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SEE CORR. I

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ORGANIZATION OF A SMALLPOX ERADICATION CAMPAIGN

Prepared by the Secretariat

The eradication of smallpox is attainable because the only reservoir is man, infection is manifest, carriers do not exist and successful vaccination provides effective immunity.

The Expert Committee on Smallpox defined smallpox eradication as the elimination of the disease on a world-wide basis. It also stated that this term may also be applied to the elimination of the disease from continents or large regional areas, but it is more difficult to apply to individual countries especially if they are contiguous with countries where the disease is endemic.

A country can be considered free from the disease if no indigenous cases have occurred for three successive years and if such local outbreaks as may occur from imported cases have been rapidly controlled.

The aim of a national eradication campaign should be to vaccinate 100 per cent. of the population of the country. Experience has shown that a target of vaccinating 80 per cent. of each segment of the population has been found in practice to be unsatisfactory in certain cases. It has been found that though the number of vaccinations made in some campaigns was 80 per cent. or more of the estimated population, there were often groups, e.g. infants under one year of age and men working in the fields during the day, where only about 30 per cent. were vaccinated. In these areas the numbers of persons remaining unprotected were sufficient to keep infection alive.

Liquid vaccine is not suitable for mass campaigns in hot climates. Minor upsets in the rigid requirements for the storage and transport of the vaccine is liable to reduce its potency. A potency reduction not sufficient to lead to a fall in the proportion of successful primary vaccinations is often sufficient to cause a marked fall in the proportion of successful revaccinations. When this happens the high take rate in primary vaccinations can be very misleading and

may vitiate a campaign. Freeze-dried vaccine, which is more stable, is a much more satisfactory product. In eradication programmes, therefore, high priority must be given to providing adequate quantities of potent freeze-dried vaccine and to ensuring that they are handled with the precautions necessary to maintain the optimum potency up to the moment when the vaccine is applied. It should not be forgotten that after reconstitution freeze-dried vaccine must be carefully handled because it is then as labile as liquid vaccine. Every batch of vaccine in an eradication campaign will have to conform to the minimum requirements of potency laid down by WHO or the national government. In addition every batch of vaccine should be tested in the field before it is issued for general use. One of the best methods for testing the potency of a new batch of smallpox vaccine is to use it for the vaccination of small groups of 100 or 200 persons before it is issued for general use. The results of this small trial will indicate if the batch of vaccine is satisfactory. Care must be taken, however, to include revaccinations as well as primary vaccinations in these trials, and the revaccination results should, if possible, be compared with those obtained with a vaccine batch of known high potency, or at least with the records of success rates with previous batches so that any change can be quickly investigated.

Though WHO gives assistance and advice, eradication campaigns are national programmes and should be under the direction of an experienced senior medical officer designated by the government. A centralized and efficient administrative organization which should be responsible for all aspects of the campaign should be established. The necessary legislation should be prepared and implemented.

A smallpox eradication campaign should be planned in three phases: preparatory, attack, and control or maintenance. It may be integrated into the public health services or may be independent, according to the stage of development of the health services of the country.

It may be advisable for countries which are about to establish campaigns first of all to organize limited pilot projects to uncover possible difficulties in relation to the potency and supply of vaccine; to study administrative or other

problems which may arise in practice and to devise means of overcoming them; and to train supervisors, vaccinators and others and to acquaint them with the field conditions they will encounter in a mass campaign.

In the preparatory phase of a campaign, it is necessary to collect as much information as possible on the epidemiology of the disease, not only in the country but also in neighbouring countries; on availability of trained personnel; and on facilities for transportation and refrigeration.

Financial and administrative arrangements should be settled from the beginning and if the campaign is planned to last for some years assurance should be obtained that the budget will be sufficient for the whole programme.

In all campaigns concurrent evaluation is as essential as the final assessment of the programme. The evaluation should be carried out by independent teams to discover defects in time to remedy them while the programme is still active. The worth of the concurrent evaluation instituted recently in India has been clearly shown and has significantly improved the success of the programme.

WHO commitments in addition to advice in planning, etc., are normally the provision of personnel (short-term consultants or a medical officer for a longer period), equipment and supplies, principally freeze-dried vaccine. All other items are usually the responsibility of the government.

