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EXPANSION OF THE USE OF IMMUNIZATION
IN DEVELOPING COUNTRIES

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LIST OF PARTICIPANTS

Ethiopia

Dr T. Woldemariam, Paediatrician, Ethic-Swedish Paediatric Clinic, Addis Ababa

Ghana

Dr M. A. Baddoo, Director of Medical Services, Ministry of Health, Accra
Dr E. G. Beausoleil, Deputy Director of Medical Services (Public Health), Ministry of Health, Accra
Dr F. C. Grant, Deputy Director of Medical Services (Medical Care), Ministry of Health, Accra
Dr K. Ward-Brew, Senior Medical Officer, Epidemiology Division, Ministry of Health, Accra

Kenya

Dr W. Koinange Karuga, Head, Department of Communicable Disease Control, Ministry of Health, Nairobi
Dr P. Muiva, Provincial Paediatrician, Eastern Provincial General Hospital, Machakos

Liberia

Dr E. Cooper, Public Health Physician, J. J. Dosseh Hospital, Harper, Maryland County

Nigeria

Dr P. Y. Odunsu, Registrar (Epidemiology), Epidemiological Unit, Federal Ministry of Health, Onikan Health Centre, Lagos

Sierra Leone

Dr G. Gage, Acting Principal Medical Officer, Ministry of Health, Freetown

Somalia

Mr I. A. Warsame, Head, Environmental Sanitation Unit, Ministry of Health, Mogadishu

Sudan

Dr Abdel Hamid El Sayed, National Director, Smallpox Eradication Campaign, Ministry of Health and Social Welfare, Khartoum
Dr Y. M. A. Haddad, Assistant Commissioner for Health Services, Khartoum

Uganda

Dr J. K. B. Kyewalabye, Principal Medical Officer, Ministry of Health, Entebbe

United Republic of Tanzania

Mr E. E. Lyimo, Senior Health Officer, Ministry of Health Headquarters, Dar es Salaam

Zambia

Dr G. Arhammar, Maternal and Child Health Specialist, Ministry of Health, Lusaka

Representatives of other organizations

Organization for Coordination and Cooperation in the Control of Major Endemic Diseases (OCCGE)  Dr J. G. Breman and Dr L. Sentilhes, Bobo-Dioulasso, Upper Volta
Observers from Ghana

Mr J. M. Abbeyquaye, Health Education Division, Ministry of Health, Accra
Dr Y. Aboagy-Atta, Regional Medical Officer of Health, Accra
Dr K. O. Adadey, Medical Officer (Communicable Diseases), Ministry of Health, Cape Coast
Dr M. E. K. Adibo, Regional Medical Officer of Health, Bolgatanga
Dr V. U. Agadzi, Senior Medical Officer, Department of Chest Diseases, Korle Bu Teaching Hospital, Accra
Mr B. Aidoo, Principal Technical Officer, (Communicable Diseases Control), Sunyani
Mr E. K. Anokye, Senior Technical Officer (Communicable Diseases Control), Ashanti
Mr K. Anowih, Epidemiological Division, Ministry of Health, Accra
Mr E. Amoah, Technical Officer, Ministry of Health, Accra
Dr R. O. Asante, Senior Medical Officer, Ministry of Health, Accra
Dr B. A. Boatin, Medical Officer (Communicable Diseases), Ministry of Health, Tamale
Mrs C. Donkor-Ware, District Public Health Nurse, Ministry of Health, Kumasi
Dr D. D. Nicholas, Department of Community Health, University of Ghana Medical School, Accra
Dr L. Osei, Medical Officer, Department of Community Health, University of Ghana Medical School, Accra
Mrs A. Roberts, District Public Health Nurse, Ministry of Health, Kumasi
Mr D. E. Sapong, Principal Technical Officer (Communicable Diseases Control), Western Region
Mr T. B. Y. Tawia, Health Education Division, Ministry of Health, Accra

Observers from Nigeria

Mr E. R. Dallah, Rural Health Education Unit, Ministry of Health, Enugu
Mr S. U. Osuigwe, Divisional Administration Department, Planning Administration Unit, Cabinet Office, Enugu

Secretariat

Dr D. Amah, WHO Representative, Accra, Ghana
Dr F. Assaad, Medical Officer, Virus Diseases, WHO, Geneva
Dr W. Chas. Cockburn, Director, Division of Communicable Diseases, WHO, Geneva
Dr B. Cvjetanovic, Chief Medical Officer, Bacterial Diseases, WHO, Geneva
Dr Z. Islam, WHO Epidemiological Surveillance Centre, Brazzaville, Congo
Dr S. K. Litvinov, Epidemiologist, WHO Epidemiological Services, Ghana
Professor Adetokunbo O. Lucas, Head, Department of Preventive and Social Medicine, University College Hospital, Ibadan, Nigeria (Temporary Adviser)
Dr F. T. Perkins, Head, Division of Viral Products, National Institute for Biological Standards and Control, London, England (Temporary Adviser)
Dr F. D. Schofield, Programme Leader, Health Planning, WHO, Geneva
Mr T. Sundaresan, Statistician, Health Statistical Methodology, WHO, Geneva
INAUGURATION

The first WHO seminar on expansion of the use of immunization in developing countries was held in Kumasi, Ghana, from 12 to 19 November 1974. The seminar was inaugurated by Dr M. A. Baddoo, Director of Medical Services on behalf of Colonel A. H. Selormey, the Commissioner of Health.

Professor A. O. Lucas, Head of the Department of Preventive and Social Medicine, University College Hospital, Ibadan, Nigeria, was elected Chairman; Dr W. Koinange Karuga, Head, Department of Communicable Disease Control, Ministry of Health, Nairobi, was elected Vice-Chairman; and Dr F. T. Perkins, Head, Division of Viral Products, National Institute for Biological Standards and Control, London, was elected Rapporteur.

Dr Baddoo, in welcoming participants to Ghana, outlined the numerous health problems facing his country. One of the most pressing problems was the incidence of childhood diseases that could be prevented by successful vaccination. Although antibiotics had done much to prevent serious complications nothing could replace prevention by vaccination in reducing infant mortality. The country was aware of the problems caused by frequent pregnancies, overcrowding, and malnutrition, and an active programme of family planning had been established in order to relieve these difficulties, but if people were being asked to have fewer children they must be promised a greater expectancy of infant survival.

The Commissioner of Health, said Dr Baddoo, was warm in his praise of the work that had already been done by his health departments and stressed that the benefits of any programme must reach into rural districts. The authorities were conscious of the costs involved in the procurement of vaccines, equipment and supplies for mounting efficient campaigns. They realized also that a vaccination programme, if it was to be successful, must take cognizance of local conditions, beliefs and cultures. These were difficulties that were not insuperable. Ghana had faith in the overseas friends who were helping the country in its efforts to control disease.

Dr Cockburn, Director of the Division of Communicable Diseases, WHO, spoke on behalf of the Director-General of the Organization, who had a heartfelt personal interest in this programme. About half the world’s population had brought infectious diseases under control but in the remainder the diseases were still raging. This had stimulated 25 countries to draw attention to these differences at the Twenty-seventh World Health Assembly and a resolution was carried asking WHO to assist the developing countries to bring under control the diseases susceptible to immunization.

The problems had to be dealt with in unison for nothing would be achieved without the full commitment of the countries involved and the major part of the effort would have to be found from available national resources. Vaccination was a continuous on-going programme, especially for childhood diseases, and as such had to become an integral part of a routine health programme, taking its place in the comprehensive health services. Even though it might be several years before a major impact was made on the incidence of the diseases, it was important to expand coverage year by year so that eventually the diseases would be overcome.

Speaking on behalf of the Regional Director for Africa, Dr D. J. Amah, WHO Representative, Ghana, stressed the need to work out strategies for immunization programmes that would take into consideration the constraints existing in the developing countries. He acknowledged the assistance given by other United Nations agencies in supporting communicable disease control programmes in the Region, and paid tribute to the efforts of other bodies in providing aid from national sources.

WHO Official Records, No. 217, 1974, p. 28 (Resolution WHA27.57).
INTRODUCTION

At the first working session the Chairman and the Director of the Division of Communicable Diseases, WHO emphasized that the seminar was designed to deal mainly with immunization against seven diseases: measles, poliomyelitis, tuberculosis, pertussis, tetanus, diphtheria, and smallpox.

In recent years there has been in the developing countries a surge of interest in those communicable diseases that can be controlled by immunization. The reason for this is not far to seek. In most countries with a temperate climate the immunization programmes initiated over the previous three or four decades have come to fruition; diseases such as poliomyelitis, diphtheria, and tetanus have been almost eliminated and pertussis and measles have been greatly reduced in incidence. BCG has been shown to protect for 10-15 years and smallpox has disappeared as an endemic disease. In contrast, these diseases (except for smallpox, the campaign for the eradication of which is on the eve of success) are still of high incidence or increasing in incidence in the developing world.

Immunization programmes exist in most or all of the countries concerned but they are not yet sufficiently developed to cover more than a minute proportion of the susceptible population. In fact most children have no possibility of obtaining the benefit of any of the vaccines available in other parts of the world.

The Twenty-seventh World Health Assembly discussed immunization thoroughly during its meeting in May 1974 and resolved that the World Health Organization should take active measures towards assisting Member States to analyse the difficulties and constraints that had hitherto prevented the establishment of adequate programmes, to advise on how these might be overcome, to facilitate the supply of vaccines to countries as their capacity to use them effectively increased, and to develop a system of ensuring the quality of vaccines purchased or otherwise obtained by countries lacking laboratory facilities for the control of biological products.

In any national immunization programme the main effort has to come from national resources because once established an immunization programme cannot be allowed to falter. It must continue to ensure the immunization of a sufficiently high percentage of susceptible subjects entering the community year by year. Thus programmes can advance only as the capacity of the country to use vaccines effectively is increased. There ought therefore to be in the medium- and long-term programmes a realistic system of phasing out the external aid that might initially be necessary. There will however be a small number of countries that will have to be treated as special cases, and certain services such as quality control and the purchase of vaccines through international agencies on a reimbursable basis could be continued for all countries.

As an indication of the numbers involved it is estimated that in 1975 the total population of the developing world is about 2000 million and that the number of children born and reaching one year of age is about 70 million. If 80% of these children were vaccinated against the seven diseases the total cost for vaccine for all the developing countries would be 15-20 million dollars, given the most favourable purchase terms. This sum must be multiplied 2-1/2 to 3 times to cover other costs such as cold-chains, transport, and equipment. Salaries of personnel would be additional.

