitment of the countries of the Region to eradicating this disease by 1990 has served to accelerate the progress of the EPI itself and has made the programme more effective in contributing to the development of the primary health care system as a whole. This is particularly evident with respect to surveillance and laboratory services. The initiative has been effectively used to increase the resources available to the EPI within the Region and to improve the coordination among donors.

Global poliomyelitis eradication can now be envisioned. The general success of the EPI, the success of the existing eradication initiative in the Americas and the adoption of the eradication goal by Europe all point toward the inevitability of global eradication. Efforts should now be pursued to adopt this goal, using it as a means to strengthen and accelerate the impact of the EPI in preventing all of the target diseases and as a means to increase its contributions to building the primary health care infrastructure. Notwithstanding the desirability of further improving vaccines and vaccine delivery schedules (see below), the technical and managerial tools needed to accomplish this task are now at hand. For the next meeting of the GAG, each Region is requested to review the potential for achieving Regional eradication within the next decade so that the GAG, in turn, can assess what might be a feasible date for global eradication.

Facilities for the laboratory diagnosis of poliomyelitis need to be accessible throughout the world. Each Region should establish regional and/or sub-regional reference laboratories to which diagnostic specimens can be referred, mainly through strengthening existing laboratories.

The occurrence of an epidemic of Type 1 poliomyelitis in West Africa in 1986 offered an opportunity to study the field efficacy of oral polio vaccine (OPV) in The Gambia and high potency inactivated polio vaccine (IPV) in the Kolda region of Senegal.

Based on the results of the 2 case-control studies, it is concluded that:

- Both the OPV and IPV vaccines used in the Gambia and Senegal are effective in preventing poliomyelitis. Data from the two studies suggest comparable protection from two doses of IPV and three doses or more of OPV.
- OPV remains the vaccine of choice for routine use in developing countries based on its low cost, its ease of administration, its superiority in conferring intestinal immunity (which may limit the person to person spread of wild polio virus), and its communicability (which may protect a proportion of unimmunized children). It is the vaccine of choice for epidemic control.
- Studies in the following areas should be pursued:
 - = clinical evaluation of different dosage schedules and potency formulations of OPV designed to maximize vaccine efficacy,
 - = field studies of the efficacy of IPV and OPV whenever the circumstances permit,
 - = clinical evaluation of different schedules of IPV-DPT designed to provide adequate protection against pertussis as well as poliomyelitis,
 - = clinical evaluation of different combined schedules of IPV and OPV designed to make optimal use of both vaccines.

2.3 Research and development

The establishment of an EPI Research and Development Group is welcomed. The maturation of national immunization programmes is bringing the recognition of new problems which must be solved before the full potential of immunization to control vaccine preventable diseases can be realized. Research is needed to address these operational problems as well as to find ways in which the new knowledge and new tools being provided by basic research can be used to the best advantage in national immunization programmes. The Global Advisory Group is to be kept informed of the work of the Research and Development Group.

2.4 Human immunodeficiency virus (HIV) infection and routine childhood immunization

The consensus statement resulting from the August, 1987 WHO Consultation on HIV and Routine Childhood Immunization is endorsed (Annex 6). The EPI should continue to review new information pertaining to HIV infection and immunization and to issue additional joint statements with the WHO Special Programme on AIDS as appropriate. Research to develop ways to administer vaccines which simplify or eliminate sterilization requirements should be pursued.

2.5 Measles control

An estimated 2 million children die annually from measles and its complications. Delayed mortality, occurring up to 12 months after infection, causes many additional deaths.

Measles control is made difficult because of continued disease transmission in areas with moderate to high coverage and a high incidence of measles in children less than 9 months of age.

Strategies for increasing the impact of immunization services on disease incidence should be further explored. These include investigations of alternative strategies for the use of Schwarz vaccine (including the use of two-dose schedules), the provision of immunization services at every contact with the health services and the effectiveness of immunization campaigns in urban areas.

The Edmonston-Zagreb strain of measles vaccine, if it proves effective in immunizing children below the age of 9 months, will also help increase programme impact. Current studies of this vaccine strain should be completed as soon as possible and it should be determined whether constraints exist in making it (or strains with similar characteristics) available at affordable cost for EPI use.

2.6 Neonatal tetanus control

Neonatal tetanus remains a serious and neglected problem in many parts of the world. Progress in the control of this disease through immunization remains insignificant compared with the progress in immunization coverage of infants.

Neonatal tetanus is typically a disease of the illiterate and the poor, the same groups which have least access to antenatal and delivery care. While antenatal and delivery services need to be improved and expanded, reliance on them alone will not suffice. Urgent steps should also be taken to improve immunization coverage.

The recommendations of the Eighth International Conference on Tetanus in Leningrad (1987) are therefore endorsed. The following issues deserve special emphasis:

- All countries should accept the challenge of eliminating neonatal tetanus from the world, launching special initiatives for this purpose as required.

- The target group for tetanus toxoid immunization should be widened to include all women of childbearing age, with special emphasis on pregnant women.
- Countries should improve the monitoring of neonatal tetanus by:
 - routinely reporting tetanus toxoid immunizations administered by target population and by dose, and
 - including evaluation of the TT immunization status of mothers in immunization coverage surveys for children.

2.7 Missed opportunities for immunization

Studies from several developing countries have indicated that the majority of children attending curative care facilities are eligible for immunization but are not immunized during that visit. They have also identified children who have received some, but not all of, the antigens for which they were eligible. Further studies should be undertaken to document the magnitude and the significance of this problem both for children and for women of childbearing age. Cases of vaccine preventable diseases can also reveal missed opportunities. They should be investigated, using standard case definitions, to determine why immunization services failed. Finally, it is recommended that strategies for reducing the problem of missed opportunities be studied. It is desirable that clinicians working in curative care settings be involved in this work.

2.8 Local area monitoring

The Local Area Monitoring (LAM) project should be continued. Given the incompleteness of currently available data, no efforts are warranted at global level for the present to expand the number of existing sites. Efforts are warranted, however, to improve national surveillance, and the expansion of this or other sentinel systems within Regions or within individual countries should be promoted. These may include rural as well as urban sites. Such efforts often reveal weaknesses in routine data collection and analysis which are not recognized by those concerned; they can also bring to light missed opportunities for exploiting available data which are otherwise lost.

2.9 Accelerated immunization programmes

A review of acceleration strategies employed in 22 countries confirmed the validity of the joint WHO/UNICEF statement on "Planning Principles for Accelerated Immunization Activities". Advantages of programme acceleration activities identified in the review include:

- increased political support for universal childhood immunization,
- effective social mobilization, and
- increases in immunization coverage.

Problems which were identified in at least some programmes included:

- inadequate planning,
- administrations of large numbers of immunizations to children too old to benefit from them,
- high drop-out rates,
- high cost,
- disruption of other ongoing primary health care services, and
- inability to sustain coverage at the level achieved during the acceleration.

Future acceleration activities should be undertaken so as to assure:

- a contribution of these activities to the long-term development of sustained immunization programmes,
- the selection of strategies of acceleration appropriate to the local situation (including periodic pulses (months, weeks or days), phased geographic expansion, and intensified publicity emphasizing the use of existing facilities),

- adequate monitoring of immunization coverage and costs, and
- donor coordination.

2.10 Social mobilization

Techniques and principles which have proved to be effective in promoting the use or the purchase of products or services can be adapted and applied to the task of changing peoples attitudes about the importance of immunization. The health sector may be able to achieve greater impact from communications efforts if national experts in communications, advertising and marketing are consulted in the research, design, production and distribution of materials and messages about immunization. Personal distribution of materials by leaders or organizations that are respected within the community is an effective means both of involving those leaders or organizations and of transmitting the messages.

2.11 Hepatitis B immunization

Chronic infection with hepatitis B virus is common in many countries. Such infection is a cause of hepatocellular carcinoma and other chronic liver disease. Hepatitis B vaccine is safe and effective in preventing infection, and its cost is now decreasing. Its use early in infancy can reduce chronic carrier rates by over 75%.

Hepatitis B immunization programmes should primarily aim at the prevention of chronic carriage of hepatitis B virus and should be considered in all population groups with chronic carrier rates of hepatitis B virus of over 2%; they become a major public health priority for populations with carrier rates above 10%.

Countries with chronic carrier rates of hepatitis B of over 2% and with the resources to initiate and sustain hepatitis B immunization programmes should introduce hepatitis B immunization as an integral part of existing childhood immunization programmes. This vaccine should be used in ways which strengthen existing programmes.

A minimum of 3 doses of hepatitis B vaccine is recommended, given by the intramuscular route. The first dose is recommended at birth or as soon as possible thereafter, the second dose 4-12 weeks after the first and the third dose 2-12 months after the second dose. While intramuscular administration is the only recommended route at this time, further studies on other modes of delivery which could contribute to further reductions in vaccine costs, including intradermal administration, should be encouraged.

Immunization schedules should be integrated so that the use of hepatitis B vaccine does not require any extra contacts with the health system beyond those already needed for vaccines included within national childhood immunization programmes.

While the use of hepatitis B immune globulin is effective in complementing the use of hepatitis B vaccine in preventing perinatal infection, its high cost and the need to administer it within hours of birth will preclude its use in most developing countries.

2.12 Vitamin A and iodine supplementation

In countries with recognized vitamin A and/or iodine deficiency problems of public health significance, EPI managers should collaborate with nutritionists and the Programme for the Prevention of Blindness in exploring ways in which the EPI might contribute to supplementation programmes reaching the vulnerable groups.

In countries where vitamin A and/or iodine supplementation programmes already exist, coordination between them and the EPI should be ensured.

Training and reference materials relating to vitamin A and iodine supplementation need to be developed for peripheral workers and for mid-level managers.

Recording systems should be established, using existing health care cards where possible, to document the administration of supplements and to protect children from the risks of excessive doses of vitamin A or iodinated oil.

The major actions recommended in the joint WHO/UNICEF statement on Vitamin A for Measles are endorsed:

"High dose vitamin A supplementation should be provided to all children diagnosed with measles in communities in which vitamin A deficiency is a recognized problem. In countries where the fatality rate of measles is one percent or higher it is sensible on the basis of current evidence to provide vitamin A supplement to all children diagnosed with measles."

Studies to investigate further the relationship of vitamin A supplementation with measles outcome are still needed, especially in areas where vitamin A deficiency is not a recognized problem.

Projects to implement and monitor vitamin A and iodine supplementation protocols within the EPI should be developed in selected countries.

3. SUMMARY OF THE GLOBAL AND REGIONAL PROGRAMMES

3.1 Global overview

In December, 1987, data obtained through the EPI information system showed for the first time that immunization coverage with three doses of DPT or polio vaccines in infants are at a 50% level in developing countries (Annex 4: Table 1; Figure 1). This is a major public health achievement. When the programme was initiated in 1974, no direct estimates of coverage were available, but, based on the quantities of vaccines being used at that time, coverage of infants with a third dose of DPT or polio vaccines must have been well below 5%.

Immunization programmes in developing countries are now preventing more than a million deaths each year from measles, neonatal tetanus and pertussis and over 188 000 cases of poliomyelitis (Annex 4: Table 2). Official reporting systems remain weak, however, and notify, often with considerable delay, only a small fraction of the cases which actually occur (Annex 4: Figure 2). Full immunization coverage, the programme goal for 1990, would avert many additional deaths and cases of disease: measles still kills nearly two million children each year, neonatal tetanus kills some 800 000 children and pertussis nearly 600 000 (Annex 4: Table 3). A quarter of a million polio cases still occur annually.

The theme for World Health Day, 7 April 1987, was "Immunization - a chance for every child". The EPI UPDATE prepared for that occasion noted that:

- Good immunization coverage parallels good health infrastructure. Coverage approaching 80% is reported from the European Region. Coverage below 40% is reported from the African and South East Asia Regions.
- Half of the infants in the developing world are in just four countries: China, India, Indonesia and Nigeria. Improvements in the coverage in these countries will have a significant impact globally.
- Programme acceleration is needed to attain the 1990 goal of universal childhood immunization. Acceleration requires two complementary actions: social mobilization and improved management of health services.

- Social mobilization can provide an initial spark, but is more important in ensuring that programmes are sustained. It has the power to change attitudes so that society no longer finds it acceptable for children to suffer and die from vaccine preventable diseases.
- Improved management should focus on using every opportunity to immunize eligible children and women. It should emphasize immunizing as early in life as possible, minimizing contraindications and providing immunization in all health facilities seeing children and women.

The EPI's major challenges at present remain accelerating and sustaining national immunization efforts. Acceleration must not become an enemy of sustainability. There is some risk that national programmes and outside collaborators, in pushing hard to reach the 1990 goal, do so in ways that cannot be sustained. Of course this is contrary to the fundamental objective of the EPI. 1990 cannot be considered as a finishing date: it is in fact a starting date for the ongoing immunization of all children of the world. Resources being committed to the programme now will need to be continued (and increased, as more children are born and more vaccines are added) for the foreseeable future. This is likely to present a particular challenge to external donors, who often find that short-term high-visibility efforts are easier to support than are longer-term efforts. Yet many national programmes will experience extreme difficulties unless external support can be extended into and beyond the next decade.