When campaigns are being prepared a plan of operations (see Annex I) should be made which takes all the necessary points into consideration, which outlines the principles and methodology to be followed, including a detailed plan for the day-to-day execution of the programme.

When WHO assistance is required, a formal agreement between the government and WHO has to be prepared. An outline of the form of this agreement is given in Annex II. This can be modified according to local problems or special conditions.

The terms given below are used in accordance with the definitions by the Expert Committee on Smallpox:

Vaccination

The cutaneous inoculation of smallpox vaccine into a person not previously successfully vaccinated. (Synonym: primary vaccination)

Revaccination

The cutaneous inoculation of smallpox vaccine into a person who has a vaccination scar or convincing documentary evidence of previous successful vaccination or revaccination.

Repeat vaccination or repeat revaccination

Re-inoculation of smallpox vaccine into a person in whom vaccination or revaccination did not produce a major reaction.

Successful vaccination or revaccination

Occurrence of a major reaction following vaccination or revaccination.
(Synonym: take)

Major reaction

1. Presence of a typical Jennerian vesicle on examination one week after primary vaccination.
2. Presence of a vesicular or pustular lesion or an area of definite palpable induration or congestion surrounding a central lesion, which may be a scab or ulcer, on examination six to eight days after revaccination.

Equivocal reaction

Any response to vaccination or revaccination other than a major reaction.

(A major reaction indicates virus multiplication with consequent development of immunity. An equivocal reaction may be an allergic response elicited by inactive vaccine or poor technique or may be the consequence of immunity adequate to prevent virus multiplication. Since these cannot be differentiated vaccination or revaccination must be repeated.)

PLAN OF OPERATIONS

The following should be taken into consideration in the preparation of national smallpox eradication campaigns to be carried out with the co-operation of WHO.

1. The objective of the campaign.
2. Administration and allocation of responsibilities.
3. The preparatory phase.
4. The attack phase.
5. The maintenance phase.
6. Evaluation.
7. Commitments of the government and WHO.
8. Agreement between WHO and the country concerned.

1. Objective of the campaign

The objective of a national campaign is to eradicate smallpox from the country by the vaccination of the entire population. The attack phase should last as short a time as possible and be completed within three years. This has to be followed by a maintenance phase of indefinite duration.

2. Administration and allocation of responsibilities

Campaigns are to be conducted under the responsibility of the government with the technical advice and material assistance of WHO and other international organizations if necessary. Administrative and financial matters and the effective technical direction of the campaign are the responsibility of the national government. A full-time senior medical officer should be appointed for the direction of the campaign. He should be directly responsible to the central health administration and should be well experienced in smallpox control as well as in administration.

Annex I

He should seek help and advice from the health authorities or advisory groups and WHO officers but he himself should take final decisions. He should be in direct contact with the Minister of Health or with the Chief of Public Health Services.

An efficient administrative organization should be established and should have adequate funds. It should be responsible for the supply of vaccine and other equipment, transport, statistics and maps, propaganda, training and staff welfare. The smallpox eradication service should preferably be incorporated into the existing structure of the public health service and its activities should be coordinated with those of other departments. In some countries where the health services are being developed the eradication campaign will have to be set up as an independent campaign. Whether integrated or independent it should be directed centrally by the responsible officer and at provincial or district levels an officer, preferably a medical officer, should be in charge of the campaign.

If legislation for compulsory vaccination or revaccination, notification of cases, isolation of cases and surveillance of contacts, quarantine measures or health education is found to be necessary, it should be prepared early in the planning stage and measures taken for its implementation.

The WHO Regional Office should represent WHO on the functions, activities, rights and duties of WHO as laid down in the plan of operations. Some of these responsibilities may be delegated to the local WHO representative or WHO officers appointed to the campaign.

3. The preparatory phase

In this phase a careful assessment of the smallpox epidemiology in the country should be made.

All available information should be collected, e.g. the number of cases and deaths which have occurred in the previous 10 years; incidence and case mortality rates; geographical and age distribution of cases; previous vaccination campaigns and their results; social economic conditions and the level of health education of the population; the existing arrangements for smallpox vaccination, and so on.

Annex I

The actual and potential availability of staff must be considered and personnel recruited. In some countries it may be necessary to employ female as well as male vaccinators because of religious customs. The welfare of the staff should be taken into consideration; salary scales must be adequate and steps taken to alleviate as far as possible the hardships and irregular hours necessary for effective field work. Thought has to be given at this stage to possible employment of the staff, e.g. in other public health activities, when eradication has been achieved.