The required output of the seminar was a document that would:

- set out clearly the public health importance of certain communicable diseases in Africa and the need for immunization especially against childhood diseases;
- describe the national resources at present available and what is now being done in the field of immunization;
- indicate general objectives for expanded immunization in Africa;
- assess realistically the difficulties now existing and possible ways of overcoming them;
give an indication of costs, keeping in mind the long-term nature of immunization programmes;
indicate the possible sources and nature of international or other assistance that might be available.

National reports

National reports made by participants from 11 English-speaking African countries described their ongoing immunization activities and the major difficulties at present being encountered. In some cases future plans were briefly outlined.

All these countries are mounting successful surveillance and immunization programmes against smallpox, and all but one has reached the maintenance phase of the smallpox eradication campaign. In many countries the resources of the smallpox programme such as vaccinators, supervisors, transport, and the public co-operation engendered are now being used to reduce the backlog of BCG vaccination of children and adolescents, as well as to maintain continued surveillance and vaccination against smallpox. In a few countries, measles vaccination and vaccination against yellow fever are also being undertaken by the smallpox programme teams, either as a routine procedure or in response to threats of epidemics.

Immunization with diphtheria, pertussis, and tetanus vaccine (DPT) and sometimes with poliomyelitis vaccine is continuing in static centres in all countries but with widely differing levels of coverage. These static services at hospitals, health centres, and dispensaries also provide BCG and smallpox vaccination in many countries. Coverage of the susceptible age groups by the static units appears to be disappointingly low but it has not been definitely measured in most cases. Coverage of the target populations by the mobile teams appears better in general, though it is very variable and seldom reliably assessed. The national reports were immensely valuable in bringing up practical problems, difficulties, and constraints and they were comprehensively discussed as a separate item on the agenda. However, in preparing this report, the most important points raised were included in those sections where they are most relevant.

THE ROLE OF IMMUNIZATION IN THE CONTROL OF COMMUNICABLE DISEASES

Communicable diseases in the developing world

One of the principal difficulties in the developing world (and to a lesser extent in the developed world) is to obtain accurate information on the incidence and mortality of disease. Such data as are available are only suggestive - not more than the tip of the iceberg. Several instances of underreporting can be given. In one country the total number of officially notified cases of poliomyelitis during a period of 5 years was less than 10% of the number admitted to the main hospitals in one part of the country during a six-month epidemic in the course of those five years. In another country a hospital reported that the incidence of neonatal tetanus was not particularly high but scrutiny of the hospital records showed that 60% of neonatal deaths were due to tetanus.

Despite the gross deficiencies in reporting there is good evidence that communicable diseases are by far the most important public health problems in the developing world. Recently two sources of information were used to demonstrate this point. The first was an analysis of the answers to a questionnaire sent to Member States by WHO asking for information on what they considered to be their principal public health problems, and the second a listing of the principal causes of death from data taken from official national records. These data showed that in the African Region in the period 1957-1960 the first 10 public health problems were various communicable diseases and nutrition and that in the period 1965-1968 practically no change had occurred. Of the 10 principal causes of death about half were communicable diseases. A similar picture is seen in Central and South America, Asia, and parts of the Eastern Mediterranean area. In Europe, North America, and parts of the Western Pacific, however, communicable diseases constitute only a small part of major public health problems and rank lowly among principal causes of death. Data on the specific diseases against which effective immunization is available and which are worldwide in childhood - measles,
poliomyelitis, tuberculosis, pertussis, diphtheria, and tetanus - are extremely difficult to obtain on a national scale but numerous special studies and surveys have shown that they make a considerable contribution to childhood morbidity and mortality. This is especially true for measles, which, in the African child, occurs earlier in life than it does in children living in temperate climates. It is often severe, and fatality rates are high, particularly in the malnourished. Measles has been estimated to account for as much as 10% of deaths in children under five years of age, and though vaccination has achieved significant reductions in morbidity and mortality in some African countries the majority are not yet able to sustain regular programmes.

Where surveys have been carried out, pertussis has also been found to be a serious disease with a high mortality rate.

Poliomyelitis is endemic in Africa and in some areas is beginning to change to the epidemic behaviour familiar in the temperate-climate areas of the world before the advent of vaccine. A recent study in one area of Ghana indicated that the incidence, measured by evidence of typical paralysis in children in schools was 7-8 per 1000, which is a higher rate than that in the USA in the prevaccination era.

Immunization - a method of choice

The communicable diseases that are important public health problems can be roughly separated into two groups - those for which safe immunization agents of proved efficacy are already available, and those whose solution requires the acquisition of new knowledge or the application of long-term measures (e.g., improvements in nutrition or environmental conditions).

The evidence available for the safety and efficacy of the immunizing agents for the most common of these infections is so well known that detailed discussion of the subject is not necessary, but points arising from the national reports of the participants and of special relevance to Africa are described below.

Immunization against some diseases of special local importance

Though the seminar was primarily concerned with the seven diseases of childhood listed on page 2, current interest made it desirable also to consider vaccines for cholera, typhoid, cerebrospinal meningitis, and yellow fever.

Cholera. It is generally accepted that routinely used cholera vaccines give protection to about 50% of vaccinees for about six months. As this is unsatisfactory, several new vaccines are under investigation but at present none can be recommended for large-scale use. In the face of an approaching epidemic vaccination is helpful, but improvements in sanitary conditions can be more effective, and the cost of such improvement is sometimes less than the cost of vaccination. However, if the experimental vaccines are found to give better and longer-lasting protection, the role of vaccination will have to be reconsidered. In 1973 the World Health Assembly recommended the abolition of compulsory vaccination for international travel, because experience had shown that no country could prevent the importation of cholera by vaccination alone. So far only a few countries have accepted the recommendation. In special circumstances, where overcrowding is unavoidable and adequate sanitation is not likely to be possible (during a pilgrimage, for instance) mass vaccination is justified.

Typhoid. Strictly controlled field trials have confirmed the effectiveness of two doses of typhoid vaccine, but the degree of protection depends on the degree of contamination and the size of the infecting dose. Studies in volunteers and data from outbreaks have shown that neither vaccine nor previous attack gives a high degree of protection against an overwhelming dose of organisms.

Heat-killed phenol-preserved vaccine is the product of choice. Acetone-dried vaccine, which is difficult to prepare and is more expensive, may give rather better protection but the difference is not of practical importance. Many countries use TAB vaccine, though there is no evidence to show that the paratyphoid A component gives protection. The paratyphoid B component may be effective, but not in the concentration of organisms usual in vaccines. It has been shown that at least 600 million organisms in a dose are needed for protection. Where paratyphoid is not a problem, typhoid vaccine without the paratyphoid A and B components would be the vaccine of choice.
Cerebrospinal meningitis. The incidence of cerebrospinal meningitis has increased markedly in the last few years in several countries. Most strains of the causative organisms are still susceptible to sulphonamides, which are effective in treatment. During the last two years vaccines made from the polysaccharides of the cell wall of the microorganism have been shown to be protective against group A and group C meningococci. Though a single dose of as little as 50 μg of the polysaccharide gives protection, the vaccines are rather expensive and there is concern about their stability. There are no standards for the production or control of these antigens; they are still considered to be in the early stages of development, and careful studies of their efficacy and of the circumstances in which they would be of value are necessary.

Yellow fever. In much of Africa yellow fever is an ever present risk and, owing to the complexity of vector control measures, vaccination is the main weapon against the disease. However, in urban areas vaccination should be accompanied by efforts to reduce the vector populations to the lowest possible level. The vaccine is completely effective and one dose probably affords lifelong protection, but it is very sensitive to tropical temperatures. Epidemiological conditions justify an increase in the use of vaccine in areas at risk, but costs and sensitivity preclude a rapid increase in coverage of populations at risk. In these circumstances, therefore, it is important to have an established programme for the detection of the earliest cases and to maintain stocks of vaccine, insecticides, etc., for emergencies.

Cost/effectiveness and cost/benefit of immunization

It is impossible to measure all benefits in health by cost/effectiveness and cost/benefit analyses, and monetary values cannot replace the diminution of physical and mental suffering that come from successful prevention of disease. Nevertheless cost/effectiveness and cost/benefit analyses are methods used by economists and applied in the health field for the purpose of making the best use of limited resources and as such they are very useful.

Cost/effectiveness analysis may be defined as the scrutiny of the costs of all inputs into a programme and of the outputs, in this case the health effects, measured by the reduction in mortality, morbidity, and invalidity rates, or by other relevant indices.

Cost/benefit analysis is an evaluation of the costs and benefits of an immunization programme, both items being expressed in monetary terms. The analysis consists in a comparison of these costs and benefits and the result, expressed as benefit/cost ratio, (i.e., benefits divided by costs), indicates the degree of benefit to be derived from immunization against a particular disease.

Immunization programmes, like other health activities, are subject to financial constraints. Cost/effectiveness analysis can be used to determine whether vaccination will give better results for a given investment than other possible control measures, such as sanitation, chemoprophylaxis, health education, or simply treatment. When immunization is found to be justified, the above methods can be used further to determine which of various immunization schemes and programmes will produce the desired control of the disease for the lowest cost.

Cost/benefit analysis can be carried out to ascertain whether investment in the immunization programme will bring, in addition to health effects, any financial benefit. Such analysis can provide health planners with evidence for the economic justification for immunization programmes, and this helps to convince the decision-makers to make the appropriate investment in these programmes.

Cost/efficiency analysis can be used to monitor the efficiency of the programme.

Collection and evaluation of data. The costs of an immunization programme should be established after listing all the expenditures related directly or indirectly to the programme - vaccine, refrigeration, equipment, manpower, publicity, etc. If the same personnel, storage facilities, etc., were used for other purposes as well as for immunization programmes, the respective amounts of staff time, resources, etc., spent on immunization should be determined. For the cost/benefit analysis, the costs of the illness concerned should be listed; they include the cost of treatment of the sick, lost wages, and losses through temporary or permanent disability.
For the analysis of cost/effectiveness, the relevant data for calculating the effects include mortality and morbidity data, as well as information about the occurrence of disability. For cost/benefit analysis, it is necessary to compute in monetary terms the benefits derived from immunization, such as savings on hospitalization, isolation, terminal disinfection, appliances and prostheses, and wage losses. It is possible to express the losses associated with premature death in the form of the loss of expected earnings and the loss of investments for the care and education of children, but this cash value is not (as already stated) the sum total of the worth of a human life.