The Programme's central strategies have been developed by the EPI Global Advisory Group (GAG) and endorsed by the World Health Assembly and are now well defined. In 1982, the World Health Assembly endorsed a Five Point Action Plan recommended by the GAG which focussed on establishing a basic immunization infrastructure in each country (Resolution WHA35.31). The Action Plan called for promoting the EPI in the context of primary health care, for investing adequate human and financial resources in the programme, for ensuring adequate evaluation and for pursuing research as a part of programme operations.

In 1986, again following the GAG's recommendations, the World Health Assembly endorsed three general and four specific actions needed to achieve the 1990 goal (Resolution WHA39.30).

The general actions are to:

- promote the achievement of the 1990 goal through collaboration among ministries, organizations and individuals in both the public and private sector,
- adopt a mix of complementary strategies for programme acceleration, and
- ensure that rapid increases in immunization coverage can be sustained through mechanisms which strengthen the delivery of other primary health care interventions.

The specific actions are to:

- provide immunization at every contact point,
- reduce drop-out rates between first and last immunizations,
- improve immunization services to the disadvantaged in urban areas, and
- increase the priority for the control of measles, poliomyelitis and neonatal tetanus.

In 1986, in follow-up to the World Health Assembly resolution, the GAG endorsed a series of recommendations relating to each of the above action points. These recommendations remain a relevant guide for national and international actions in support of the EPI.

There are many questions, however, which arise in the course of programme implementation and which are posed by new observations, by the availability of new or improved vaccines or materials or even by new diseases such as AIDS. A major portion of this meeting of the GAG was devoted to this purpose. The items themselves are presented as separate topics in later sections of this report.

3.2. African Region

3.2.1. African immunization year

In its 1985 meeting, the Regional Committee for Africa declared 1986 as African Immunization Year. This resolution has played a significant role in mobilizing resources and promoting the Expanded Programme on Immunization.

In 1987, particular attention was paid to the evaluation of the activities of the African Immunization Year, in order to formulate further actions for the achievement of the goal. This report summarizes the main findings and recommendations resulting from this evaluation.

3.2.2. Country level

Reports are available from 39 countries:

- 39 countries developed action plans for the period 1986-1990.
- In 31 countries the programme acceleration was launched by presidents, heads of state or ministers of health.
- In 30 countries 2379 new immunization posts were established.
- 26 countries organized mass immunization rounds.
- More than 20 000 people were trained in 641 courses, seminars and workshops, bringing the total number of trained staff in the African region to about 46 000.
- While in 1984 the total number of immunizations was 42 million, in 1986 this number increased to 62 million.
- Regional immunization coverage for a third dose of DPT was 20% in 1984 and 33% in 1986. Twenty countries in the region have exceeded 50% coverage (Figure 1).

3.2.3. Health centre level

During this evaluation 20 WHO consultants visited a total of 424 immunization centres in 39 countries:

- 91% had satisfactory scheduling of immunization centres.
- 88% used needles with sterilization between injections.
- 82% had regular and sufficient vaccine supply.
- 78% had adequate cold chain system.
- 78% gave measles vaccine at or after the age of 9 months.
- 75% did not keep half used vials for use on the next day.
- 74% were adequately staffed.
- 57% had sufficient needles.
- 50% gave DPT at 6 weeks of age.
- 50% did immunize in case of mild illness.
- 42% used syringes with sterilization between injections.
- 34% gave OPV at birth.
- 23% had sufficient syringes.
- 22% had clearly defined immunization targets.
- 22% had steam sterilizers (almost all centres had some kind of sterilization equipment).

3.2.4. Major conclusions and recommendations

- All countries need to continue to accelerate their immunization programmes.

- Immunization services need further expansion; new fixed and outreach centres need to be established. All health facilities should provide immunization to children and women at every contact.

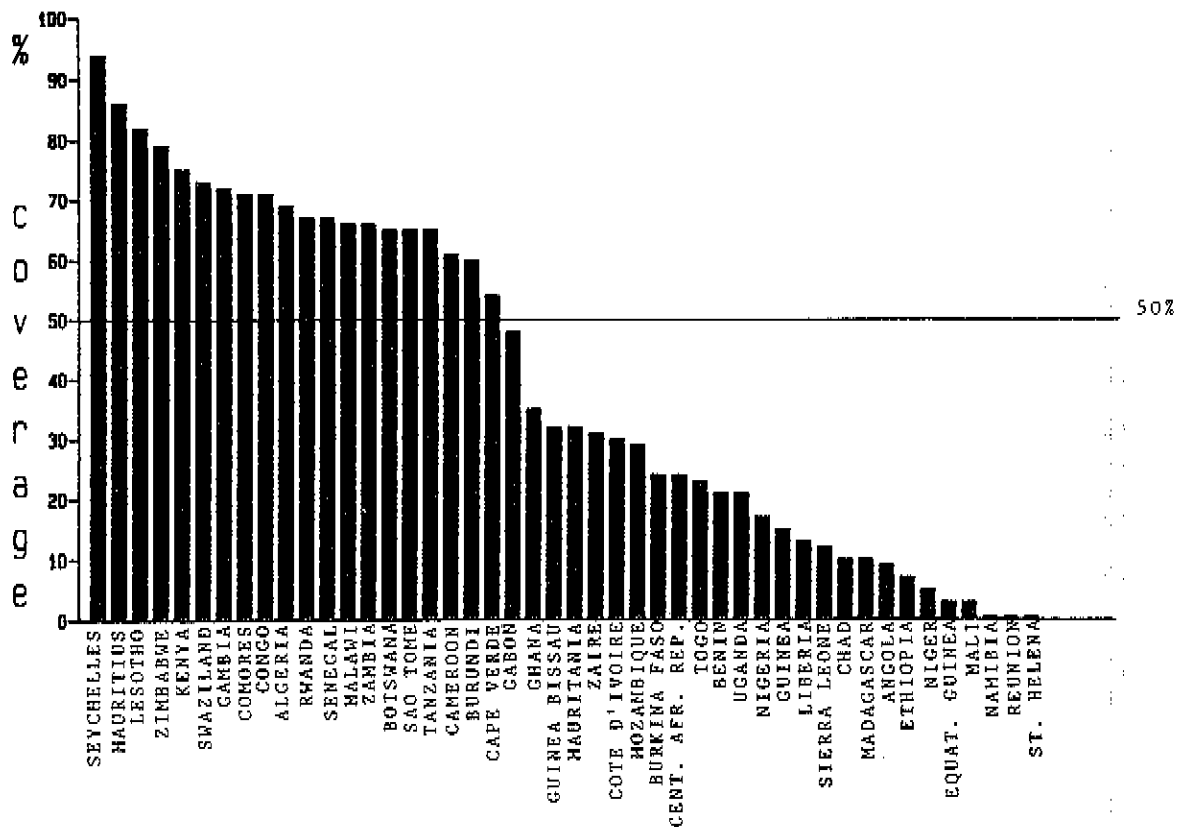
- All informational and promotional facilities should be utilized to motivate mothers to bring their children to be immunized as early in life as possible.

- In order to prevent missed opportunities for immunization, a vaccine vial or ampoule should be opened even for one child or woman.

- Quality of service delivery should be improved by augmenting the commitment of the health staff.

- Present international support to and collaboration with the programme should be continued.

Figure 1. Reported immunization coverage of 3 doses of DPT in children less than 12 months of age, African Region, 1986



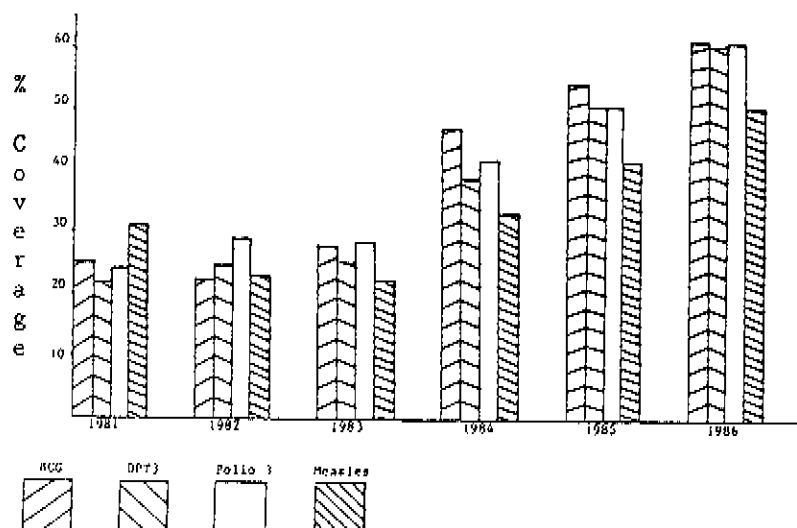
3.3. Eastern Mediterranean Region

3.3.1. Immunization coverage

During the last two years, 13 of the 24 countries/areas in the Region have accelerated their immunization programmes. As a result, immunization coverage with 3 doses of DPT or polio vaccine had increased to 60% at the end of 1986 (Figure 2). Fifteen countries/areas with 46% of the region's population now report rates of over 60% for a third dose of DPT or polio vaccines as compared with 11 countries/areas and 25% of the population in 1985.

Drop-out rates remain of concern, although there has been a considerable improvement in recent years: whereas in 1983, 9 countries had drop-out rates for DPT of more than 50%, none of the countries had such rates in 1986.

Figure 2. Reported immunization coverage in children less than 12 months of age, Eastern Mediterranean Region, 1981-1986



3.3.2. Disease incidence

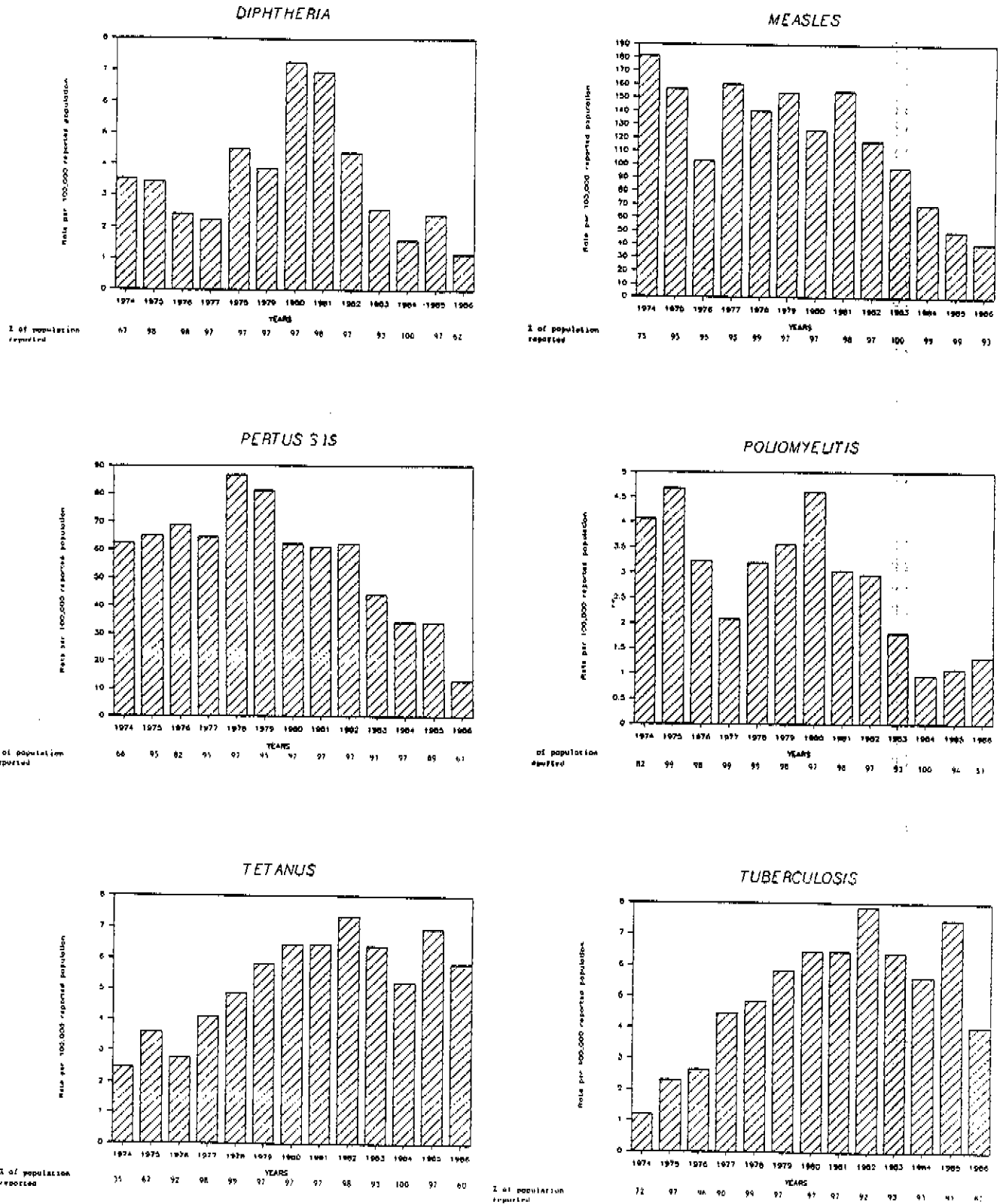
Figure 3 shows the reported incidence rates in recent years. Any interpretation of declining incidence rates must be approached with caution. Nevertheless, it is of interest to note that the reported incidence rates of diphtheria, measles, pertussis and poliomyelitis are showing a steady decline in recent years, while incidence rates for tetanus (all ages and neonatal) and tuberculosis remain fairly constant. These data are consistent with expected programme impact.