Simple procedures can be used for the calculation of cost/effectiveness and cost/benefit. There are many ways of calculating whether a certain vaccination programme is financially beneficial. Mathematical procedures have been simplified by the construction of a nomogram for the rough determination of cost/benefit of vaccination programmes against specific diseases.²

Projections of cost/effectiveness and cost/benefit can be made from mathematical models simulating alternative immunization programmes showing their effectiveness and benefits over a period of time. WHO offers a rapid computer service for the analysis of cost/effectiveness and cost/benefit for tetanus, cholera, typhoid, and cerebrospinal meningitis. The user must provide essential information on the population, the incidence of the disease, the costs of vaccination and treatment, and the kind of immunization programme contemplated. The value of the answer obtained from the computer depends on the quality of the data presented and the care taken in formulating the questions asked in order to elicit the information from the user.

Improvement of immunization programmes. Cost/effectiveness and cost/benefit analyses may also be utilized for the improvement of immunization programmes since they can show how to minimize costs and maximize effectiveness and benefits.

The primary use of cost/effectiveness and cost/benefit analyses is to assist in selecting an immunization programme that will meet set targets and will best suit the available economic resources and health requirements, but these analyses should be carried out regularly to enable immunization programmes to be readjusted as needed in order to achieve better health effects and to obtain greater benefits.

VACCINES - GENERAL INFORMATION

Production, control, and supply of vaccines

The production and control of vaccines demand meticulous attention to detail and considerable expertise and countries should not contemplate the establishment of production laboratories without very seriously considering all the difficulties - the need for highly trained staff, the need to secure independent assessment of safety and potency, and the high cost of small-scale production. There is already ample production capacity to satisfy total world requirements. The most important problem is to determine how vaccines of assured quality can be delivered at the lowest price so that they can be used on the large scale now required in the developing countries.

With the use of modern equipment, which permits the manufacture of very large batches, the cost of vaccines in bulk is only a fraction of the cost of the packaged products. Filling, freeze-drying, labelling, and packaging, together with the overheads levied to cover the cost of buildings, research, and marketing, account for the major part of the final selling price. The cheapest way of obtaining vaccines, therefore, is to buy in bulk and to fill into ampoules in the country in which they are to be used. However, this necessitates the establishment of adequate facilities for filling and of a small-scale but expertly staffed control laboratory within the country to carry out the tests that have to be made on the product after filling. Tests of sterility and freedom from abnormal toxicity do not call for a highly sophisticated laboratory service. Antigen-identity tests and tests for potency are more complex and (in the first place at any rate) may have to be done elsewhere - especially

when dealing with live vaccines. WHO can help in having the necessary tests made for a period and in finding suitable laboratories that provide training in the essential techniques. The establishment of a control laboratory has much to commend it. The country can obtain its vaccine requirements at a lower price, it is in better control of the supply situation, and it can carry out checks on the vaccines at all stages of distribution from the central stores to the point where they are administered, without having to wait for outside help. Finally, and most important, the existence of a national control laboratory greatly increases the standing and degree of responsibility of the health authority.

The difficulties and initial costs of establishing a control laboratory should not, however, be underestimated, and instead of each country developing its own filling and control facilities consideration might be given to the establishment of regional laboratories for that purpose.

Though there is no real shortage of vaccines in the world, most developing countries have to face considerable financial problems in obtaining supplies. WHO and UNICEF have made arrangements by which countries can purchase vaccines on a reimbursable basis through these organizations and, where possible, local currency is accepted as payment for a part or the whole of the cost.

One of the most important considerations in an immunization programme is to ensure that vaccines retain their potency throughout the storage period. Vaccines are labile biological substances and transporting them is difficult. Unless the difficulties can be overcome there is always the risk that vaccines that have lost their potency during transportation will be used in immunization programmes.

Three problems have to be considered - ordering, refrigeration, and speed of transportation.

Ordering, shipping, and storage

When a decision has been taken about the diseases to be dealt with in the programme, an assessment of vaccine requirements must be made. This can be done by calculating:

- the estimated number of children it will be possible to reach (not the total susceptible population), multiplied by the number of doses per child;

- the wastage of vaccine during operations (on average about 10-15% but sometimes up to 20% for smallpox vaccine and 40% for BCG);

- the stocks to be held in reserve in case of outbreaks, breakdown in the cold-chains, etc.

The number of vaccine doses per package depends on the strategy that has been decided on. While the supplying of vaccine in single-dose containers for use in health centres, hospitals, and other institutions, may reduce vaccine wastage, it is considerably more costly to prepare vaccine in one-, two- or five-dose containers than in 10-, 20- or 100-dose containers. Whenever possible, therefore, immunization programmes should be designated to permit the use of the larger multiple-dose containers, but in most instances a proportion of ampoules containing smaller numbers of doses can be provided.

Ordering should be done well ahead of time so that about 12 months' supply is always available in the central cold store, both to ensure a steady supply and to use in emergencies, whether epidemiological or logistic.

Most countries have a system of ordering by tender, but if the specifications of the tender are not comprehensively framed the vaccine provided may not (for a number of reasons) be of first quality. This constraint can be overcome by using the following procedure. The Ministry should specify the quality of vaccine required and should purchase it only from the primary producer or his direct representative. The vaccine should be accompanied by a release certificate from the control authority of the country concerned and by a statement to the effect that the product is licensed in the country of origin. The purchaser should request that before the contract is signed, the protocol of production and control should be
made available and the literature distributed with the product should be presented for consideration. The specification should give details of the method of delivery and packaging to be followed. Airfreighting should be encouraged. The producer is in the best position to sell vaccines at the lowest price if he is given orders two or three years in advance; he can then fit the order into his overall production schedule and deliver the vaccines at the right time.

WHO's role in this process is to ensure that the vaccines comply with WHO requirements for biological substances. It is also able to give advice on the most suitable product, especially when several companies offer vaccines at similar prices and of apparently similar quality.

Some countries have experienced delays in transit. If this occurs especially with live vaccines, the consignment should always be checked for potency, with WHO's help if necessary, before being issued.

Refrigeration

It is essential to ensure an unbroken cold-chain from producer to vaccinee; any break in this chain can seriously affect the potency of vaccines, especially those containing living organisms. All reputable manufacturers have adequate facilities for storing their vaccines, and the problem begins when the vaccine leaves the producer. The problem was particularly important in countries with high ambient temperatures. In order to minimize the risk of breakdown of the cold-chain the health authority should ensure:

- that advance warning of the date and time of receipt is given so that the vaccines can be transported immediately from the point of entry into the country to the central cold store; this involves alerting the customs authorities to avoid delays in clearing customs.
- that the central cold store has adequate storage space for a year's supply of vaccines under continuous refrigeration.
- that the regional centres have adequate refrigeration space for a 6-month supply of vaccines for both static and mobile teams in the area.
- that the mobile units have local mobile refrigeration space sufficient to hold all the vaccines required for a complete local operation.
- that vaccines are transported in insulated containers in which the vaccine is held at a suitably low temperature; deep-frozen cooling packs are often suitable for the purpose.

The design of containers and the insulation properties of the material from which they are made require further investigation. Containers can be quite expensive, and it would be of considerable help if WHO could stimulate research into their design.

Although some vaccines are relatively stable (e.g., adsorbed diphtheria and tetanus toxoids), others, particularly live virus vaccines distributed in the liquid form (e.g., oral poliomyelitis vaccine), are labile, especially if a stabilizer has not been added. Stabilizers are added to freeze-dried measles vaccine and liquid poliomyelitis vaccine; thus measles vaccine can be expected to maintain its potency for one year and poliomyelitis vaccine for six months when stored in a domestic refrigerator that functions continuously at a temperature between 2°C and 10°C. If possible, measles vaccine should be kept at a temperature well below 10°C. In the case of freeze-dried measles and other live freeze-dried vaccines it is important to remember that the diluent should be chilled before being added. If it is at a temperature of 40°C it might reduce or destroy the potency of the vaccine.

If it were possible to obtain more stable vaccines that did not demand continuous refrigeration, many of the problems of getting potent vaccines to the vaccinees would be eased. WHO should give high priority to establishing research on this subject.
The specifications for shipping vaccines must be recorded in great detail. Some vaccines, especially those containing a preservative (such as DPT in multidose vials to which merthiolate has been added, or cholera or typhoid vaccines killed and preserved with phenol), must not be allowed to freeze, as they might well do in the unheated cargo section of an aircraft. Others (such as poliomyelitis vaccine and measles vaccine) must be maintained at -20°C or below throughout shipping. This is to ensure that the vaccine is not thawed during transport and refrozen in the cold store on arrival because thawing and refreezing might have a deleterious effect on potency.

Before embarking on large-scale programmes a feasibility study of the cold-chain under practical conditions should be undertaken, and instructions based on the results of the study should be distributed to all personnel involved.

It has recently become possible to include in the containers for the distribution of frozen food an indicator that changes colour with temperature. This device shows whether the food has remained frozen throughout transportation. The inclusion of such indicators in boxes of vaccines should be encouraged, and further work on an indicator specific for this purpose should be undertaken.

The country reports indicated that some countries have inadequate arrangements at the central stores, more have problems at the regional level, and all countries experience difficulties at peripheral levels, particularly with kerosene refrigerators, which are often not properly maintained and which frequently lack new wicks and glasses and regular supplies of kerosene.

Methods of administration of vaccines

There are widely differing views concerning the sites at which the vaccines should be given particularly when, as is generally the case, the number of times a child is presented for vaccination is severely limited. Generally speaking the arms are preferred.

The use of the bifurcated needle for smallpox vaccination has been very successful and the intracutaneous route is used universally for BCG. Owing to scar formation, sites where the skin is subject to stretching should be avoided. DPT should be given intramuscularly and live poliomyelitis vaccine orally, either on sugar or in syrup. Poliomyelitis vaccine stabilized with syrup simplex can be given to babies by dropping it directly on the tongue, but when magnesium chloride is used the bitter taste of the stabilizer must be masked with sugar, syrup, or a suitable fruit juice. The sites used for vaccines that leave a scar should be easily seen for rapid checking, since the checking of scars is useful for evaluation purposes. Such scars can also be used as "markers" for other vaccinations performed at the same time.

There are various views on the need to disinfect the skin. In several extensive smallpox vaccination programmes the skin was not disinfected (unless it was frankly dirty, when the arm was washed with soap and water) and there was no increase in the severity of the normal reactions. If a disinfectant is used, however, it should not be left on the arm because of its deleterious effect on the vaccinia virus, and for this reason 70% alcohol that is immediately wiped off or allowed to evaporate is probably the most suitable.

Although the jet gun has been used in many areas it is no longer favoured except in mass campaigns. Breakdown of the equipment and the difficulty of repairs sometimes cause serious interruptions in mass vaccination programmes. Jet guns are also wasteful in the use of vaccine. The choice between glass syringes with needles that have to be resharpened and disposable plastic syringes and needles is governed mainly by cost. In the developed countries the use of disposable equipment is cheaper but it has been found that some plastic syringes are not suitable for measles and yellow fever vaccines because they inactivate the virus. There are, however, many makes of plastic syringes that are suitable for these vaccines, and tests of suitability should be guaranteed by the supplier.

* Freezing destroys the immunizing capacity of such vaccines. When water crystallizes the concentration of preservatives increases to levels that have a denaturing effect on the immunizing antigens.
The use of combined vaccine is very convenient, but no single vaccine can contain the antigens for all seven diseases. When a child is taken to an immunization session as many vaccines as possible should be administered, so long as the child is of an age to give a good immunological response. The administration of multiple antigens simultaneously or in combination does not increase reaction rates and does not materially interfere with antibody responses. However, there is some evidence that bacterial vaccines containing gram-negative organisms may interfere with the response to live virus vaccine and this possibility requires further study.

Much time and effort can be saved by arranging the clinic in the correct order for the most efficient flow of patients. Simple clear manuals on immunization procedures are being prepared by WHO and it is hoped that they will be of value to all concerned with immunization programmes.

Optimum age of administration of some vaccines

Measles. The earliest age at which measles vaccine should be given in Africa requires serious consideration. The persistence of maternal antibody favours delay until 9–12 months of age, but clinical evidence of serious cases below 6 months of age and the desirability of ensuring protection before the peak age for infant malnutrition favours starting at as early an age as will give immunity to a reasonable proportion of susceptible children.

In practice, the number of months between visits of the vaccinators will determine the age of vaccination of most children. The seminar agreed that, at present, 6 months is the earliest age at which measles vaccine should be offered but that further studies of this point are needed, both in the big cities where measles transmission is, for practical purposes, continuous and in rural areas where epidemics occur every year or two.

It was also agreed that the upper age limit for measles vaccination should be not more than 3 years. In rural areas, where measles epidemics are regular and seasonal, it would be possible to prevent them by completing regular mass vaccination of susceptible children shortly before the dates at which the epidemics usually occur.

BCG. Where it is feasible to give BCG at or soon after birth, this should be done, but in most countries only 10–20% of infants can be reached with sufficient ease to do so. Every opportunity should be taken to vaccinate every child once, as early as possible, during the first 15 years of life.

DPT. Since diphtheria is not yet an important public health problem in most parts of Africa, and since, after the neonatal period, tetanus is not an important risk until 3 years of age, the main considerations relate only to pertussis. Maternal antibody does not protect against this infection. Not only are attacks in infants under 12 months of age clinically severe, they are also very common. With pertussis, unlike measles, it is possible that the risk of infection in infants can be reduced by the effective immunization of the older age-groups, which reduces the amount of infection in the community. In general, however, immunization should be started early, at the age of 2–3 months, and should be completed in the first year of life if logistically feasible.

Vaccination schedules

From the country reports it was clear that with a few exceptions multi-visit schedules are still being employed, particularly in static health units. Such schedules result in very low proportions of completed immunizations. They produce severe problems of supply and cold storage and great vaccine wastage due to uncompleted schedules.

With the present highly potent antigens a minimum of two visits only might be a workable compromise provided that this schedule can be shown to give an acceptable degree of protection against pertussis and poliomyelitis.

The schedule would be as follows:

First visit - DPT, poliomyelitis vaccine, BCG (as marker).

Second visit - DPT, poliomyelitis vaccine, measles vaccine, smallpox (as marker).
The first visit might be made when the infant is 2-3 months of age; the second visit should not be made before the age of 6 months. If the child could be seen six months after the second visit a third dose of DPT and poliomyelitis vaccine would be given.

The longer the interval could be extended beyond one month between the first and second doses of DPT, the easier and cheaper it would be to run the programme but the greater the risk that pertussis infection would intervene before the second DPT had been given, in which case the child would presumably be virtually unprotected. Here too, as in the case of measles, compromise is needed between epidemiological and logistic considerations, and a series of such compromises should be studied under realistic and differing conditions in order to indicate a model for general use.

Studies of the risk of poor immunological responses versus the logistic advantages should be carried out to compare two-dose and three-dose schedules at varying intervals of poliomyelitis vaccine. Likewise the degree of immunity transferred from mother to child by different schedules of tetanus vaccination should be investigated.

PLANNING A NATIONAL IMMUNIZATION PROGRAMME

Epidemiological assessment of diseases to be controlled by immunization

Epidemiological assessment consists of the measurement, as objectively as possible, of the relative public health importance of a disease. The purposes of collecting epidemiological information are:

- to provide the national decision-makers with the facts about the numbers of illnesses and deaths in the country caused by the diseases preventable by immunization;

- to guide the setting of the objectives and the planning of an expanded immunization programme;

- to enable the managers of an immunization programme to assess its effects on health and its successes and weaknesses and to guide operations accordingly;

- to give warnings of epidemics or other health emergencies so that they can be dealt with rapidly;

- to provide indications of the long-term changes to be expected in the people's health, as a guide to future policies.

The information required comprises the following:

- incidence
- age-specific attack rates
- severity of the disease including complications and sequelae
- seasonal and temporal trends
- geographical distribution within the country
- differences in disease occurrence in different populations, e.g., densely populated urban centres versus sparsely populated rural areas.

Information on health must be related to the population, i.e., the collection of data on disease should be paralleled by the collection of data on population numbers by age, sex, distribution by administrative units, etc.

The sources of information can be divided into two broad groups: routine reporting of morbidity and mortality and population surveys.

Routine reporting of cases and deaths. Hospitals, health centres, and medical practitioners are usually requested to notify cases and deaths from a number of communicable diseases. The diseases covered by an expanded immunization programme could be included in the list of notifiable diseases. In practice, the reporting in developing countries is deficient, and morbidity and mortality data are frequently unreliable. This is scarcely
surprising when it was realised that in Africa there is on average one doctor to 21,000 people and one nurse or midwife to 1000 people at best and 20,000 at worst. Notwithstanding these shortcomings, it is surprising how much information can be obtained by scanning hospital records. Furthermore, a study of hospital records can give an idea of the relative importance of one disease (or manifestation of a disease) compared with another and may likewise elucidate the interaction of underlying infections and other conditions (e.g., malnutrition).

Use could be made of laymen - teachers, school leavers, responsible persons in communities - for reporting on some communicable diseases.

A reporting system should be as simple as possible and only the essential information should be requested. The feedback of information to those providing reports is particularly important in stimulating continued participation; it also constitutes evidence of action being taken.

Population surveys. These might provide immediate answers to pertinent questions required for planning an immunization programme. A population survey might include an interview survey, a clinical examination survey, and/or an immunological survey.

Interview surveys. Because diagnostic information (unless the cases are attended by a medical practitioner) is symptomatic and subject to memory, interview surveys should be limited to diseases such as paralytic poliomyelitis, tetanus, and measles that have symptoms severe enough not to be easily forgotten. In the study of cases with paralysis of limbs in Ghana - already mentioned - the questionnaire was sent to school-teachers and obtained a 95% response.

Clinical examination survey. Only a gross clinical check limited to long-lasting sequelae (e.g., deformity or chronic underlying conditions such as kwashiorkor) is possible in most cases.

Immunological surveys. Tuberculin tests give an accurate indication of past tuberculosis infections. Schick tests can determine the distribution of diphtheria infections. Serological surveys give evidence on prevalence of different types of poliomyelitis viruses and on measles and other infections.

Serological surveys are important in the evaluation of the effectiveness of an immunization programme. An initial survey carried out before embarking on such a programme provides epidemiological information on the disease distribution in the community and constitutes at the same time a baseline for later evaluation of the programme. Support should be given to national laboratories to develop the capacity to undertake such investigations. These laboratories might eventually undertake quality control of vaccine.

Coverage objectives

The immediate objective of an immunization programme is to reduce morbidity and mortality and to further other national interests. The objective must be quantified so that achievements can be measured in terms of how many of the set objectives have been met.

In formulating the objective the following should be considered:

(1) Diseases to be covered by the programme. The seven following diseases are considered the core of nationwide expanded national programmes: measles, poliomyelitis, diphtheria, whooping cough, tetanus, tuberculosis, and smallpox. However, before embarking on an immunization programme against measles, where the vaccine is very sensitive to both light and temperature and is expensive, the possibility of the continuity of the programme should be assured. Epidemic poliomyelitis might not yet be recognized as a problem in all developing countries but recent studies in Ghana and in many other countries suggest a high incidence of endemic infantile poliomyelitis.

\[\text{\footnotesize{1 Materials for Schick tests are no longer easy to obtain, but enough for small-scale surveys are probably available.}}\]
Typical facial diphtheria might be infrequently seen outside urban centres but, as the inclusion of diphtheria toxoid in the triple antigen does not add to the cost and does not produce increased reactions, the inclusion of diphtheria in a multi-antigen immunization programme would be warranted.

(2) Ages to be covered. Ideally this depends on an assessment of both age-specific attack rates and immunity profile. In practice, however, the diseases can be divided into two groups:

(a) diseases where natural infection exhausts the susceptible population at an early age, e.g., poliomyelitis, measles and whooping cough; for these diseases vaccination should be limited to the age groups of known susceptibility, thus limiting wastage of vaccine and effort.

(b) diseases against which susceptibility is maintained beyond early childhood, e.g., smallpox and tetanus; here immunization might be repeated at school entry. Children who have no BCG scar at school entry should likewise be given BCG.