3.3.3. Evaluation

Since the last GAG meeting, EPI programme reviews have been conducted in Djibouti, Iran, Jordan, Oman, Sudan, United Arab Emirates and Yemen Arab Republic.

To overcome the problem of incomplete disease reporting, the Regional Office is promoting the idea of obtaining more complete information from local area monitoring. Such sentinel reporting has further developed during 1986. Several major cities, notably Karachi, Khartoum and Tehran, have all produced worthwhile data on disease incidence using this approach.

Figure 3. Reported incidence rates of EPI target diseases, Eastern Mediterranean Region, 1974-1986



3.4. European Region

3.4.1 European Advisory Group

The first meeting of the European Advisory Group on EPI was held in Copenhagen in September 1986. The Group noted that many countries reported not a single case of diphtheria, poliomyelitis or neonatal tetanus in recent years. It urged implementation of the elimination targets specified in the Regional Health for All strategy and elaborated in the Karlovy Vary Conference on Immunization Policies in Europe. The Group emphasized that additional resources are needed at Regional level.

In August 1987, a preparatory consultation for the second Advisory Group meeting was held in Gothenburg. The second meeting is planned for December 1987 in Rome. Major topics will be the elimination of poliomyelitis, training needs of national programme managers, standardization of case definitions, coverage assessment methodology, contra-indications, immunization schedules, cold chain assessment and the agenda for a meeting of European programme managers.

3.4.2. Other Regional Activities

- Workshop on communicable disease monitoring, Rome, November 1986
- Senior level seminar on EPI, CDD, ARI, Moscow, May 1987
- 8th International Conference on Tetanus, Leningrad, August 1987

3.4.3. Developments in countries

Diphtheria was reported in Sweden, Turkey and the USSR; increases in the incidence of pertussis in France, Greece, UK and USSR; high numbers of tetanus cases remain in France, FRG, Greece, Poland, Spain, Turkey, UK, USSR and Yugoslavia; declining rates of measles in Albania, Bulgaria, Czechoslovakia, Hungary, Netherlands, Norway, Poland, Rumania, and Sweden.

Reports on 1986 immunization coverage were provided to EURO by 47% of the member states.

Denmark, France, Netherlands, Portugal and Switzerland have introduced immunization with measles, mumps, rubella vaccine (MMR) in the age group 12-15 months.

Denmark, Portugal and Switzerland have included measles, mumps and rubella in the list of obligatory notifiable diseases.

In the United Kingdom, immunization programme managers have been nominated at district level.

Cold chain assessments are ongoing in Czechoslovakia, Hungary, Greece and Rumania. Bulgaria, Portugal, Spain, the United Kingdom and the USSR also agreed to participate, while France, Italy and Yugoslavia have shown interest.

The EPI has been promoted in Member States by personal contacts in meetings, conferences, seminars and courses. Support of national programmes with feedback information, technical advice, some equipment and materials would further help with such promotion. In addition, demonstration of success stories and analysis of failures could be used to motivate programme managers.

3.5. South-East Asia Region

3.5.1. Immunization coverage

Since the onset of the EPI in the region, there has been a gradual increase in immunization coverage rates, although measles coverage is still low.

Immunization coverage with 3 doses of DPT has increased to 48% and with 3 doses of OPV to 41% (see table 1). Four of the countries already report coverage rates in excess of 60% with these vaccines.

Considerable acceleration will be required to meet the 1990 target of universal immunization coverage. High drop-out rates and missed opportunities to immunize children and women in general health facilities are priority areas for improvement of immunization coverage.

Table 1. Reported immunization coverage (in %) in children less than 12 months of age and pregnant women, countries ranked for coverage with DPT3, SEAR, 1986

Country	Infants				Pregnant women
	BCG	DPT3	OPV3	measles	Tetanus2
Mongolia	52	81	86	10	-
Sri Lanka	76	77	77	47	44
Thailand	83	62	62	39	45
DPR Korea	53	61	62	44	-
India	29	53	45	1	40
Indonesia	67	48	46	47	26
Nepal	67	38	34	66	14
Maldives	28	25	25	13	11
Burma	32	20	4	3	21
Bhutan	32	16	16	14	5
Bangladesh	5	5	4	3	5
SEAR	35	48	41	12	32

3.5.2. Disease incidence

In DPR Korea, Mongolia, Sri Lanka and Thailand an overall reduction in the morbidity of some of the EPI target diseases has already demonstrated the impact of the programme. Reported numbers of cases of diphtheria and pertussis have declined in the period 1983-1985, while the number of measles cases (for which immunization coverage is still low) has remained quite stable. It is estimated that with present coverage levels over 17 million episodes of EPI diseases and almost 300 000 deaths are being prevented annually (table 2).

Six countries in the South East Asia Region have now set targets for disease reduction, including measles, neonatal tetanus and poliomyelitis. With the marked reduction in cases of poliomyelitis in DPR Korea, Mongolia, Sri Lanka and Thailand the stage has now been set for the consideration of a goal of polio elimination in these countries and ultimately in the South East Asia Region.

3.5.3. Monitoring and evaluation

EPI SEARO has developed a country level computerized EPI information system which is now available for adaptation to national health information systems. This system is "user friendly" and compatible with regional and global EPI information systems. Since the 1986 EPI GAG meeting, EPI programme reviews have been conducted in Bangladesh, India, Indonesia and Thailand. Cold chain evaluations using cold chain monitors were conducted in India and in Nepal.

Table 2. Estimates of morbidity and mortality (in thousands) from EPI target diseases, SEAR, 1986

Disease	Without immuniz.		With current level of immunization*			
	Expected cases	Expected deaths	Expected cases	Expected deaths	Averted cases	Averted deaths
Neon. tetanus	485	388	338	270	147	118
Measles	34 931	699	30 949	619	3 982	80
Pertussis	31 050	155	18 195	91	12 855	64
Diphtheria	388	29	191	14	197	15
Childhood TB	39	35	30	27	9	8
Poliomyelitis	194	12	91	5	103	6

* For current level of immunization coverage in the South East Asia Region, see table 1.

Note: For assumptions, see document SEA/EPI/MEET .87/17

3.6 Western Pacific Region

The Western Pacific Region initiated EPI in 1976. To achieve the 1990 goals and objectives the following plan of action is being used:

- Review and development of plans of operation, with emphasis on programme delivery at peripheral levels and the inclusion of WHO recommendations with regard to immunization schedules, quality of vaccine produced and used, cold chain systems, health training and education.
- Development of the managerial and training capabilities of senior and middle-level health personnel responsible for the implementation of the programme. Particular attention is being paid to the strengthening of national facilitators who will go on to organize and conduct national training courses.
- Development and strengthening of disease surveillance activities.
- Dissemination and exchange of information related to the programme in the Region.
- Support for studies on the epidemiology of target diseases, and for operational research on methods of improving vaccine logistics and delivery.
- Supply of vaccines to countries with no domestic production capacity, as well as collaboration with national authorities to standardize vaccine quality, where such capability exists.

Satisfactory progress has been achieved by most countries in the Region. Nonetheless, programme acceleration remains of the highest priority if the 1990 objective is to be accomplished. Specifically, further expansion of EPI activities will continue to be needed in China, Kampuchea, Laos, Papua New Guinea, the Philippines and Vietnam.

A review of the 1986-87 achievements of EPI in the Western Pacific Region in relation to the World Health Assembly's Five-Point Action Programme, is summarized below:

3.6.1 Promote EPI within the context of primary health care (PHC)

EPI plans at national level are being developed within the context of primary health care, with emphasis on programme delivery at the peripheral level. EPI evaluations have been merged with PHC in countries where EPI was not a part of PHC.

The majority of EPI training courses conducted at the national level have included materials related to other primary health care elements (diarrhoeal disease control, breast-feeding, growth monitoring, nutrition, environmental health and disease surveillance).

3.6.2 Invest adequate human resources in EPI

Several training courses have been conducted during the period covered by this report. The first EPI programme managers' workshop in the Western Pacific Region was conducted in 1986. Since that time, training courses have been held in China, the Marshall Islands, Papua-New Guinea, the Philippines, the Solomon Islands, Vanuatu, Vietnam.

3.6.3 Invest adequate financial resources in EPI

EPI regionally receives financial support from several external agencies for its activities. These include UNICEF and Rotary International, among many others. Substantial support in terms of manpower are being borne by the national authorities. The majority of countries in the region continue to be in need of external financial support, particularly in view of the current global economic situation.

3.6.4 Ensure that programmes are continuously evaluated and adapted to achieve maximum reduction of target disease deaths and cases

During the period under review, 9 immunization coverage surveys were conducted in 5 countries (Table 3). Table 4 shows the immunization coverage.

Problems remain with high drop-out rates (5-25%) between the first and last doses of multiple dose vaccines. Coverage rates for measles have improved from previous years, but remain low overall due to the relatively recent introduction of this vaccine in some countries in the Region. Measles coverage in Tonga and Samoa was, however, almost 90%.

Table 3. Results of immunization coverage surveys, WPR, 1987

Vaccine	Range of estimates(%)
BCG	61 - 98
DPT 3	24 - 93
OPV 3	24 - 92
Measles	19 - 92
Fully immunized	13 - 89

Evaluations of the cold chain were carried out during the year in Papua New Guinea, Singapore, Brunei Darussalam, Hong Kong, and Malaysia. Courses on logistics were held in China, Hong Kong, Malaysia, Philippines, and Vietnam.

EPI information systems are being upgraded for improved reporting of the target diseases. Programmes are being encouraged to look at the value of starting sentinel disease surveillance systems.

Table 4. Distribution of countries according to immunization coverage, WPR, 1985

Vaccine	Immunization coverage level			
	0% - 39%	40% - 59%	60% - 79%	80% - 100%
BCG	New Zealand	Vanuatu Viet Nam	Kiribati New Caledonia Papua New Guinea Philippines Singapore	Cook Islands Fiji Fr. Polynesia Hong Kong Macao Malaysia Tonga Tuvalu Vanuatu Western Samoa
DPT3	Kiribati Macao TTPI Vanuatu	Malaysia Papua New Guinea Tokelau Viet Nam	Am. Samoa Cook Islands Korea New Zealand Philippines Singapore	Brunei Guam Hong Kong Tonga Tuvalu Western Samoa
Polio3	Kiribati Macao Papua New Guinea TTPI Vanuatu	Am. Samoa Fiji Malaysia Philippines	Korea Fr. Polynesia New Caledonia Viet Nam	Brunei Cook Islands Hong Kong Singapore Tonga Tuvalu Western Samoa
Measles	Kiribati Macao Malaysia New Caledonia Papua New Guinea Vanuatu Viet Nam	Philippines	Fiji Fr. Polynesia Singapore	Cook Islands Guam Korea Tonga Tuvalu Western Samoa

Programme evaluations were carried out since November 1986 in provinces of China, Papua-New Guinea, the Philippines, Vanuatu, and Vietnam.

Seroprevalence studies have demonstrated that chronic hepatitis B carriage is endemic in many countries of the Region, with carrier rates of 2.7-11%. A lead has therefore been taken in the integration of hepatitis B vaccine into EPI by the Region. China, Hong Kong, Japan, New Zealand, Niue, American Samoa, Nauru have introduced this vaccine into their EPI schedule. Progress has also been achieved in standardizing Hepatitis B immunization schedules.

4. THE REGION OF THE AMERICAS

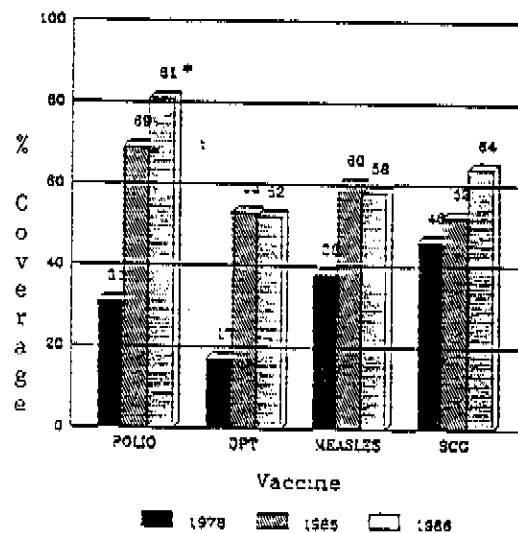
The EPI continues to make progress towards the 1990 target of providing immunization to all children of the Region, and of eradicating indigenous transmission of wild poliovirus from the hemisphere of the Americas.

Coordination among the agencies supporting the Programme in the Americas has permitted smooth implementation at the Regional and country levels. Intensive efforts at country level in the area of programme planning and financial analysis have produced National Work Plans for the five year period 1987-91 for every country. These will form the framework for program implementation and inter-agency coordination in support of national programmes in the Americas.