(3) Percentage reduction in morbidity and mortality. Except for smallpox, for which the stated worldwide objective is eradication, the establishment of the percentage reduction in mortality and morbidity to be aimed at depends on the operational constraints, epidemiological factors, and effectiveness of the vaccine. Assessment of reduction in morbidity and mortality requires an efficient reporting system. For a number of diseases, such as diphtheria, tetanus, measles, and poliomyelitis, reduction in morbidity can be inferred by a change in the immune status of the population, which can be measured by serological sample surveys. There is no completely satisfactory serological test to evaluate the protective effect of the vaccine against whooping cough, but, when wisely interpreted, the results of laboratory tests of vaccine potency and of agglutination tests on children's sera can be valuable. For BCG vaccination the presence of a scar provides a means of assessing protection.

Targets for population coverage should be set out in the plan of operations. Such targets might differ for different age groups and different risk groups. In evaluation it should be checked that the specified coverages have been achieved for each segment of the population and for every geographical area as set out in the plan and not just an overall coverage, which might conceal many deficiencies. Where several vaccinations are envisaged, the plan should provide guidance on the relative importance of keeping to the target for the different vaccinations.

Coverage targets are mostly empirical in nature. When the epidemiological characteristics of the diseases are better known, it may be possible to establish minimum targets more precisely, using simulation models. Exercises of this type can be very rewarding because ambitious targets for population coverage can be quite expensive and may not be necessary, at least for some diseases.

Constraints and potentials

For the purpose of an immunization programme a constraint means a factor that either reduces the probability of obtaining a health objective or reduces quantitatively the desired degree of attainment.

Constraints may be related to problem recognition, population coverage and epidemiological factors, organization, structure and functioning of health services, resources, logistics, and social and political background.

Problem recognition. A lack of proper appreciation of the problem of childhood communicable diseases controllable by immunization can stem from:

(1) lack of information on morbidity and mortality. Even if reporting is unreliable, however, an estimate of the health importance of diseases can be obtained from quite simple information systems.
(2) lack of up-to-date technical information on vaccines (e.g., combinations, stability).

(3) unrealistic vaccination schedules. Ideas about the immunization schedules in the developing countries have been influenced by the experience in countries with highly developed comprehensive health services, where repeated attendance at a health centre or family doctor's consulting room is not difficult. Operational studies have shown that simpler methods and schedules directed towards the community rather than to the individual are effective.

While governments in the developing countries recognize communicable diseases as major public health problems, many do not sufficiently appreciate that immunization is the most effective method of controlling some diseases and the only way of preventing others.

**Population coverage and epidemiological factors.** With some diseases, e.g., diphtheria and poliomyelitis, an increase in the proportion of immune persons in the community cuts down the rate of transmission. In the case of diphtheria, it had been estimated (and shown in practice) that immunization of 75% causes a steady decline in disease incidence. With measles a higher percentage is required. At the same time, to reach say 85% of the child population with any immunizing agent instead of 80% presents many more problems than the 5% difference might imply at first glance. With tetanus, immunization provides protection to the individual without interfering with transmission, and to reduce neonatal tetanus by immunization requires the immunization of pregnant mothers.

Another example of an epidemiological factor is population density. A sparsely populated rural area presents operational problems and a one-yearly cycle of immunization may be adequate. In contrast, a densely populated urban centre may require two immunization cycles per year.

**Organization, structure, and functioning of health services.** The pattern of responsibilities and accountability of the various health authorities and of divisions and departments within these authorities may constitute a constraint. Responsibility for immunization may be shared by a number of health agencies (e.g., governmental and voluntary social groups), and extensive coordination may be required to obtain high coverage. The structure (i.e., the pattern of facilities and operational units forming the health system) may also constitute a constraint to coverage.

The efficient functioning of the operational units forming a health care system and the smooth working relationship between the units is crucial for success. A concrete example is the frequent lack of coordination between the mobile teams and the static units. The mobile teams in many countries arose by necessity, specifically for the smallpox eradication programme, as an independent entity with a time-limited disease-limited single objective that has now been achieved. In every country there now exists a need to preserve and strengthen this valuable resource while at the same time making the static units much more effective. For the purposes of a national expanded immunization programme, this constraint can be overcome only by a unified operational control of both facilities.

**Resources.** Immunization, however important, is only one activity of the health services and has to share the often meagre resources with other activities. The main problem for an expanded programme of immunization in securing its share of the resources seems to be the need for systematic planning. It is necessary to plan by first stating the objectives. Then the costs entailed in reaching these objectives are worked out on the basis of present costs per fully immunized child. In all countries the costs of each component of an immunization programme (vaccines, salaries, equipment, consumables, transport, postage, public information, etc.) can be calculated, but this is seldom done at present. Thus it is not possible to determine the actual expenditure per child fully immunized. Without this information the medical authorities and the political decision makers are unable to decide on the extent to which a national immunization programme can be expanded or on the amount of resources to be allocated to its expansion.

**Logistics.** The logistics (distribution of vaccine to focal points within the country have to be worked out in accordance with a pre-arranged timetable that ensures that the vaccines are maintained at suitable temperatures and are available at the right place and
time to meet the needs of the teams, whose timetables have also to be carefully worked out. Highly scattered rural populations, rough terrain, rains, etc., create severe logistic problems.

**Social and cultural background.** Public cooperation in vaccination programmes may be hampered by ignorance, by broken promises, or by badly organized campaigns. It must be stressed that immunization is not a treatment for the sick but a measure by which healthy children remain healthy. There is obviously only a certain distance that people are willing to travel, and response to immunization programmes has been found to be affected by this. However, distance per se plays a less important role than the socioeconomic, cultural, and educational conditions in an area of reasonable accessibility.

Other factors that might affect people's cooperation in rural areas are the local practices (e.g., harvesting, village marketing) and the social structure (e.g., loyalty to traditional chiefs).

**The part played by national and local conditions**

For an immunization campaign to be successful, all the national and local conditions have to be taken into consideration. Many of these factors are enumerated in Annex 1, in which consideration is also given to the evasive actions that can be taken to overcome constraints placed on the programme. When all the local conditions have been taken into account, the moment is reached when a decision is made to employ one particular strategy in order to achieve the objective. In Annex 2 the interrelationship of factors that have an effect on each other are mentioned, and the suggestions of alternative strategies made by the various countries are listed. The use of simulation models is worth consideration, and mention of these is made in Annex 3.

**Pilot operational studies**

When the constraints and strategies have been fully considered and a plan of action arrived at, it is sensible to initiate pilot operational studies in order to ensure that the programme will be successful. In Annex 3 the factors to be taken into account and the limitations of pilot studies are outlined.

**The expanded immunization programme: developing the plan**

**Resources.** The resources required for a large-scale immunization programme are detailed in Annex 4. It is most important that a separate budget be allocated for the programme, and once the programme has started there must be no cutback in financial support. In the budget calculations, provision must be made for the on-going costs.

The key factor in a successful campaign is the personnel. If they are not satisfied with their salary or working conditions the programme was not likely to succeed. The equipment, including transport, on which they depend must be reliable; the breakdown of any piece of equipment is liable to cause chaos.

**Records and supervision.** A significant activity of any immunization programme is the keeping of accurate records. This may be extremely difficult in a developing country, especially for field workers, but great stress must be placed on the need for such data. Annex 5 outlines the recording systems that have been found to be most successful under practical conditions and reviews the organization of the supervision needed to keep the programme on schedule.

**The part played by the community.** There are many factors that might influence the willingness of a community to participate in a campaign. Without their confidence and full cooperation the programme cannot be a success. Annex 6 records the experiences gained from some campaigns, including experience of the most effective publicity medium and of the use of local lay personnel as a means of achieving cooperation.
Evaluation. The evaluation of the effect of an immunization programme provides valuable data to the health authorities. The social, political, and economic targets should be outlined in order that the degree of success can be assessed. Such an evaluation should be made periodically throughout the programme to correct any deficiencies that may be exposed. Emphasis is placed on epidemiological evaluation to ensure that the vaccines are effective and on the provision of feedback information to maintain the interest of the field workers.

Inventories of present activities

WHO has drafted an inventory for distribution to countries requiring help. The inventory is being designed to collect the data from each country to assess where an increased effort would have the greatest effect.

INTERNATIONAL COLLABORATION AND AID

In April 1974, at a meeting of consultants in Geneva, WHO's role in providing assistance to countries wishing to expand their immunization programmes was considered. It was agreed that the starting point for WHO would be the expressed desire of a country for assistance in determining whether it could significantly and rapidly increase vaccination rates against the (mainly) childhood diseases.

Because a prime requirement is the keenness of the country to develop a programme and to organize its own resources to best advantage, countries that have already made progress in developing immunization services will (in the first stages) be in the best position to make use of the external aid available. WHO's input would follow the lines described below:

1. Assistance in studying the epidemiological situation, advice on objectives, costs, etc., the provision of guidelines for the organization of the programme, and the provision of practical manuals on immunization procedures.

2. Assistance in ensuring the good quality of vaccines by undertaking quality control tests, particularly for vaccines purchased through WHO. For at least some vaccines this constitutes a long-term commitment, but it should in due course be phased out or much reduced when national or regional quality control laboratories are established. WHO assists in establishing these laboratories.

3. Assistance in establishing vaccine production laboratories when this is absolutely essential.

4. Establishment of applied research programmes on practical problems such as spacing and number of doses, easier methods of vaccine administration (e.g., oral or scratch methods), the reduction of sensitivity of certain vaccines to heat and light, the optimum use of medical and auxiliary workers, and the development of simple methods of epidemiological assessment.

5. Organization of seminars.


7. Collection and dissemination of information on national programmes and on associated epidemiological data.

8. Assistance in facilitating the procurement of vaccines, equipment, and transport. For vaccines, this includes investigating the advantages of bulk supplies, making possible the purchase of supplies with local currency, extending the WHO Voluntary Fund to accept gifts in cash and kind, cooperating with UNICEF, and holding discussions with governmental and commercial vaccine producers on means of reducing costs and increasing supplies.

UNICEF's programme of assistance with vaccines, particularly BCG, is already very large, but there is interest in developing it further and widening its scope as governments develop their capacity to use the vaccines effectively in national immunization programmes.

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1 Copies of the inventory are available from Virus Diseases, World Health Organization, 1211 Geneva 27, Switzerland.
National organizations for international aid and development are also prepared to consider assisting countries with expertise, training, vaccines, and equipment. They include such organizations as USAID, the Swedish and Canadian International Development Authorities, and the Netherlands Assistance Programme.

WHO can play a most important role in coordinating external aid from different sources, and neighbouring states can with advantage set up collaborative activities in order to achieve effective control of certain diseases.