4.1 Immunization coverage

Vaccine coverage rates for Polio, DPT, and BCG in children less than one year of age increased between 1985 and 1986. Coverage for two or more doses of OPV has reached 80% (Figure 4).

Figure 4. Reported immunization coverage in children less than 12 months of age, AMR, 1978, 1985 and 1986.



Note: Coverage for Brazil, Cuba, Mexico and Paraguay based on 2 doses.

Coverage with measles has shown a 5% decrease. This reflects a lower coverage level in Brazil and Mexico, as well a decrease in the Andean sub-region.

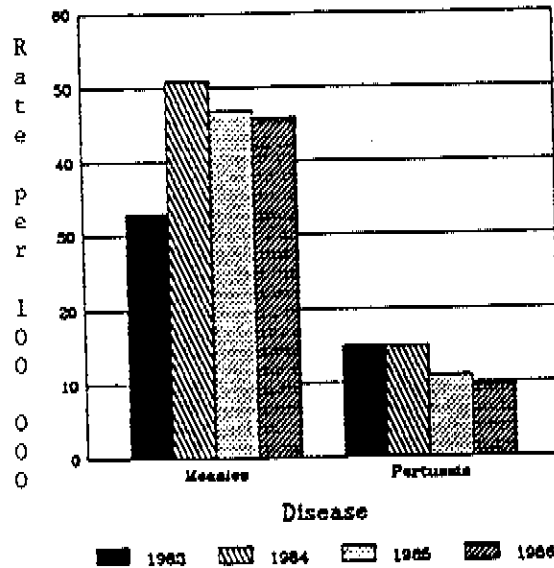
Overall, EPI acceleration and the use of national immunization days are being used by countries to improve coverage. Much remains to be done, however, if the stated goal of universal childhood immunization is to be achieved.

4.2 Disease incidence

The downward trend in the incidence of poliomyelitis observed until 1985 has been altered by a polio outbreak in Brazil, coupled with increases due to improved case reporting. The decline in measles and pertussis incidence continues (Figure 5), although caution must be applied in interpreting data on these two diseases, as surveillance systems for them are not as well developed

as for polio. Nonetheless, there is a decline in cases throughout all AMR sub-regions, consistent with the increase in vaccine coverage.

Figure 5. Measles and pertussis incidence rates per 100 000 population, AMR, 1983-1986.



4.3 National immunization days

Thirteen countries carried out national immunization campaigns: Bolivia, Brazil, Colombia, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Paraguay, Peru, and Venezuela. This strategy has been recommended by the AMR EPI Technical Advisory Group (TAG) for those countries where polio remains endemic. Furthermore, by including other EPI antigens in these immunization campaigns, coverage has been improved for the other EPI vaccines as well as for OPV.

4.4 National plans of action

National plans of action have been developed by all AMR Member States covering the five-year period of 1987-91. The plans cover all aspects of programme implementation, defining specific activities for 1987, and projecting needs for the coming years. Overall, the level of financial resources is in the order of US\$ 450 million, with 85% being financed from national budgets, and 15% from Inter-Agency Coordinating Committee (ICC) member agencies.

4.5 Training

Over 1500 health professionals have been trained in ten countries on surveillance. The improved polio surveillance in the Region would not have been possible without the availability of these trained individuals at the country level. A field guide for Polio Eradication has been widely distributed, with a final edition to be distributed very soon.

4.6 Laboratory

Six reference laboratories for poliovirus have been designated in Latin America, and the Caribbean. These are located in Argentina, Brazil, Colombia, Guatemala (INCAF), Mexico, and Trinidad and Tobago (CAREC). The central reference laboratory at the Centers for Disease Control (USA) is coordinating the training of staff of these institutions in DNA probe technology.

4.7 Technical Advisory Group (TAG)

The TAG for EPI and Polio Eradication in AMR/PAHO met for the fourth time on 20-22 April, 1987. The Group's conclusions and recommendations are summarized as follows:

- Disease surveillance is clearly the critical element in disease control and eradication. It must therefore be given the highest priority. Although surveillance is improving in many countries, it is still not adequate in any member country, and remains to be established in many. Cases of "suspected" polio reported should include all cases of paralytic disease in persons less than 15 years of age. All cases of Guillain-Barre Syndrome in this age group should be considered "probable" polio until proven otherwise. The case definitions and classifications developed by TAG should be used by all AMR countries. Finally, a detailed register of all "suspect" cases, with categorization into "confirmed", "probable", and "not polio" (with explanations) to be defined within set time limits, should be maintained by all member countries.
- High immunization coverage levels achieved and maintained are a key to polio eradication. National immunization days should be undertaken by all Group One (polio infected) countries at least twice a year. DPT, measles, and TT (for eligible women), should be included in these campaigns in addition to OPV. Every effort should be made to ensure that such immunization days strengthen ongoing immunization services. Whenever possible, a dose of OPV should be given immediately after birth. Immunization coverage should be assessed and monitored for each municipio (or comparable geo-political unit) in each country.
- Progress has been made in developing a network of polio reference laboratories, but substantial work remains to ensure that specimens are processed and reported promptly, with reliable results.
- Containment measures should be implemented promptly in response to all "probable" cases of poliomyelitis.
- The primary research priorities are:
 - = Determination, as quickly as possible, of the best formulation and schedule of administration of OPV under conditions pertaining to the Americas. The occurrence of the type 3 epidemic in Brazil in 1986, and the demonstration of lower-than-desired seroconversion rates to P3 (and to a lesser extent to P1) warrant this action.
 - = Review of official country guidelines for contra-indications. This should be combined with efforts to ensure official adoption of the guidelines issued by EPI and endorsed by the Latin American Pediatric Association.
 - = Identification of the percentage of children visiting health facilities who are eligible to receive immunizations, but who are not immunized, with the reasons for withholding the vaccine (missed opportunities for immunization).
 - = Development of techniques to evaluate the effectiveness and efficiency of national immunization days.
 - = Comparison of the efficacy of Edmonston-Zagreb and chicken allantoic membrane measles vaccines in infants 6-9 months of age.
 - = Evaluation of the efficacy of alternative measles immunization strategies (e.g. two-dose strategies, mass campaigns).
 - = Development and utilization of rapid detection techniques for the identification and characterization of polio viruses.

- Evaluation of the impact of neonatal tetanus in the Americas.
- Development of effective surveillance methods for pertussis.

4.8 Inter-Agency Coordinating Committee (ICC)

Three Joint Statements were issued by the ICC in their meetings of January and September, 1987. The first related to the joint review of national plans of action and the joint signature of agreements with the governments for their implementation. The second, to the implementation of a joint plan for social communication in support of EPI in the Region. The final Joint Statement covered the issue of EPI policy and strategy for the Americas. This Statement emphasized the issues of:

- the impact of EPI on disease incidence,
- improving surveillance systems,
- the use of national immunization days for increasing immunization coverage, and
- the value of the polio eradication initiative as a standard-bearer for the development of the entire EPI.

Inter-agency coordination will play an increasingly important role in developing sustainable immunization programmes for the remainder of this decade, and beyond.

4.9 Technology transfer

AMR/PAHO cooperates with member countries and collaborating international agencies to maintain and improve vaccine production standards and vaccine supply within the Region.

In order to facilitate the development of appropriate vaccines for diseases of importance to the Americas, AMR/PAHO is studying the feasibility of establishing regional centers for the development, field-testing, and production of such vaccines.

4.10 Social communications

In the Americas, the last years have seen initiatives for accelerating the EPI in the Region, and the innovations that have been introduced include greater attention to social communication and mobilization.

The general goals of social communication in support of EPI have been set as follows:

- education of the population on the prevention of diseases preventable by immunization,
- education of the population concerning their right of access to immunization services and their responsibility to exercise that right, and
- participation by and mobilization of all social sectors to carry out immunization and epidemiological surveillance initiatives.

A plan of action for 1987-88 was prepared, having been designed to promote initiatives and offer supporting materials within the established strategic lines of work to strengthen the EPI's social communication efforts. Subregional meetings will be held for assessment and exchanges of short and medium term plans of action, with participation of responsible EPI officers and social communication experts.

4.11 National plans of action: financial analysis

In order to ensure optimal utilization of resources and to avoid duplication of efforts, agencies supporting the polio eradication initiative formed an

inter-agency coordinating committee (ICC) with the aim of overseeing the implementation of the programme at regional level.

As additional resources became available, one issue that became critical was related to country programming and financial analysis. In order that the sustainability of the programme could better be assessed, a methodology for EPI national programming (which had been developed since 1981 by PAHO) was further elaborated with input from other ICC agencies.

The national plans cover a five year period (1987-1991). They state the objectives and the targets of the programme and describe its strategies and tactics. They provide a detailed analysis of activities to be implemented, including a time frame for completion of each activity. Responsibility for each item is identified along with the total cost in terms of capital cost and recurrent cost. Costs are then analyzed by source of funding. If the source is an external agency, a further breakdown is also done. This is completed for the four year cycle.

The plan of action is first elaborated by national health authorities and then discussed jointly with the the ICC agencies. Once these discussions have taken place and a consensus reached, a Memorandum of Understanding which outlines the responsibilities of the Government as well as the ICC agencies is signed between the Government and the ICC agencies for the implementation and support of the plan.

There is provision for quarterly meetings of ICC agencies and the Government for monitoring and fine-tuning of the plan. At the end of each year an evaluation is performed and an outline of activities for the forthcoming year is prepared.

Plans have been prepared for 19 countries in Latin America and the Caribbean. This represents 96% of the population of the Region. To date over US\$ 340 million have been committed by governments and US\$ 63 million by ICC agencies for implementation of these plans.

The proportion of external funds varies from a low of 4% in Brazil to a high of 48% in Bolivia; nearly 75% of these inputs represent capital expenditure, especially for the cold chain, transport, training laboratories and social communication. Nearly 90% of the recurrent costs are being covered by national funds.

When these figures are analyzed by year, it is observed that most of the capital expenditure is needed in the first two or three years, and that national expenditure accounts for the bulk of the recurrent costs. A very small proportion of the national resources are devoted to capital expenditure.

These data suggest that external funding will be required beyond 1991 at levels similar to those before acceleration began. There is a slight increase in national expenditure as the five year period ends, suggesting the commitment of the government to the programme, indicating that the programme will be sustained.

This analysis is preliminary and will continue. But it demonstrates the powerful political commitment on the part of governments and ICC agencies to achieve the goals of EPI and the eradication of polio from the hemisphere by 1990.

5. POLIOMYELITIS ERADICATION

5.1 Poliomyelitis in the Americas

Since September 1985, when all the countries of the Region of the Americas pledged their commitment to the eradication of poliomyelitis by 1990, major emphasis has been placed on the improvement of surveillance activities and the active search for cases. These efforts are reflected in the increase in cases reported and in the overall polio morbidity rate for the Region.

By the end of 1986, 931 cases of poliomyelitis were reported for 13 countries as compared with 869 and 536 cases in 1985 and 1986 for 15 and 13 countries respectively.

In 1987, up to week 42, 12 countries reported 708 cases, while in the same period in 1986, 835 cases were reported from 11 countries. This decrease in reported cases is attributed to a significant decrease in poliomyelitis activity in Brazil even though (with the exception of Guatemala and Haiti) all countries of the Region are reporting more cases than the previous year.

For 1986, age information was obtained for 890 of the 931 confirmed cases and shows that 79% of the cases were under 5 years of age. The immunization status of 70% of cases was obtained. For the Region, 61% of the cases had received less than three doses of OPV. When Brazil data are excluded, this proportion increases to 72%. In Brazil, 46% of cases had received three or more doses of OPV.

For 1987, all countries provided data on virus isolation. Enteroviruses were isolated from 90 (27%) of the 336 stool samples for which final results were obtained: 48% were Type 1, 8% were Type 2, 40% were Type 3 polio virus, 2% were vaccine-like polio virus and 2% were other enteroviruses. If Brazil data are excluded (where 54% of the isolates were Type 3 polio), the distribution of the 3 polio viruses is respectively 69%, 2%, and 29%.

During 1986, 931 of the 1 552 cases of the "probable" and the "suspected" reported cases were confirmed as poliomyelitis. Only two countries, Honduras and Venezuela, had less than 50% of their reported cases confirmed, an indication that the case definition of suspected and probable polio cases is reasonably specific.

Information on the source of notification was available for Brazil and Mexico. Routine notification only accounted for one third of the reported cases in Mexico, compared with 80% in Brazil.

Because surveillance systems are still being developed, the interval between onset of symptoms of poliomyelitis and notification of the case is still above the maximum of 2 weeks set as an indicator of reporting efficiency. In 1987, the proportion of cases reported within 2 weeks of onset of symptoms ranged from 38% in Colombia to 60% in Peru.

A key element in the eradication programme is the organization of containment activities. To date, these have not been performed on time in most countries. They have usually not succeeded in stopping the circulation of the wild polio virus. Most cases are confirmed by the presence of residual paralysis 60 days after the onset of symptoms. Generally, all reported cases are followed up for the verification of residual paralysis, but delays in confirmation are frequent. In Peru where 100% of reported cases were followed up in 1986, the average time between onset of disease and confirmation was 4 months. The disease most frequently confused with poliomyelitis was Guillain-Barré Syndrome (GBS). This diagnosis represented at least one fifth of the discarded poliomyelitis cases occurring in children under 5 years of age.