CONCLUSIONS AND RECOMMENDATIONS

The seminar clearly defined the problems that existed in the participating countries, the means by which they themselves could help to overcome them, and the most effective forms of assistance that could be offered by international organizations and other external sources of aid.

It recognized that most of the countries could contribute greatly to the expansion of programmes by making better use of available national resources.

As shown in the Introduction, the cost of expanded immunization programmes is not as great as might have been expected. It would constitute a relatively modest proportion of a national health budget.

The amount of information on the morbidity and mortality of the diseases against which immunization could be practised is meagre and every effort should be made to increase it so as to give a reasonably accurate baseline from which to measure the effectiveness of the expanded programmes. However, establishment of immunization programmes should not be delayed until the information is complete.

More information about national resources and constraints is also required so that external aid can be used most efficiently. One of the most important points to be kept in mind is that an immunization programme once established has to be maintained indefinitely and thus should become an integral part of the health service. Initially external aid can be provided, but in due course the country must take over full responsibility for the programme.

The importance of controlling the seven diseases - measles, poliomyelitis, pertussis, tuberculosis, tetanus, diphtheria, and smallpox - cannot be overemphasized. They cause high morbidity and mortality rates, and a sustained effort should now be made to bring them rapidly under control by use of available vaccines of proven efficacy.

The inputs from the countries themselves and from external sources are listed below.

**National inputs**

1. Obtain information as quickly as possible on the epidemiology of the communicable diseases that can be prevented by immunization.

2. Prepare an inventory of present immunization activities in the country.

3. Study thoroughly ways of achieving social and political cooperation and of strengthening the management of immunization programmes.

4. Make plans for the government to assume responsibility for all the costs of the ongoing programme within a reasonable number of years.

**Inputs from external sources**

Assistance might be requested from WHO for the following services:

1. Cost/benefit and cost/effectiveness analyses.

2. Design of expanded immunization programmes.
(3) Preparation of manuals for vaccination procedures.

(4) Training of staff for the development of laboratory services, including the quality control of vaccines.

(5) Provision of information on storage and handling of vaccines.

(6) Establishment of appropriate information systems and epidemiological and statistical services.

(7) Development of pilot projects.

(8) Purchasing and quality control of vaccines.

UNICEF is prepared to assist in the supply of vaccines and vehicles and to support the development of national laboratory services.

The Swedish International Development Authority, which was represented at the seminar, would consider supporting immunization programmes through WHO, under defined conditions. Other bilateral or multilateral arrangements for aid have been available in the past and would be available in the future. WHO has an important role to play in coordinating such assistance.

Participants requested WHO, in conjunction with national authorities and other external agencies if necessary, to organize urgent investigations into:

(1) the development of insulated containers that would be more satisfactory for use in the tropics than those already available;

(2) the development of more practicable and less expensive systems of refrigeration for storage of vaccines at national, regional, and peripheral centres;

(3) the development of an accurate indicator of the temperature changes to which a vaccine might have been subjected during transport and storage;

(4) the development of more stable vaccines;

(5) the promotion of cheap and effective forms of transportation.
ANNEX 1. STRATEGIES

For the purposes of discussing immunization programmes at the seminar the word "strategy" was understood as embracing the whole sequence of actions needed to put into effect the final medical action - the vaccination of a high proportion of the susceptible children.

Part of the strategy can be undertaken within the health service, but part depends on action from outside, such as the interest of the mothers of susceptible children and the help from paid or voluntary workers.

The vaccination techniques such as syringe and needle, jet gun, bifurcated needle, and oral administration are universally applicable, but the strategy by which these techniques are most effectively brought into action differs from country to country and even from one part of a country to another.

Certain developed countries have evolved immunization schedules suitable to their own conditions, the vaccinations being carried out in static clinics or in doctor's offices with a high degree of coverage. But these schedules are not necessarily the best for other communities, and they are certainly not feasible without highly developed health information and public information systems, easy identification and education of mothers, convenient systems of public transport, and greater resources than are available in most developing countries. Static immunization units on their own achieve poor coverage among rural populations, for reasons that are well known. Special problems are also presented by nomads, and by the slum dwellers in large cities.

Since the conventional immunization strategies of developed countries are not feasible elsewhere, owing to the existence of so many constraints, new strategies must be devised that take account of local epidemiological conditions and population densities. They must take advantage of those local social institutions that best suit the ways of life of the people and must be adapted to the special features of the local geography and communication systems and to the capabilities of the health and other social services.

The planning of countrywide or provincial immunization strategies must be undertaken by people who really know about local conditions. Although WHO has experience of various strategies in different countries, which might be helpful for technical comparisons, the main social, political, and administrative elements of a strategy are most likely to be suitable and acceptable if they arise from local experience and new ideas.

Strategies to overcome or avoid constraints

Constraints may be overcome by planned efforts to remedy a lack of essential resources (e.g., financial resources, equipment, and technical and administrative skills) and by obtaining the cooperation of governmental or private institutions outside the health sector. Constraints may also be avoided by using new strategies, i.e., other organizations in the country or other methods or procedures than those already used to apply the necessary medical and administrative techniques, taking local conditions into account. For example, it is particularly important to bear in mind that immunization schedules other than those used in the developed countries could be employed. For the cold-chain it might be possible to make use of the refrigeration facilities of brewers, meat packers, fish distributors, veterinary services, or ice-cream vendors. For the purposes of influencing public opinion, leaders at all levels of political organizations may be able and willing to help.

The first consideration should be given to ways of avoiding each major constraint without calling for extra resources. For example, health personnel with experience in the field and other people with commercial or social experience in different sectors of national life should be consulted on methods of overcoming or avoiding major constraints. Originality should be encouraged and vested interests discounted in relaxed wide-ranging discussions of the "free association" type. All new ideas should be noted because a successful strategy is likely to be a synthesis of individual contributions.
Each new objective in an expanded programme may be attended by constraints, which must be identified and listed. Where no new strategy is to be employed, the constraints that affect the current programme will continue to operate and will probably hinder the attainment of the new objectives. Obviously priority must be given to removing the most serious constraints and thereafter removing all constraints in order of importance.

It is necessary to try for new ideas, to explore new strategies that might circumvent old constraints, and, in particular, to study strategies in relation to the various population patterns and densities within the country. If a new strategy cannot be devised then constraints can be removed only by increased use of resources such as money, supplies, extra man-hours of work, more or better training, more or better supervision, and assistance from other agencies or people inside or outside the country. One must inquire whether anyone in the country or in other countries, especially those with a similar background, have been able to remove any of these constraints and at what cost.
ANNEX 2. FACTORS INFLUENCING THE CHOICE OF STRATEGIES

A stage is reached at which planners have to decide on the factors to which they attach most importance in finally choosing a strategy. It is necessary first of all to group the complementary health strategies. The possibility that two or more strategies could support each other should be taken into account, provided this leads to higher programme effectiveness (e.g., combining vitamin A administration or treatment of yaws with childhood immunization in some countries might increase public support for all three). Two or more health strategies might be grouped together to save such resources as motor fuel, workers' time, or effort by the public (e.g., combining regular school booster immunizations with the screening of pupils for trachoma). Furthermore, all health strategies that depend on the same resources or demand public cooperation need to be examined to see if any are opposed to each other or mutually exclusive (e.g., community nurses who are busy immunizing children at local primary schools or market places cannot, on the same days, service routine mother and child health clinics at their health centres, and neither can the mothers attend both on the same days).

Obviously a choice has to be made between irreconcilable strategies, while complementary strategies tend to support each other. However, other strategies may be presented as alternatives on the basis of their intrinsic cost/effectiveness or other advantages.

Additional criteria for making a choice between immunization strategies should be the same as those originally used to decide on the new objectives; favourable criteria would be greater health effect or coverage and better social or political acceptability. In addition, the particular population pattern and densities to which individual strategies were meant to be applied (villages, scattered hamlets or homesteads, nomads, towns, cities) have to be considered.

The list of strategies and the criteria for their choice should be submitted by the chairman of the planning team to the final decision makers, who might wish to suggest additional criteria.

The decision may be obvious from the evidence provided for and against each strategy, but if they are not there may be a need:

- to test alternative strategies in comparable populations, designing special comparative studies as part of the ongoing operational programme, or

- to express the criteria quantitatively in order to compare the likely cost/effectiveness of different strategies.

In carrying out the latter task statistical help may be required to determine where the quantitative data differ significantly and to apply a weighting system to the criteria for choosing strategies.

Examples of successful alternative strategies provided by participants from experience in their own countries

Case 1. In a large city where birth registration is compulsory and widely accepted, it is now necessary to present a certificate of the baby's BCG vaccination before obtaining the birth certificate. In the same city, school enrolment, which is close to 100%, now depends on a certificate of completed smallpox and tetanus vaccination.

Case 2. Local laymen and laywomen administer poliomyelitis vaccine under supervision to the local children, and it is considered possible to train them also in other techniques such as administering smallpox vaccine using the bifurcated needle. This strategy saves many man-hours of health workers' time and the cost of transporting some health workers to the rural areas, and it engenders local enthusiasm for immunization.
Case 3. Because financial stringency allows only a small amount of vaccine to be bought on the health budget, a revolving fund has been established in the static immunization units. Mothers pay a small amount in advance for vaccinations and their children receive the government vaccine. With their contributions more vaccine is bought for the children of mothers coming later for vaccination, and so on. A refund is given for every child who completes a full course of immunization, thereby ensuring an increased number of children completing the course. The strategy also avoids the wastage of vaccine, time, and money that occurs when a child is not brought back for the second and third doses of DPT.

Case 4. The cold-chain being inadequate, the richer individuals in the rural areas readily make their private refrigerators available to the immunization teams in order to store vaccine.

Case 5. After two rounds of mass smallpox vaccination, difficulties were encountered in sustaining the maintenance phase of the smallpox vaccination campaign, owing to the poor condition of the vehicles and lack of money for their maintenance. The strategy devised to overcome this problem is based on the operation of a few large health centres with a daily attendance of 60-100 patients seeking medical care. The clerk giving the outpatient his record card (or the medical assistant examining the patient) vaccinates all those without a scar. There are no additional costs and most of the vaccinations are primary. During the year when the system was introduced the number of smallpox vaccinations rose from 300,000 to 1.2 million.

Case 6. Travelling variolators produced small outbreaks of smallpox as they went from village to village. Many of them have since accepted free supplies of freeze-dried vaccine to use in their work and variolation has stopped.

Case 7. In an area where children were traditionally scarified by tattooing to protect them against witchcraft, this psychological reassurance is accepted as being provided nowadays by the scars produced by the immunization programme.

Case 8. In a country close to political independence, people were very resistant to smallpox vaccination because it was a completely new idea to them. But when a respected political leader explained that a vaccination scar could be taken as a sign of their independence and of their faith in the new nation the public response changed at once to enthusiasm.

Case 9. In a country with a very scattered population, BCG mass vaccination has been combined with census preparations, with political meetings, and with explanations of a new alphabet (as well as with smallpox maintenance and antimalaria work), thus making great savings in transport and the public's time and ensuring good cooperation from official leaders and the public.

Case 10. Traditional birth attendants (village midwives) are being given training and the title of assistant health visitor. On returning to their villages they act as advance motivators for the mobile immunization teams and, knowing each baby and its age, can persuade mothers to bring their children for vaccination.

Case 11. In an area where special black strings are tied around children's wrists by the traditional priests for protection against smallpox, the smallpox/measles vaccination workers removed the priests' objection to the programme by agreeing to let them apply the smallpox vaccination as well as the strings.

Case 12. In a country with a large nomadic population, the nomads return to certain known wells and waterholes for a month or two at the height of the dry season. There they find smallpox and BCG vaccination teams awaiting them. High coverage is achieved.

Case 13. The problem of broken lamp glasses in kerosene refrigerators has been overcome by local construction of a metal funnel with a hole through which the flame is visible.
ANNEX 3. PILOT OPERATIONAL STUDIES

Even after careful planning it is a common experience that certain aspects of field programmes are found to have been inadequately considered, particularly when they have not been tried before in the environment in which they are to be operated. Here, as well as when two or more strategies need comparison in practice, pilot trials can be valuable.

It was reported that, in two particular aspects of field programmes, pilot studies are found helpful. These are:

- a study of the feasibility, effectiveness, and costs of the planned strategy;
- the design of administrative records, job descriptions, managerial checklists, and records for independent assessment.

There were three provisos to be noted with regard to pilot operational studies:

- they should not delay the main operations but should take place as the first steps in the new ongoing programme, while resources are being gathered and recruitment and training undertaken for the main programmes;

- they should be on a large enough scale and in typical enough environments to allow their results to be applicable to the programme as a whole;

- they should not be given bigger inputs, either in resources such as money, transport, and manpower or in the competence of the supervisors, than it would be feasible to provide proportionately for the total programme.¹

Pilot studies that employ any kind of resource that cannot be used in the management of the national immunization programme are not only misleading but wasteful and lead to eventual disappointment.

Simulation models

It is possible, with expert assistance, to use epidemiological (mathematical) models even when the available information is crude and preliminary. This exercise may at least help to eliminate unproductive strategies and narrow down the comparison of strategies likely to be successful. Such selected strategies can be further examined in pilot studies, and if they prove effective it is reasonable to expect that they would be effective on a large scale.

¹ An exception might be made for the resources expended on the evaluation of pilot studies; these might be justifiably increased when there is need to collect special information for a short period only.
ANNEX 4. RESOURCE ALLOCATION FOR AN EXPANDED IMMUNIZATION PROGRAMME

Budget

Budgetary procedures differ from country to country. What matters is that expected funds are released on specified dates, predetermined by operational needs. Reliance can be placed only on past experience in each country. Planned expansion, whatever the budget in theory, should not go further than the resources that are likely to be made available in practice. Conversely, resources should not be allocated if the programme does not have the capacity to utilize them.

Separate budget lines are advisable for the following groups of expenditures:

- recruitment, training, and refresher courses;
- transport running costs, such as fuel and vehicle repairs;
- local purchase of consumable items such as methyl alcohol, kerosene, and butane gas and for payment for minor services rendered by local people;
- publicity, information, and health education costs at national, regional, and local level, including publicity costs of coverage competitions between communities.

In some countries more than one ministry is responsible for the budgets of immunization programmes. Such constraints call for even more careful planning and management than when a programme is under the control of only one authority.

Allocating financial resources is not the end of the matter. Other resource allocations such as transport often present worse problems. Vehicles may not be under the control of the Ministry of Health. Even when they are, the immunization programme manager may not be allocated his share of the transport at the times his programme needs it.

His field supervisor is frequently in the same position. The district medical officer who controls the transport locally may give higher priority to other users, thus interrupting supplies, wasting vaccine, disrupting public cooperation through broken appointments, and adversely affecting staff morale by preventing efficient supervision. Timetables, fuel, and mileage for use of vehicles must be laid down and agreed on far in advance. When an allocated vehicle is not available as scheduled, the fact must be reported to higher authority immediately. Local supervisors should each have sole control of a motorcycle, when this is necessary for efficient field supervision.

Most budgets of current immunization programmes are made with far too little provision for spare parts and replacement costs of vehicles. Such replacement costs have to be budgeted out of annual recurrent expenditures. It is therefore important to know the average mileage that may be expected of each type of vehicle before replacement becomes necessary.

Contingency cash has also to be budgeted to meet, by hire or purchase, the most common transport emergencies. The programme manager must plan his programme at every level jointly with the controller of transport. Every immunization manager must try to find strong incentives to encourage the controllers of transport to allocate vehicles according to the previously agreed timetables and budgets.

Personnel

The payment of salaries and allowances for personnel can usually be relied on. Staff engaged wholly on immunization programmes are often on terms and conditions of employment different from those of other health workers. This can cause problems for such staff. In smallpox programmes, for example, people are recruited to be trained as vaccinators, but
very few countries consider establishing rules for their promotion based on their performance. When the number of teams is reduced, deployment to other health work is not considered within the national civil service regulations. Thus incentives for better performance have been lost and good workers needlessly discouraged.

Incentive payment for health workers or other civil servants spending nights out in the field are routine in many government services and constitute a useful reward for mobile vaccination teams. However, it is important for supervisors to ensure that these allowances achieve their purpose - i.e., the provision of good meals and rest for the workers - otherwise they might be used for other purposes (e.g., put entirely into savings at home) with the result that the vaccinators live such a rough life in the field that they are unfit to meet the demands of their daily work.

In some countries the mobile smallpox teams have, through WHO, been receiving an additional allowance, over and above the routine field allowances from their own governments. This is reasonable for special efforts within a time-limited programme, but it is causing concern in some countries. Government departments other than ministries of health also have workers who spend many nights away from home and who resent the special treatment given to smallpox vaccination teams.

Most health workers or other people such as drivers, mechanics, and storekeepers employed in a national immunization programme work for that programme only some of the time, being engaged on other work at other times. It is essential for the proper management of their immunization activities that their supervisors allocate to each one of them a specified number of hours of work to be spent doing immunizations on specified days of the week or specified dates in the year.

**Equipment and supplies**

Sufficient supplies of inoculation equipment must be made available. They may include jet injectors, glass syringes, and reusable needles, or disposable syringes and needles, or other instruments such as the bifurcated needle for smallpox vaccination. Sterilization may be achieved by flaming, as for BCG needles, or boiling in sterilizers heated by electricity, kerosene, gas, or other means. Consumable equipment includes cotton-wool, soap, towels, dusters, disinfectants, kerosene, gas, etc. Mobile teams require camping equipment - tents, beds, lights, cooking utensils, and stoves, and there is a need for adequate supplies of record cards and other stationery.

For large-scale programmes it is useful to appoint a good stores officer to take charge of the central store.

**Team transport**

Transport difficulties are a major problem. The authorities responsible for immunization programmes seldom have direct control of the transport needed, and so planning of the use of this resource is virtually absent. Fuel costs have risen steeply, and transport has now become the major expense of all programmes designed to reach rural populations.

Expensive four-wheel-drive vehicles with high fuel consumption are not needed in all rural areas. Where roads are reasonable cheaper vehicles with lower running costs are feasible, provided immunization is not conducted in the wet season. The planners of immunization programmes should always carefully work out the possibilities of combining their activities with other "outreach" health or social programmes, thus making savings both on transport and on the public's time.

It is uneconomic for a ministry of health to set up its own workshop for repair and maintenance unless it has a large number of vehicles under its control. Good engineers and mechanics are not usually willing to work for government rates of pay because the remuneration offered by the private sector is much more attractive.
ANNEX 5. RECORDING, REPORTING, AND OVERALL SUPERVISION

Forms should be available for the recording of vaccinations. The form should be simple, with the minimum of entries and requiring the minimum amount of clerical work. It should be carefully designed and tested in the field prior to general adoption. Items should follow a logical sequence, and space should be provided for any written comment the reporting staff may wish to make.

For a mobile team a tally sheet (in which circles are crossed off for each subject vaccinated) might be adequate for the daily recording of vaccinations given. One such tally sheet (used in Kenya) is shown on page 28. When administering DPT and/or poliomyelitis vaccine and when using smallpox or BCG scars as markers, the health worker may indicate how many children are receiving a first dose and how many a second dose. The tally sheet should be used by the team leader for checking daily outputs and coverage. The form design used for daily recording should serve as well for weekly and monthly reporting.

In fixed centres individual records of vaccines may be kept but tally sheets similar to those used by the mobile teams can be used for weekly and monthly reporting.

In the weekly and monthly reports of the mobile teams and fixed centres, the actual amount of vaccine used should be given.

A system for the regular reporting on the stock of vaccines, supplies, and equipment, on the consumption of motor fuel, and on the operational condition and cost of the cold-chains and vehicles should be established.

The administrative structure for reporting should be clearly defined. At every hierarchical level the reports arriving from several points (e.g., from vaccination teams to a district health officer) should be studied in relation to the present plan of action (especially from the point of view of coverage), collated, and commented upon before being forwarded to higher echelons. When visiting field workers, the supervisor should take with him the reports and the comments on them (including commendations) and discuss them with the workers.

Supervision

Overall supervision is the responsibility of the central national programme headquarters staff. Since the programme depends heavily on proper field execution, it is important that the supervisory staff (and the director of the programme) should frequently visit the intermediate level of operations and periodically the peripheral level. The supervisors and central supporting staff should be appointed prior to the development and planning of the programme. In order to ensure effective supervision, job descriptions of all persons operating in the programme (including the supervisors) should be written out in detail. Detailed manuals of the supervisory activities should also be provided.