In the Region of the Americas surveillance systems have been activated to meet the needs of the programme, namely early detection of suspected cases and prompt responses of outbreak control. Still, much remains to be done if the goals of the programme are to be achieved by 1990. Only recently, most of the additional field staff that will cooperate at region, inter-country and country levels have been appointed. Furthermore, the network of laboratories is in the final stages of establishment. Training for surveillance is being intensified for 1987. It is anticipated that the programme will be at full speed by the start of 1988 at which time strategies and activities can be adjusted and accelerated as appropriate.

5.2 Studies of poliomyelitis vaccines in the Gambia and Senegal

The occurrence of an epidemic of Type 1 poliomyelitis in West Africa in 1986 offered an opportunity to study the field efficacy of oral polio vaccine (OPV) in The Gambia and high potency inactivated polio vaccine (IPV) in Senegal.

Case control methods were used to estimate vaccine efficacy in an outbreak of Type 1 poliomyelitis in The Gambia, where OPV was used, and in the Kolda region of Senegal, where the newer, more potent IPV was used. The studies differed in the criteria used to select cases and in other methodologic aspects. In The Gambia, many cases were diagnosed early in their illness, several of whom either subsequently recovered without residual paralysis or died. Diagnoses made in the field were confirmed by three regional physicians and/or hospital staff in Banjul. In Senegal, only cases who had residual paralysis after at least 60 days and in whom the diagnosis was confirmed by a neurologist and an infectious disease specialist were accepted. These specialists were kept blinded to the vaccination status of the cases at the time of clinical examination.

In The Gambia, the efficacy of three or more doses of OPV compared to zero doses was estimated to be 79% (95% confidence interval 63% to 88%). The clinical efficacy was similar to a recent serologic study in The Gambia demonstrating 81% seroconversion to Type 1 following three doses of trivalent OPV. In Senegal, the efficacy of two doses of IPV compared to zero doses was estimated to be 89% (95% confidence interval 62% to 97%). This estimate is also similar to the seroconversion rate after two doses reported earlier in Senegal.

The differences in the methods used in the two studies limit the reliability of any comparisons made between the results. However, the overlap in the confidence intervals of the estimates of vaccine efficacy suggests that three or more doses of OPV may have an efficacy comparable to two doses of IPV.

The clinical efficacy of one dose of IPV compared to zero doses was 36% (95% confidence interval 0% to 67%).

6. RESEARCH AND DEVELOPMENT

In July, 1987, in recognition of the need to intensify research and development efforts in the Programme, an EPI Research and Development Group was formed under the Chairmanship of Dr William Foege. Its terms of reference are provided in Annex 5.

The Group held its first meeting in Atlanta, Georgia on 22-23 September, 1987. Studies relating to the following areas were identified as priorities:

- AIDS and immunization,
- improved vaccines (including vaccine vectors, vaccine stability, acellular pertussis vaccines, measles vaccines and measles immunization.

strategies to protect children under nine months of age, and new vaccines with potential for inclusion within the EPI),

- poliomyelitis eradication,
- barriers to immunization programmes and methods to improve coverage rates,
- surveillance,
- coordination of ongoing research,
- improved management methods, and
- use of the EPI for delivering other services

Reports from the Group's meetings will be circulated to the members of the EPI Global Advisory Group as well as to other interested parties. The Rockefeller Foundation and UNDP have contributed some US\$ 600 000 to the EPI in 1987 for research and development in the area of applied vaccinology. Both organizations foresee the possibility of continuing their support in future years.

7. HIV INFECTION AND ROUTINE CHILDHOOD IMMUNIZATION

The Group reviewed the report "WHO Consultation on HIV and Routine Childhood Immunization" from the workshop held in Geneva on 12-13 August, 1987. The recognition of HIV infection is posing a number of questions in the area of immunization, and research to address them is for the most part already underway. Annex 6 contains the August 1987 consensus statement on this topic which was endorsed by the EPI Global Advisory Group.

8. MEASLES CONTROL

It is estimated that 70 million cases of measles occur annually in developing countries, causing some 2 million deaths. While these figures are based on sound epidemiological data, recent studies suggest that the deaths attributable to measles may be more than was thought.

Measles has a significant impact not only on children's health in the acute phase of the illness, but also for some time afterwards. Studies of the delayed effect of the impact of morbidity after measles infection suggest that children who have had measles have a significantly higher incidence of diarrhoea, respiratory problems and many times more days of illness than controls. Measles immunization is therefore likely to reduce mortality by more than the proportion of deaths usually attributed to measles.

Recent studies in Bangladesh, Haiti, India, Senegal and Zaire have supported this. Typically, mortality was reduced 45-60% in the immunized group compared with the 3 control groups aged 7-35 months.

The timing of the attack of measles is important. In Guinea-Bissau, children who were in contact with measles infection during the first six months of their life had a 3-4 times higher mortality than community controls between 3 months and 5 years of age.

The optimal timing of immunization was discussed. In many countries a significant proportion of cases occur in children below 9 months of age. There is a need to explore other options for the use of the Schwarz strain of vaccine presently in use. One such option might be a two-dose vaccine schedule for areas of high measles transmission, the first dose probably at 6 or 7 months and the second at perhaps 9 months. The Edmonston-Zagreb strain of vaccine may provide another solution if studies confirm that it can be effectively used in children below the age of 9 months.

The inter-relationship of vitamin A deficiency and measles infection is complex. The main impact can be seen in mortality, eye disease and levels of nutrition. Where vitamin A deficiency is a public health problem, it is appropriate to supplement dietary vitamin A with vitamin A given in association with EPI vaccines.

9. NEONATAL TETANUS CONTROL

In 1987 neonatal tetanus remains after measles the second killer of children among the EPI diseases. At present immunization coverage levels still 800 000 newborns die each year from neonatal tetanus and only 200 000 deaths are being prevented.

Community based neonatal tetanus mortality surveys have been carried out in 32 countries which contain 58% of all infants in the developing world excluding China, but survey data are still missing in some of the most populous countries.

Routine reporting of neonatal tetanus has progressed in all regions and varies from 21% of countries in the African Region to 64% in the South-East Asian Region. Nevertheless many countries still do not report neonatal tetanus.

Coverage of pregnant women with 2 doses of tetanus toxoid is less than 20% in the developing world excluding China. This low coverage affects all Regions (Figure 6). The estimated percentage of pregnant women immunized with 2 doses of TT varies greatly with a maximum of 34% in the South-East Asian Region.

In 1987 tetanus immunization coverage remains less than half the coverage achieved with the third dose of DPT or poliomyelitis vaccines (Table 5).

Figure 6. Percentage of pregnant women immunized with 2 doses of tetanus toxoid, by Region, December 1987

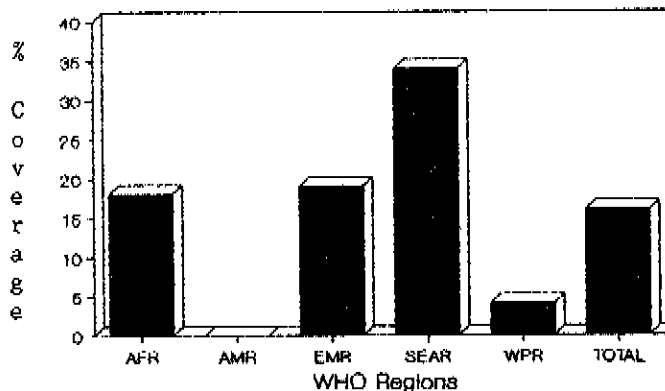


Table 5. Changes in immunization coverage of infants and of pregnant women, 1984-December 1987

Year	Infants				Pregnant women
	BCG	DPT3	Polio3	Measles	Tetanus2
1983	27	28	22	13	11
1984	50	46	47	38	11
1985	47	46	48	42	12
1986	52	52	54	43	16

However progress in the control of neonatal tetanus in relation to high tetanus toxoid coverage of pregnant women has been documented in Sri Lanka and in the city of Maputo (Mozambique).

At the Eighth International Conference on Tetanus in Leningrad, data on neonatal tetanus control were reviewed. It was concluded that "the control of neonatal tetanus is an emergency and accelerated efforts to immunize women at risk are a must". If 50% of the children of the world can receive the third dose of DPT, there is no reason why the mothers of these children cannot receive at least 2 doses of tetanus toxoid.

10. MISSED OPPORTUNITIES FOR IMMUNIZATION

Anecdotal evidence has for some time indicated that opportunities are frequently missed for partially immunized children to be brought up to date on their immunizations when seen at health-care facilities for other reasons. An approach EPI has taken to address this issue has been to incorporate into immunization coverage surveys a questionnaire on "Reasons for Immunization Failure". An analysis of 18 such surveys performed globally in the last 7 years reveals that non-completion of the recommended immunization schedule is blamed by questionnaire respondents largely on a handful of reasons (Table 6).

Many countries separate curative and preventive services, so that immunizations are provided only during defined hours, on different days, or even at facilities physically separated from the other clinics. A number of studies have attempted to gauge the magnitude of this problem (Table 7). Methodologically, the question has been approached either by interviewing mothers as they leave clinics with their child ("exit interviews"), or by the retrospective review of clinic records.

By utilizing curative care clinics for immunization it may be possible to reach a population which utilizes preventive care services poorly. Simply reviewing with parents the immunization status of their children should help to reinforce the importance of immunizations in their minds. The value of providing immunizations at non-preventive, acute care clinics was well illustrated in a 1980 study in the Gambia, where already most M.C.H. clinics provided

Table 6. Failure to have children immunized, summary of major reasons volunteered by mothers in 18 immunization coverage surveys

<u>OPERATIONAL AND LOGISTICAL PROBLEMS:</u>	24 %
Time inconvenient/ site too far....	14%
Lack of vaccinators/ other staff...	5%
Lack of vaccines/ other supplies...	5%
<u>LACK OF INFORMATION ON:</u>	
Programme benefits.....	12 %
Sites and dates for immunization.....	6 %
The total number of immunizations needed.....	5 %
<u>CHILD ILL:</u>	11 %
Therefore not brought to clinic....	2%
Therefore dose not given.....	1%
Unspecified.....	8%
<u>LACK OF MOTIVATION BY CARETAKER</u>	5 %
<u>FEAR OF ADVERSE EFFECTS</u>	4 %
<u>TOTAL</u>	67 %

integrated curative and preventive care. Of the children immunized against measles, 76% had received the vaccine during the course of a visit for acute care, not well-child care. Of those eligible who had not yet been immunized, the commonest reason (38%) was that the clinic attended did not provide immunizations as part of acute care visits.

Table 7. Summary of studies on missed opportunities for immunization

Country	Year	Nr of children	Type of study	% Missed opportunity
Cameroon	1982	212	survey	22
India	1983	446	record review	86
Pakistan	1984	4429	exit interview	90
Nepal	1985	80	survey	63
Bhutan	1985	113	record review	79
Indonesia	1986	104	exit interview	74
USA	1986	18	survey of cases	94
Turkey	1987	132	exit interview	61
Thailand	1987	63	exit interview	56

There are many reasons why opportunities may be missed to immunize eligible children. Many are, however, likely to be readily correctable. EPI therefore prepared, in 1983, a protocol entitled "Study of Immunization Status and Reasons for Postponing Immunizations" for the purpose of encouraging the assessment of immunization coverage as well as missed opportunities for immunization. That protocol has now been updated and revised, and is entitled: "Protocol for Assessment of Missed Immunization Opportunities". This new protocol has been field-tested and is currently in the process of being finalized.

In countries where missed opportunities for immunization are found to be frequent, it is hoped that the national authorities will be encouraged to re-examine their strategies aimed at combating this problem. This may be of particular importance in areas where access to health services is limited, for under such circumstances missed opportunities for immunizations may result in a significant number of avoidable deaths and disability in children.

11. LOCAL AREA MONITORING

The routine EPI disease surveillance system has not been sufficiently sensitive to demonstrate any impact of EPI on the incidence of targeted disease. The Local Area Monitoring (LAM) Project, a sentinel surveillance system comprising of data from the 25 largest cities in the 25 most populated countries in EPI, was thus started.

Progress with the LAM has been hampered by the unavailability of quality data in the sentinel sites originally selected. Analysis of the compiled data has, in consequence, not been possible without substantial margins of error being introduced, for example by the necessity of using case and population data totaled for all ages where age-specific data were unavailable. Nonetheless, information from six sentinel cities, one with the best data from each W.H.O. Region, shows an encouraging trend in incidence for selected diseases with maturation of their immunization programmes over time. It has so far been possible to collect good quality data for the desired timespan in only 8 of the 25 cities designated as sentinel sites for LAM, however.

12. ACCELERATED IMMUNIZATION PROGRAMMES

During the past three years some 60 countries have embarked on accelerated immunization programmes in pursuit of the goal of universal childhood immunization by 1990. A review of acceleration in 22 countries was undertaken as a step in the ongoing assessment of these accelerations.

Although early accelerations were primarily national campaigns, the review showed that the acceleration strategies included a range of approaches - periodic pulses (i.e immunization days or weeks), phased geographical expansion from one region to another and intensification of a routine programme as well as the full blown national campaign with multiple antigens. Many countries used several approaches.

The experiences in the 22 countries reflect strengths and weaknesses in the accelerated programmes and, as can be expected, both country specific and common problems in management and implementation were evident. Rapid action led to the development of successful plans for acceleration in a number of countries but in others the short planning time frame and insufficient planning process led to important logistical shortcomings. These included shortages of vaccines, cold chain failure, oversight of important groups and neglect of important technical considerations such as appropriate sterilization procedures. Planning for the longer term programme was rarely initiated at the time of the acceleration. Training for the acceleration was usually provided through short, intensive seminars. However, substantial training gaps were evident in many situations.

Organizational arrangements, including intersectoral coordinating committees, generally made it possible to draw together contributions from many groups, but their functioning was not uniformly harmonious and they were often quickly disbanded after the acceleration. When the full participation of the Ministry of Health and its commitment to the acceleration was lacking, a variety of difficulties such as inter-ministerial rivalries and curtailed follow-up were encountered. The contributions of social mobilization and strong political commitment to the accelerations success were clearly demonstrated in most of the countries.

Substantial increases in coverage with each of the EPI recommended antigens were achieved through the accelerations. These were in the order of 20-40 percentage points. However, the documents reviewed pointed to the many limitations of coverage data such as inaccurate denominator information, inconsistent definitions, variations in sampling methods, absence of base line information - all pointing to the need to interpret coverage information with caution. Post-acceleration coverage has generally decreased, although not to pre-acceleration levels.

Approximately half of the immunizations were given to children over the age of one. The problem of drop-outs between vaccine doses was not significantly reduced in the accelerations. Tetanus toxoid, moreover, has frequently been omitted during the accelerations. Large regional coverage variations were noted as well as more limited coverage increases in urban areas.

Reported immunization costs varied widely, reflecting major differences in methodologies applied to studying costs as well as variations of performance in different sites.

The acceleration experience reviewed suggests the need for attention to sustainability issues. There are numerous indications of the effect of acceleration in strengthening the capacity of the health system to maintain high levels of immunization coverage. Development of comprehensive plans, improved cold chain, increased monitoring, more widespread technical skills and broader understanding of immunization needs are among the positive factors. Political and donor commitment and use of new communication techniques are additional strengths. However, resources were at times shifted from other programmes, routine immunizations were neglected after the acceleration, equipment was withdrawn and personnel were discouraged by post-acceleration let-down. Heavy donor resource inputs and assumption of operational tasks by donors occasionally fostered the view of the accelerations as an international initiative.

The accelerations stimulated a number of other primary health care initiatives in many of the countries but it is still too early to assess the input on the primary care system.

A number of recommendations for future accelerations emerge:

- Accelerated approaches should be incorporated as a regular element of national immunization programmes, in a role of strengthening routine services:

* encourage regular consideration of accelerated approaches in ongoing planning, both short- and long-term, at national level;
= expand training of national immunization staff particularly in techniques of social mobilization.

- Donors and governments should learn from the experience which has been gained, to carry out accelerations most effectively:

- = select strategies for acceleration that are most suitable for individual countries and regions,
 - = assure an adequate planning process and time frame which includes all relevant parties and permits adequate access to relevant information,
 - = provide realistic logistical and personnel arrangements which avoid disruption of other ongoing national and international programmes.
 - = emphasize training and supervision with particular attention to immunization techniques, sterilization of equipment, record keeping, communication with parents and cold chain maintenance,
 - = simplify and standardize records and data collection methods used during accelerations, to improve monitoring and evaluation,
 - = apply the fullest possible range of social mobilization techniques to obtain participation from different sectors and broad community involvement.
- In conducting accelerations, perspective should be maintained on the need to sustain the gains in immunization coverage achieved:
- = use existing infrastructure and service delivery mechanisms, and maintain to the extent possible standard messages and routines,
 - = maintain an emphasis on the quality of immunization service during accelerations, particularly in assuring that vaccines are administered properly, that information is provided to parents, and that follow-up is done to minimize drop-outs,
 - = take advantage of the energy and enthusiasm generated for acceleration, and work to channel and direct these for ongoing immunization activities and for other child survival or PHC initiatives,
 - = ensure, to the degree possible, that resources levels are affordable, with particular attention to recurrent cost burdens in different country situations.
- The international community should maintain its commitment to achieving immunization goals through the selection of strategies and inputs that best support national efforts.
- Further testing and assessment should be carried out to identify optimal mixes of programme elements in different situations and to elucidate facilitating and inhibiting factors.

13. SOCIAL MOBILIZATION

Effective social mobilization relies heavily on communication: communication among health workers and those partner agencies and others working with them in EPI, and communication of the message of immunization's benefits to parents. Opportunities for more effective communication in both areas should be used.

UNICEF has prepared an animated film designed to inform parents about the benefits of immunizing their babies. It is the first of a proposed series of 20 animated films (five minutes in length each) which will treat different topics of good health practices. The series is designed for repeated television broadcast in developing nations. The initial film, researched in Kenya, Ecuador and Indonesia, is currently being field tested. The next step will be production of subsequent messages, assuming funding for the project can be obtained. Concurrently, a booklet of "core health messages," tentatively entitled Facts for Life, is to be developed for mass distribution as a complement to the broadcast series.

A review and summary of issues in "information, education, and communication" stressed the need for:

- better coordination among partners assisting EPI programs,
- identification of specific roles for organizations, and
- greater efforts to evaluate the effectiveness of communication initiatives.

These and other issues outlined in a joint WHO/UNICEF statement on policy and strategy (JC26/UNICEF/WHO/87.5) are to be discussed at subregional meetings, which will focus on:

- policy,
- social mobilization
- training, and
- evaluation

Such meetings can strengthen research and development, define goals and objectives, and build a sustained alliance for partner agencies in social mobilization.

Principles for obtaining the cooperation of voluntary organizations, trade and professional associations, and other private sector groups are:

- determine how the group's purpose, particularly its "service to society" objective, can be related to the cause of child survival,
- help the organization to identify a specific role complementary to the EPI,
- educate the group by means of a presentation and specially proposed publications, and
- sustain the interest of non-health sector groups, involving their members and providing recognition.

General principles of effective communication - based on experiences drawn from advertising and marketing sectors - are also applicable to raising awareness of the benefits of immunization. The health needs to seek advice and counsel from advertising and marketing experts in the process of research, design, production, and dissemination of messages designed to influence parents to complete immunizations schedules for their children.

14. HEPATITIS B IMMUNIZATION

The plasma derived hepatitis B (HBV) vaccine is now well proven to be a safe and highly efficacious tool for preventing the development of the chronic carrier state and presumably its sequelae chronic hepatitis, cirrhosis and hepatocellular carcinoma. To date, the main impediment to this vaccine's acceptance into immunization programmes has been its high cost. However since mid-1987, two manufacturers have made the vaccine available at a cost of less than US\$ 1 per dose. It is hoped that with widespread use the price will continue to fall. Even though it is much closer to an acceptable level than previously, the cost nonetheless remains much higher than other vaccines in the EPI.

Studies have consistently shown this vaccine to be safe, effective and free from serious side effects. Minor local reactions and slight fever related to the adjuvant occur in about 5% of recipients, but serious side effects have not been recognized. The vaccine is heat-stable (but must not be frozen), and is suitable for handling in a similar way to DPT vaccine. Dosage varies slightly with manufacturers, but is generally 5 or 10 µg per dose for infants and children. The manufacturer's recommended dose should be administered.

Administration of the vaccine is by intramuscular injection into the anterolateral aspect of the thigh of infants and into the deltoid muscle in older individuals. It can be given at the same time as other EPI antigens. Three doses should be given in the first year of life (the first as soon after birth as possible, the second 4 to 12 weeks later, and the third 2-12 months after the second dose) so that it conveniently coincides with the giving of

other EPI antigens. The cost of HBIG is so high as to virtually preclude its use. If used, it should be administered as soon after birth as possible (within hours).

It not yet certain whether HIV-infected infants immunized with HBV vaccine will seroconvert. However, there is no evidence to suggest that adverse reactions would occur.

15. VITAMIN A AND IODINE SUPPLEMENTATION

Vitamin A deficiency (VAD) blinds 250 000 preschool-age children needlessly each year. It is responsible, at least in 39 countries where VAD has been defined as a significant public health problem, for increased mortality in childhood. The various effects of iodine deficiency disorders on growth and development affect 800 million people throughout the world. Fetal damage due to iodine deficiency is irreversible, the other effects in childhood and adult life can be reversed by supplementation.

Action through EPI alone obviously cannot eliminate the consequences of these critical nutrient deficiencies. The immediate potential of the EPI contribution is still considerable, especially since the age-specific target populations for the three programmes overlap. Booster doses of EPI vaccines offer an additional opportunity to expand the EPI target group and achieve further overlap.

The rationale for periodic supplementation with large doses of vitamin A is to boost liver reserves. Vitamin A 200 000 IU, will protect a young child on a continuing inadequate diet for 3 to 6 months against serious consequences of deficiency. But if the tragic consequences of vitamin A deficiency are to be entirely avoided, initial diagnosis and treatment with large dose vitamin A must also be available everywhere within the health care system, including the immunization services.

The suggested vitamin A dosing schedule within the EPI involves:

- 200 000 IU to the mother within 2 months following delivery.
- 50 000 IU once to the child between the ages of 6-14 weeks.
- 200 000 to older children every 3-6 months, to be given at any EPI or health services contact.

Iodinated oil is indicated for severe IDD, and for moderate IDD until iodinated salt can be distributed. The recommended dosage schedule is:

- 0.5 ml (240 mg iodine) below 12 months, oral or i.m.
- 1.0 ml (480 mg iodine) at age 1-14 years, oral (biannually) or i.m. (every 3-4 years).
- 1.0 ml for women 14-45 years, as above.

High dose vitamin A should not be given to women of childbearing age, except within a few weeks after delivery when pregnancy is unlikely, because of the potential teratogenic risk to the fetus. However, iodinated oil is without risk in pregnancy and lactation. Both vitamin A and iodinated oil are safe public health interventions in the recommended doses.

A cold chain is not required for handling either vitamin A or iodinated oil; both preparations are stable with acceptable shelf lives even at relatively high ambient temperatures. The cost of each bulk purchased vitamin A capsule is about US\$ 0.02. Iodinated oil for injection costs US\$ 0.20 per ml. Efforts to produce a good quality and less costly preparation for oral use are in progress.

16. NEW OR IMPROVED VACCINES

There is a recent resurgence of interest in vaccines. Progress in developing new or improving already existing vaccines has been achieved due to increasing knowledge of antigens involved in either disease or protection or both. With the use of monoclonal antibodies it is now possible to identify antigenic determinants that can elicit a protective immune response.

In spite of great progress in the field of vaccinology, there are some deficiencies in current vaccines, including unwanted side effects, contaminating materials and difficulties in production, storage and delivery systems. New technologies are needed to produce a new generation of vaccines. Fresh impetus has been given to vaccine development by the emergence of modern technologies: recombinant DNA technology, synthetic peptides, internal image anti-idiotypes and subunit vaccines.

A number of vaccines are in various stages of development but several years will be needed to profit from the present revolution in vaccine research and development.

17. PROPOSALS FOR THE 1988 MEETING OF THE GLOBAL ADVISORY GROUP

The African Region has offered to host the 1988 Global Advisory Group meeting. The location within the Region has not yet been determined. The Regional Advisers requested that the meeting be held in October, as several Regional Offices undertake planning exercises in November in which the Advisers are involved. It was agreed that the meeting would be held 17-21 October, 1988. (The site was subsequently determined to be Abidjan, Côte d'Ivoire).

Items which the Global Advisory Group specifically requested be discussed during the 1988 meeting included the progress achieved by the countries of each Region in setting disease reduction targets and the potential of the countries of each Region to achieve poliomyelitis eradication during the coming decade. The suggestion was also made that Regions review the extent to which recommendations of the Global Advisory Group (such as those relating to contraindications to immunization and the use of immunization schedules which protect children as early in life as possible in countries where the target diseases remain significant killers of young children) had been adopted within each Region. The World Health Assembly will need to be informed about the proposals for EPI activities in the coming decade, and it might be appropriate for the GAG to review a report on this subject in 1988 or 1989.