The importance of field supervision cannot be overemphasized. The effectiveness of field supervision had been a principal factor in the success or failure of immunization programmes. At each supervisory level, responsibility should be assigned and authority delegated to the maximum extent possible.

A health worker generally tries to please the most important and influential of his or her supervisors. If the supervisor happens to be personally and professionally interested in achieving maximum immunization coverage, well and good, but this is seldom so. The immediate supervisors of nurses, midwives, medical assistants, dispensers, dressers, and sanitarians are usually hospital matrons, district nursing supervisors, district or health centre medical officers, and district health inspectors, all of whom have many other interests and responsibilities. Immunization in its practical day-to-day management seldom has a high priority in their scale of professional values or in their training. Their subordinates quickly realize this and adjust their work priorities accordingly.
This human managerial constraint may be found operating in many static units where immunization activities are integrated into general medical work. The immunization programme manager can overcome it only by setting targets for vaccinations to be performed according to the working hours and days budgeted as well as for the coverage to be obtained in the population for which that static unit is responsible. He has then to ensure that the health workers' supervisor bestows praise or blame, promotion or relegation according to the proportion of the time the worker should have spent on immunization, the number of immunizations that should have been completed, and the coverage that should have been achieved. The supervisors, too, must realize that their supervisors will in turn appraise their professional performance in part on the immunization coverage achieved in the populations for which they are responsible.

Two kinds of operation supervisors are crucial for field activities - the first-level supervisor and the group supervisor.

The first-level supervisor (e.g., the team leader) is immediately responsible for all aspects of the team performance. While he can stand in when necessary for absent personnel, it is best if he remains free to observe and correct the performance of the other team members, to confer with local authorities, complete necessary activity report forms, and plan for the next few days' work. He is also responsible for organizing the advance publicity and securing public cooperation. Maintenance of team morale as well as performance are the basic results of his direct supervision.

The group supervisor (e.g., the district supervisor) should draw up vaccination schedules and coordinate the activities of various groups of health workers giving the vaccinations (e.g., mobile teams or fixed-centre staff or both). He should periodically visit them and at the time of his visit formally and informally assess their work. He should have a check-list with him.

The selection of a supervisor should be based on the capacity of the individual to provide leadership and to master new skills. When subsequent appointments are made, promotion of those within the programme itself should first be considered. This helps to keep the morale high and to improve performance, because the individual selected would already have a knowledge of programme activities. First-level supervisors responsible for a vaccination team can often be selected from among the vaccinators or other health workers assigned to the teams.

The supervisor should be acceptable to and able to communicate effectively with the people he is to supervise. In the initial phase of the programme, it is preferable to start by selecting and training the supervisors, who should then participate in the selection and training of the individuals whom they will supervise.
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ANNEX 6. COMMUNITY PARTICIPATION

Great emphasis must be placed on the need to consult and obtain the support of the decision makers at the highest levels in the ministry of health. To do this it is necessary to provide them with clear statements of quantified objectives, of benefits, and of costs in order to allow informed decisions to be made and the necessary political support to be rationally based. Community cooperation can be built up on the basis of such preparation.

The cooperation of the community is essential for the success of the immunization programmes and therefore no effort should be spared in enlisting active support of all sections of the population, including political leaders, traditional healers, and housewives. Complex social relationships, traditional beliefs, and customary behaviour must be studied to find the most practicable ways and means of motivating the population to accept immunization.

It is a mistake to believe that the most sophisticated methods such as the use of films produced abroad will bring people to immunization points. For each population group certain approaches are more suitable than others, and techniques used in one community might not be suitable in another. While it is obvious that people should be approached in their mother tongue, it is less well appreciated that the methods of presentation should be those the people are accustomed to. For example, in a rural African community an approach based on a traditional dance might be the best way of conveying the message and winning cooperation.

It has been shown in many studies that the incidence of infection is highest among the illiterate, least educated, and poorest sections of the population. Therefore it is necessary to concentrate attention on them and make special efforts to get them to attend for immunization. It is necessary to investigate thoroughly the reasons for refusal of vaccination and to study ways and means of overcoming these obstacles. Experiments should be organized to test possible approaches to motivation of the people and thus determine which of them would prove most effective, since there are no ready-made prescriptions.

While motivation of the population is very important, it is no less important to ensure that when people do come for immunization they are not disappointed. The teams must arrive on time, the vaccine must be ready, and full information and reassurance about possible reactions (e.g., fever and rash after measles vaccination) should be given to mothers to prevent disillusion and subsequent non-cooperation. Maintenance of active cooperation is as important as the initial attempts at motivation.

In Africa the radio is listened to by the majority of the people, and well chosen messages by radio can greatly assist the immunization programmes. Success of a vaccination programme in one area will often induce populations elsewhere to cooperate in similar programmes.

While there is a place for specialized health education in explaining and winning over the cooperation of the population, each member of the immunization team must also take part in health education and must remember that inserting the needle under the skin may be less difficult than getting the right ideas about the necessity for and value of vaccination into the mind of the individual.

The community's role should not be limited to passive submission to immunization procedures; voluntary effort and other community resources could be harnessed and utilized to help solve some of the problems. Lay volunteer workers can assist in community health education, in tracing and contacting defaulters, and in carrying out clerical and other nontechnical duties. Local volunteers have the advantage of knowing local languages, dialects, and cultures. Intelligent lay persons can be trained to carry out simple technical functions such as the administration of oral poliomyelitis vaccine. In communities that have a long tradition of self-help, the promotion of immunization programmes can be easily adapted into the existing tradition of community action. Where such traditions are poorly developed, community participation in an immunization programme could be useful in initiating the concept of community cooperative effort. Mothers who have satisfactorily used the health
services for their children often provide the best recruits. Men's organizations could also be tapped; they might be willing to provide funds to supplement the supply of vaccines, equipment, etc.

An inventive, unorthodox, flexible approach to the motivation of people, supported by a search for the best methods of obtaining participation is the best prescription for the expansion of coverage in immunization programmes.

The country reports showed that many health authorities do not have a systematic approach to the problem of obtaining the understanding and support of the people, the community leaders, and the higher level administrators and politicians. Although all participants appreciated the great importance of this need, the sociopolitical aspects of immunization programmes are seldom taken into consideration either in the planning process or in the management of ongoing programmes. One country made a special study of what health education could achieve and found it raised coverage of the target group from 10% to 60%.

Health educators and other social scientists with practical field experience in the country should be members of the teams that plan and administer national immunization programmes.

Where coverage is low or expected to be low, investigation in the field by competent social scientists is indicated. Mothers who do not accept the service should be compared with those who do, and the efforts of the managers, health educators, community leaders, and vaccination teams should then be directed towards changing the knowledge, attitudes, motivation, and behaviour of the former group.
ANNEX 7. EVALUATION

In immunization programmes, as in any health programme, it is important to examine at every stage the extent to which the objectives set out in the plan are being realized. This presupposes that the plan sets out in sufficient detail the long- and short-term objectives. In fact an outline of the procedures for evaluation must be included in the plan.

All the objectives and intermediate targets of an immunization programme must be included in the evaluation. The ultimate objectives, such as the epidemiological impact and the political, social, and economic benefits, that are expected to result from the programme must be stated in ways that as far as possible permit their measurement to be built into the programme itself. Otherwise the necessary political and social support might not be provided or might fade away while the programme is being implemented.

A process of evaluation that merely reports on technical, administrative, and epidemiological achievements will not maintain the continuing interest of the political and social leaders, whose support is necessary. Therefore some indices of a programme's social, political, and economic achievements should be agreed with them beforehand and should be measured and published periodically throughout the programme's operations.

Administrative evaluation is part of the continuous process of management. The internal efficiency of the programme and the coverage achieved among the programme's target groups must be assessed frequently enough and in sufficient detail to enable corrective action to be applied promptly and effectively.

Evaluation itself can be considered from two points of view - the administrative aspect, which governs the efficiency with which the programme is carried out, and the epidemiological aspect, which determines the impact of the programme on the morbidity status of the population.

Administrative evaluation. This type of evaluation is intended to determine whether the operations were kept up to schedule and whether the delivery of vaccines, the availability of cold-chains, the training of vaccinators, the arrival of transport, etc., were in the right time sequence so that delays were avoided. Evaluation of this type is best carried out by using suitable managerial techniques. It also ensures that the arrangements for quality control of vaccines at the point of delivery are adequate and that quality tests are being carried out at the intervals specified in the plan. It similarly determines whether the assessment of the programme (e.g., take-rates) is being carried out at appropriate intervals and according to the sampling techniques set out in the technical guide for assessment.

A number of logistic options, or alternative strategies, may have arisen in the course of the programme - e.g., vaccination by household visits, vaccination at an assembly point in a village or a group of villages, vaccination at fixed centres such as schools. Evaluation should analyse whether the strategies selected were the best from the point of view both of feasibility and of economy.

Epidemiological evaluation. The evaluation of the effectiveness of the programme, as shown for example by the reduction in morbidity, depends on the reliability of the sources of information. While notification systems should constantly be improved, ad hoc sample surveys are likely to be more useful both for establishing baseline data and for periodical assessment against such baseline data.

For both types of evaluation a system should be established for the continuous flow of information. The criteria for establishing such a system would be:

- no more information should be collected than is necessary for evaluation;
- the design of the records and their number should be such that the effort to complete them in the field is minimal.
Such a system should provide information not only on the outputs, whether operational or epidemiological, but also on the resources consumed, so that cost/effectiveness analyses can be made.

The country reports indicated that, with the exception of smallpox and BCG programmes, independent assessment of communities for vaccination coverage by random sampling is not being undertaken. The advantages of such assessment are well worth the cost. Apart from giving the country's overall immunization status, it gives details of coverage by age and area. This in turn tells the supervisors whether the target groups are being immunized and which regions or areas need more attention. The assessment teams can be used for obtaining other medical information. Only two persons are needed to form an assessment team and they can usually be found from existing staff.

Feedback

The purpose of ongoing evaluation is to provide information that will assist operations. It does this in two ways. Firstly, it provides data that enable the static units and field teams to assess their own work and the effect of the constraints under which they work and to allow their supervisors to assess progress towards the achievement of the preset targets. Secondly, the fact that the data have been communicated to them shows supervisors and teams that the central management is interested in their results. This encourages morale and the feeling of being members of a national team. Feedback should be instituted as a routine procedure to achieve these objectives.