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Annex 2: Documents list

General Documents:

WHO/EPI/GAG/87/1	Provisional Agenda
WHO/EPI/GAG/87/2	Provisional Participants List
WHO/EPI/GAG/87/3	Provisional Documents List

Working papers:

WHO/EPI/GAG/87/WP.1	EPI Global Overview
WHO/EPI/GAG/87/WP.2	EPI Overview in AFR
WHO/EPI/GAG/87/WP.3	EPI in the Americas - Regional overview
WHO/EPI/GAG/87/WP.3.1	National EPI Plans of Action: Financial Analysis
WHO/EPI/GAG/87/WP.3.2	Lines of action in social communication at the regional level for the EPI
WHO/EPI/GAG/87/WP.3.3	Review of poliomyelitis in the Americas: Regional overview
WHO/EPI/GAG/87/WP.4	EPI Overview in EMR
WHO/EPI/GAG/87/WP.5	EPI Overview in EURO
WHO/EPI/GAG/87/WP.6	EPI Overview in SEAR
WHO/EPI/GAG/87/WP.7	EPI Overview in WPR
WHO/EPI/GAG/87/WP.8	HIV Infection and Routine Childhood Immunization
WHO/EPI/GAG/87/WP.10	Issues in Measles Control
WHO/EPI/GAG/87/WP.11	Issues in Neonatal Tetanus Control
WHO/EPI/GAG/87/WP.12	Missed Opportunities for Immunization
WHO/EPI/GAG/87/WP.13	Local Area Monitoring
JC 26/UNICEF-WHO/87.5	Mobilizing all for Health for All
WHO/EPI/GAG/87/WP.16	Hepatitis B Immunization
WHO/EPI/GAG/87/WP.17	Vitamin A and Iodine Supplementation
WHO/EPI/GAG/87/WP.18	Update on New or Improved Vaccines

Other papers:

WHO/EPI/RD/87/WP.1	Research and Development: Funding Perspectives in the Expanded Programme on Immunization
WHO/EPI/RD/87/WP.2	Research and Development Status report: Bioengineering
WHO/EPI/RD/87/WP.3	Research and Development Status report: Epidemiology
EPI UPDATE, April 1987:	World Health Day, Immunization - A chance for every child
EPI UPDATE, July 1987:	Sterilization Alert
EPI UPDATE, September 1987:	Poliomyelitis - The child crippler
	Epidemic Poliomyelitis in Gambia, 1986
	Enhanced disease prevention in the Americas: Regional Vaccinology Centres

Annex 3:

Terms of reference of the Global Advisory Group
for the Expanded Program on Immunization

1. An appropriately constituted Advisory Group of outstanding consultants will be appointed to advise WHO on its Expanded Program on Immunization. The Advisory Group will be assisted in its work by additional consultants, sub-committees and study panels for specific purposes as required.

2. The advisory Group will:

(a) advise the WHO secretaries with respect to Programme priorities over the short, medium, and long term,

(b) promote the exchange of information concerning Programme strategies and tactics among participants functioning at country, regional and global levels, and

(c) promote the understanding of, and support for, Programme goals among technical and political leaders.

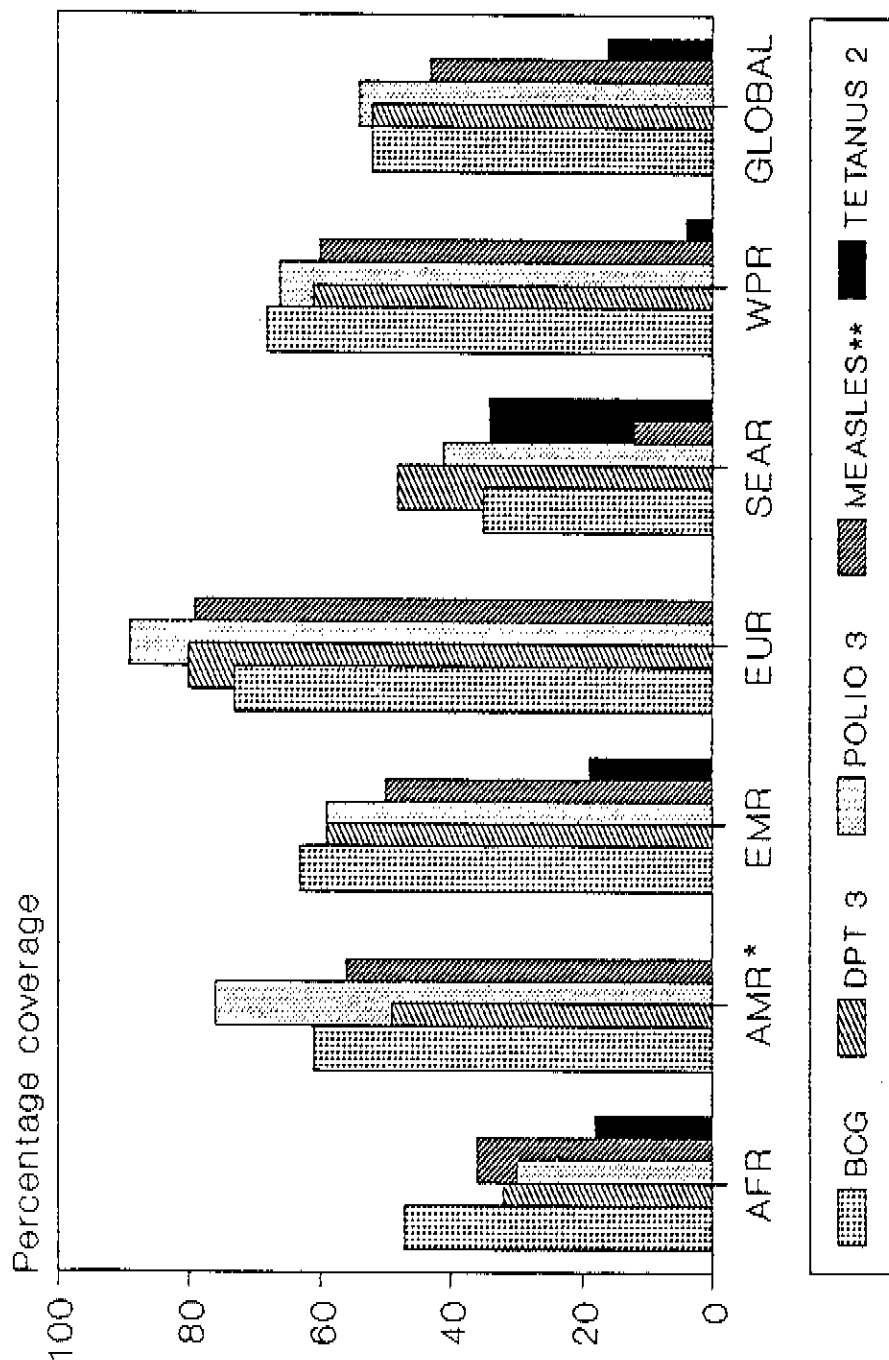
3. Composition of the Advisory Group:

Members of the Advisory Group will be appointed by the Director-General. It will consist of approximately 12 members, at least one from each Region being selected from a panel nominated by the Regional Offices. The others, selected "at large", will provide geographical and technical balance. Appointment will generally be for a period of one year, with extensions arranged so as to provide for a turnover of approximately one third of the Group year each year. Reappointments will not normally be considered before one year has lapsed from the previous termination date.

4. Meetings of the Advisory Group will be convened as required, but usually on an annual basis, and a report of each meeting will be prepared and circulate appropriately.

Annex 4: Global Programme Data

Figure 1. Estimated percentage of children immunized in the first year of life and percentage of pregnant women immunized against tetanus, by WHO Region, based on information available December 1987

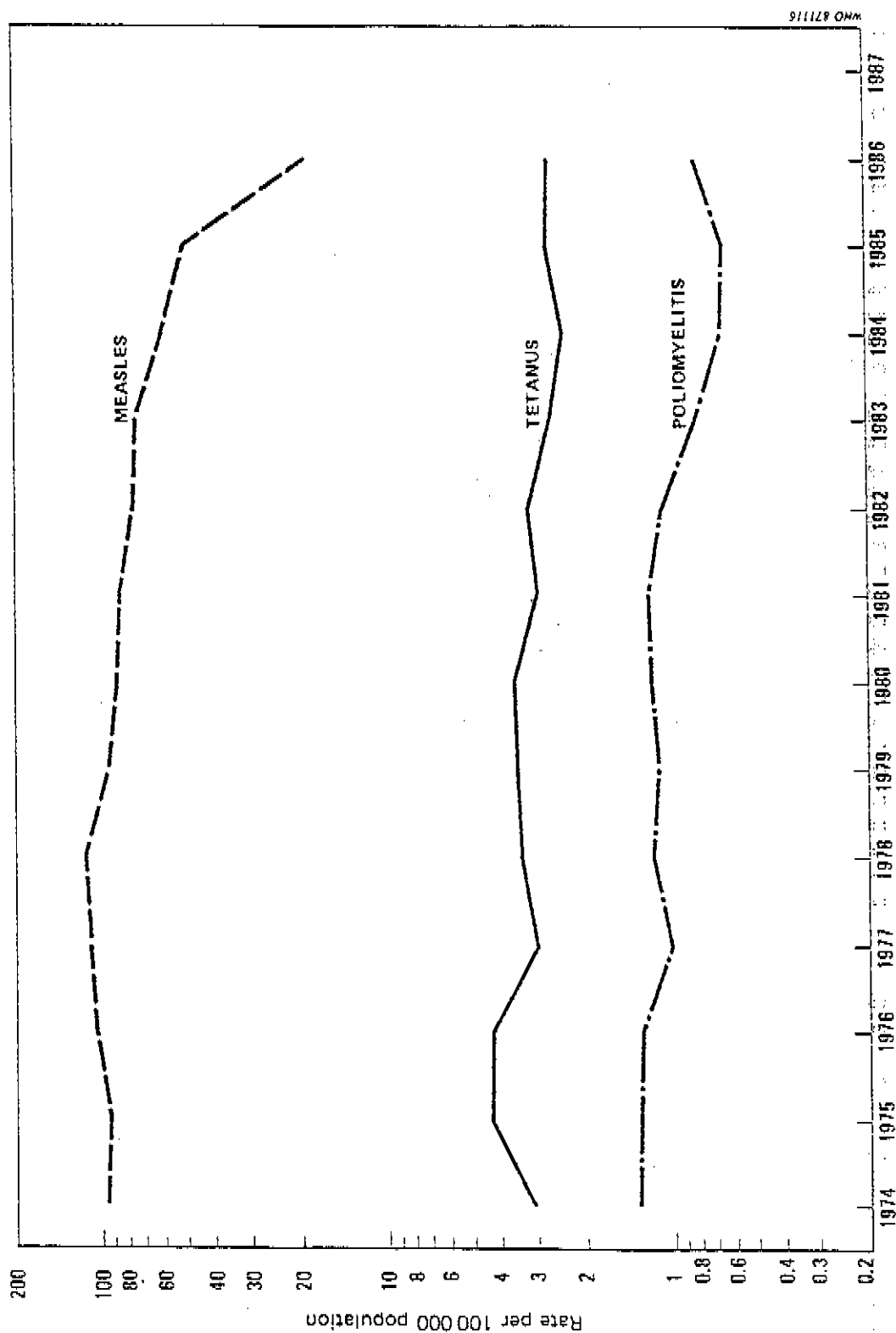


* Excluding USA and Canada

** Coverage data for children up to 60 months are included for countries recommending immunization at, or later than, 12 months.

Annex 4: Global Programme Data (continued)

FIG. 2
REPORTED GLOBAL INCIDENCE OF MEASLES, TETANUS AND POLIOMYELITIS
(per 100 000 population), 1974 - 1986



Annex 4: Global Programme Data (continued)

Table 1. Estimated immunization coverage with BCG, DPT, poliomyelitis, measles, and tetanus vaccines based on data available as of December 1987.

Country	Newborns surviving to 1 year of age (millions)	Cumulative percentage of births	Immunization coverage (%)					
			Children less than 1 year of age					Pregnant women
			BCG	DPT III	Polio III	Measles	Tetanus II	
1 India (6)	23.12	27	29	53	45	1	40	
2 Indonesia (6)	4.94	33	67	48	46	47	28	
3 Nigeria (6)	4.44	38	42	21	22	32	13	
4 Pakistan (6)	3.79	43	69	56	58	41	5	
5 Bangladesh (6)	3.17	46	5	5	4	3	5	
6 Mexico (6)	2.35	49	54	34	96	60	...	
7 Brazil (6)	2.49	52	56	52	88	55	...	
8 Iran (6)	2.00	55	83	76	79	80	32	
9 Ethiopia (4 & 6)	1.92	57	12	7	7	10	5	
10 Viet Nam (6)	1.75	59	54	42	46	38	...	
11 Egypt (6)	1.71	61	77	80	79	78	9	
12 Philippines (5)	1.53	63	72	55	53	53	49	
13 Turkey (5S & 6)	1.38	65	45	45	45	36	...	
14 Zaire (5)	1.27	66	52	32	33	39	27	
15 South Africa	1.23	68	
16 Kenya (7S)	1.08	69	86	75	75	60	37	
17 Thailand (6)	1.06	70	83	62	62	39	45	
18 Tanzania (6)	1.03	71	93	69	65	76	60	
19 Burma (6)	1.02	72	32	20	4	3	21	
20 Rep. of Korea (4 & 5)	0.94	74	47	76	80	89	...	
21 Sudan (6)	0.91	75	22	14	14	11	6	
22 Colombia (6)	0.86	76	69	57	55	56	...	
23 Algeria (5S)	0.81	77	89	69	69	67	...	
24 Morocco (6)	0.81	78	72	53	53	48	...	
25 Argentina (6)	0.72	78	89	67	79	87	...	
25 countries	86.58	78	45	46	47	29	23	
Other developing countries	18.49	22	54	46	44	41	17	
Sub-total developing countries (excluding China)	85.07	100	82	47	46	47	31	22
China (7S)	18.12	18	70	62	68	63	...	
Total developing countries (including China)	103.19	100	51	49	50	37	19	
Total industrialized countries	17.61		59	71	76	80	...	
Global Total	120.80		52	52	54	43	16	

(4) 1984 coverage data

(5) 1985 coverage data

(6) 1986 coverage data

(7) 1987 coverage data

(s) survey data

... no information available

Annex 4: Global Programme Data (continued)

Table 2. Estimated annual number of deaths prevented from neonatal tetanus; and cases and deaths prevented from pertussis and measles; and cases prevented from poliomyelitis in 25 developing countries (excluding China) ranked by number of surviving infants, December 1987.

Country	(a) Newborns (000's)	(b) Surviving Infants (000's)	(c) Prevented Neonatal Tetanus Deaths (000's)	(d) Prevented Pertussis Cases (000's)	(e) Prevented Pertussis Deaths (000's)	(f) Prevented Measles Cases (000's)	(g) Prevented Measles Deaths (000's)	(h) Prevented Polio Cases (000's)
1 India (6)	25857	23116	98	8771	98	220	7	49
2 Indonesia (6)	5347	4941	20	1643	25	2206	88	11
3 Nigeria (6)	4958	4437	6	666	10	1349	54	5
4 Pakistan (6)	4250	3791	6	1523	23	1477	59	10
5 Bangladesh (6)	3543	3172	5	113	2	90	4	1
6 Mexico (6)	2637	2550	0	574	5	1454	29	12
7 Brazil (6)	2650	2489	0	882	7	1300	26	11
8 Iran (6)	2196	2003	3	1068	8	1522	30	8
9 Ethiopia (4 & 6)	2212	1920	1	99	1	182	4	1
10 Viet Nam (6)	1889	1746	0	508	4	630	13	4
11 Egypt (6)	1837	1709	2	941	15	1264	51	6
12 Philippines (6)	1619	1551	2	570	7	781	23	4
13 Turkey (55 & 6)	1519	1382	0	437	3	473	9	3
14 Zaire (6)	1409	1271	3	289	3	471	14	2
15 South Africa	1284	1248	0	0	0	0	0	0
16 Kenya (75)	1186	1082	5	560	9	617	25	4
17 Thailand (6)	1110	1064	2	441	5	394	12	3
18 Tanzania (6)	1133	1031	6	501	4	745	15	3
19 Burma (6)	1071	1021	2	137	2	29	1	<1
20 Rep. of Korea (4 & 5)	964	940	0	469	4	794	16	4
21 Sudan (6)	1017	909	0	91	1	95	4	1
22 Colombia (6)	908	863	0	331	3	459	9	3
23 Algeria (65)	896	813	0	396	4	517	16	3
24 Morocco (6)	887	812	0	301	5	370	15	2
25 Argentina (6)	741	715	0	318	3	591	12	3
Total	73103	66578	161	21628	249	18034	535	150
Other developing Countries	20325	18489	33	5984	68	7202	216	39
Total developing Countries	93428	85067	194	27612	317	25236	751	189

(4) 1984 coverage data

(5) 1985 coverage data

(6) 1986 coverage data

(7) 1987 coverage data

(s) survey data

1. All figures less than 1000 are indicated by "<1". Figures above 1000 are rounded to the nearest thousand.

(a) Newborns: based on 1986 estimated population and crude birth rates.

(b) Surviving newborns: based on estimated number of newborns and infant mortality rate.

(c) Based on mortality estimations from surveys or reports, a vaccine efficacy of 0.95 and immunization coverage reported as of June 1987. Countries without available data were arbitrarily categorised into one of 3 levels of neonatal tetanus mortality: 5, 10 or 15 per thousand live births.

(d) Based on an incidence estimation of 80% of newborns in absence of an immunization programme, a vaccine efficacy of 0.8 for 3 doses, and immunization coverage reported as of December 1987.

(e) Based on mortality estimations of one-third of measles deaths, a vaccine efficacy of 0.8 for 3 doses, and immunization coverage reported as of December 1987.

(f) Based on an incidence estimation of 100% surviving newborns in absence of an immunization programme, a vaccine efficacy of 0.95 and immunization coverage reported as of December 1987.

(g) Based on arbitrary case fatality rates ranging from 22 to 42, a vaccine efficacy of 0.95 and immunization coverage reported as of December 1987.

(h) Based on an incidence estimation of 5/1000 newborns in absence of an immunization programme, a vaccine efficacy of 0.95 and immunization coverage reported as of December 1987.

Annex 4: Global Programme Data (continued)

Table 3. Estimated annual number of deaths from neonatal tetanus, measles and pertussis and annual number of cases of poliomyelitis in developing countries (excluding China), December 1987.

	Neonatal Tetanus(1) (000's)	Measles(2) (000's)	Pertussis(3) (000's)	Total Deaths (000's)	Cum.I of total deaths	Polio cases(4) (000's)	Cum.I of cases
25 largest developing countries	648	1525	437	2611	81	183	77
Other developing countries	170	338	117	626	19	54	23
Total developing countries	818	1864	554	3237	100	237	100

The annual number of deaths from neonatal tetanus, measles and pertussis, and the annual number of cases of poliomyelitis in developing countries (excluding China) were estimated, using the immunization coverage data in Table 1.1.3 and the following assumptions:

- 1) Neonatal tetanus: Based on survey data or in absence of survey, neonatal tetanus deaths are estimated from countries with similar socio-economic conditions.
- 2) Measles: It is assumed that the vaccine efficacy is 95% and that all of unimmunized children will acquire measles. Coverage is assumed to be zero in countries from which data are not available.
- 3) Pertussis: It is assumed that the vaccine efficacy is 80% and that 80% of unimmunized children will acquire pertussis. Coverage is assumed to be zero in countries from which data are not available.
- 4) Polio: In view of narrow limits of variation of results of poliomyelitis surveys, and in the absence of an immunization programme, a fixed incidence rate of 5 cases per 1000 newborns is used. A vaccine efficacy of 95% is used. Coverage is assumed to be zero in countries from which data are not available.

Annex 5:

Terms of reference for the EPI Research and Development Group

1. The Research and Development Group for the Expanded Programme on Immunization (EPI) will advise the Director, EPI on research and development priorities. It will be assisted in its work by additional consultants, subcommittees and study panels for specific purposes as required.
2. The EPI Research and Development Group will:
 - (a) advise the Director, EPI concerning research and development priorities in the general field of disease prevention and control through immunization and through interventions which can be appropriately delivered using vaccine delivery systems (such as supplementation with vitamin A or iodine) with primary emphasis on diseases and vaccines currently included within the global programme,
 - (b) advise the Director, EPI on the relative priorities of specific research and development proposals submitted for funding from global EPI resources,
 - (c) monitor the progress of research and development activities which have been selected for funding and recommend their continuation, revision or termination, and
 - (d) assist in the generation of research and development proposals relevant to programme priorities.
3. The Group will conduct its work in the light of knowledge of vaccine-related research and development being carried out elsewhere. The WHO EPI secretariat will have the responsibility for liaison with programmes conducting such work within WHO, while Group members and consultants to the Group will be expected to be the primary source for information concerning relevant activities outside of WHO.
4. Composition of the Group:

The EPI Research and Development Group will normally consist of between 5 and 10 members who are not staff members of WHO and who have been selected on the basis of their knowledge of the technical and operational aspects of the EPI. Members will serve in their personal capacities. The Chairperson of the Group will be appointed by the Director-General. The Chairperson will have de facto membership on the EPI Global Advisory Group. Other members of the Group will be appointed by the Director, EPI in consultation with the Chairperson, for an initial term of two years, renewable twice, up to a maximum of six years. Reappointments will not normally be considered before one year has lapsed from the previous termination date.
5. Meetings of the EPI Research and Development Group will be convened by the Director, EPI as required, but usually at least twice a year. A report of each meeting will be prepared and circulated appropriately.

Annex 6:

Special Programme on AIDS
and the Expanded Programme on Immunization

Consultation on human immunodeficiency virus (HIV)
and routine childhood immunization, August 1987

Consensus Statement

Concern has been raised that children infected with the human immunodeficiency virus (HIV) who receive routine childhood immunizations may have decreased immune responses and be at increased risk for adverse effects or acceleration of HIV-induced immunosuppression. Limited experience suggests that the likelihood of successful immunization is reduced in some HIV-infected individuals but that the risk of serious adverse effects remain low. The theoretical risk of acceleration HIV infection by simultaneous administration of multiple antigens is not supported by limited clinical information and is likely to be negligible in contrast to other natural sources of antigenic stimulation.

Having reviewed the available information in Geneva on 12 and 13 August, 1987, the WHO informal consultation on HIV and routine childhood immunization: (See Annex 1)

1. Endorses the 1986 Expanded Programme on Immunization (EPI) Global Advisory Group recommendations on the use of EPI antigens:

"In countries where human immunodeficiency virus (HIV) infection is considered a problem, individuals should be immunized with the EPI antigens according to standard schedules. This also applies to individuals with asymptomatic HIV infection. Unimmunized individuals with clinical (symptomatic) AIDS in countries where the EPI target diseases remain serious risks should not receive BCG, but should receive the other vaccines (Table)."

Table 1. Recommendations on the use of EPI antigens in HIV-infected individuals in countries where the EPI target diseases remain important causes of morbidity

	Vaccine	Asymptomatic	Clinical AIDS
Infants	BCG	Yes	No
	DPT	Yes	Yes
	OPV	Yes	Yes
	IPV	Yes	Yes
	Measles	Yes	Yes
Women	Tetanus toxoid	Yes	Yes

2. In accordance with the Global Advisory Group, notes that live vaccines are not usually given to immunocompromised individuals, but agrees that, in areas where the risk of exposure to measles and polio virus is high, the benefits of immunization outweigh the apparently low risk of adverse effects from these vaccines, even in the presence of symptomatic HIV infection. Inactivated poliomyelitis vaccine (IPV) is an alternative to OPV for immunization of children with symptomatic HIV infection who may be at increased risk of OPV-associated paralytic poliomyelitis.

3. Notes that although a theoretical risk exists, evidence for an increased rate of adverse reactions after BCG immunization among asymptomatic HIV-infected individuals remain inconclusive. Therefore,

(a) For asymptomatic HIV-infected individuals:

Where the risk of tuberculosis is high, BCG is recommended at birth or as soon as possible thereafter in accordance with standard policies for immunization of non-HIV infected children;

In a limited number of areas, the risk of tuberculosis is low, but BCG is recommended as a routine immunization; in these areas, BCG may be withheld from individuals known or suspected to be infected with HIV;

(b) For symptomatic HIV-infected individuals, BCG should be withheld.

4. Emphasized the EPI recommendation to immunize children as early in life as possible. Vaccine-associated adverse effects may be minimized and vaccine response optimized by beginning immunization before the progression of HIV-induced immunosuppression.

5. Endorses the simultaneous administration of multiple antigens such as BCG, DPT, polio and measles vaccines when indicated.

6. Strongly encourages further investigations in the following areas:

(a) Safety of immunizations in HIV-infected children:

(i) Surveillance of HIV-infected children to permit rapid identification of any unexpectedly frequent adverse events following immunization;

(ii) Establishment or modification of population-based surveillance systems to detect rare serious adverse events associated with immunization of HIV-infected children;

(iii) Comparison to the rates of frequent and less severe adverse events which occur in HIV-infected and uninfected children following immunization.

(b) The natural history of vaccine-preventable diseases in HIV-infected children.

(i) Determine of the rates of serious complications of vaccine-preventable diseases in HIV-infected children in health care facilities and in the community and correlation of such complications with the stage of HIV infection and degree of immunosuppression;

(ii) Establishment or modification of population-based surveillance systems to detect serious complications of vaccine-preventable diseases in HIV-infected children;

(iii) Assessment of the role of immune globulin in protection of HIV-infected children against vaccine-preventable disease.

(c) Immunogenicity and efficacy of immunizations in HIV-infected children:

(i) Determination of the serologic response to immunization in HIV-infected children compared to uninfected children and correlation of vaccine response to stage of HIV infection and degree of immunosuppression;

(ii) Development of methods to improve vaccine responses of HIV-infected children, if these are found to be decreased;

(iii) Determination of the persistence of vaccine-induced antibody;

(iv) Prospective follow-up of immunized HIV-infected children and retrospective evaluation of cases of vaccine-preventable diseases to determine rates of vaccine failure in HIV-infected children.

(d) Possible activation or acceleration of HIV-infection by repeated antigenic stimulation with immunizations, including simultaneous administration of multiple antigens:

(i) Detection of increased HIV replication following immunization of HIV-infected children;

(ii) Detection of immunologic abnormalities following immunization of HIV-infected children;

(iii) Retrospective studies of the relationship between total number of immunizations received and/or number of antigens received simultaneously by HIV-infected children and the onset of symptomatic HIV infection, progression of clinical HIV disease and/or fatal outcome of HIV infection. The informal consultation agreed that prospective placebo-controlled double-blind studies in which some HIV-infected children would not receive recommended immunizations are not appropriate.

(e) The immunogenicity and efficacy of tetanus toxoid immunization of HIV-infected pregnant women in the prevention of neonatal tetanus.

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