The training of personnel is important and should be done before the campaign starts and maintained during the campaign. Vaccinators may be trained in special courses but they should also receive practical experience in the field under medical supervision before being sent to their allotted districts. For inspectors the training should be longer and include theoretical and practical instruction in the epidemiology and diagnosis of smallpox and also control measures. They also need to know the administrative aspects of the campaign. They should be selected preferably from the most qualified and active vaccinators.

Facilities for transportation and refrigeration have to be ascertained. In many countries the epidemiological information routinely collected on smallpox will give a clear picture of the prevalence of the disease and thus facilitate the planning of the campaign by delineating areas of high and low incidence. If, however, this information is not routinely available an assessment of the situation should be made by means of small well-planned surveys in different parts of the country. A knowledge of the smallpox situation in neighbouring countries is also important in the planning of the campaign in border zones.

Arrangements should be made for an adequate supply of freeze-dried vaccine and for its storage and distribution. A programme of health education should be prepared.

Annex I

House to house visiting and vaccination with freeze-dried vaccine applied by the multiple pressure or the single short scratch method are recommended. House to house visiting demands great effort and intensive work but the coverage is much better when the vaccine is taken to the people instead of the people having to come for the vaccine.

Because vaccines of high potency are now available the use of instruments which cause much trauma and severe reactions, such as the rotary lancet, should be given up in favour of the multiple pressure or the single short scratch (6 mm) as soon as this can be conveniently arranged. The choice between multiple pressure and single scratch will depend on local preference.

At this stage pilot studies should be organized to provide information about practical difficulties and to devise means of overcoming them.

4. The attack phase

This is the main part of the campaign but its success depends largely on the measures taken during the preparatory phase. The aim is to vaccinate the entire population as rapidly as possible. The length of time taken will depend on the size of population; the available personnel; local geographical and climatic conditions; transport facilities; and the distribution of the population in urban and rural communities.

It is important that the attack phase is completed in the shortest possible time and in any event it should not last more than three years.

It is advisable to concentrate effort in the beginning on densely populated areas where the disease persists and from which spread to other areas is likely to occur. When the densely populated areas are solidly protected, effort should be diverted to the contiguous areas. This is the case particularly when vaccine supplies are limited and have to be used to the best possible advantage. If possible each vaccination and revaccination should be examined after six to eight days and those persons who do not show a major reaction should be vaccinated again immediately.

Annex I

If it is not possible to see a second time all the persons vaccinated, at least 20 per cent. should be examined to estimate the success of the campaign. The target must be to vaccinate 100 per cent. of the population. Special attention should be paid to the age-groups in which the disease most frequently occurs, as established by analysis of age-specific attack rates. Workers in the fields may have to be dealt with specially in order to ensure adequate coverage.

The vaccinators should be organized in teams headed by an inspector whose task is to supervise their work constantly and strictly. Each team should consist of six to ten vaccinators. A medical officer should be responsible for a group of six to eight teams. Depending on local conditions, 50-70 persons may be vaccinated by each vaccinator in a working day in rural areas; this number may be increased in large urban areas.

Adequate transport is essential in an eradication campaign. The requirements will depend on the nature of the terrain and communications. Cars, jeeps, bicycles, boats may all be necessary.

In countries with a large population it may be necessary to repeat this phase a second time or to carry out well-planned and carefully executed mopping-up operations to ensure the coverage of newly arrived members of the population as well as of pockets of population not vaccinated during the first sweep.

5. The maintenance phase

As soon as one of the high density areas has been successfully vaccinated as planned, the maintenance phase for that area may begin. Depending on the circumstances, it may be independent, ~~or~~ under the control of the normal public health service, or combined with other special control programmes such as malaria eradication or yaws control. The vaccination of newborn children, immigrants and floating populations and routine revaccination of the whole population will be the principal activities of those in charge of this phase. An epidemiological investigation should be made of each outbreak or sporadic case which occurs. The

Annex I

spread of the disease should be controlled by vaccination round the foci of infection and other control measures. Every suspicious case should be carefully examined and laboratory diagnosis should be made every time there is any doubt in the diagnosis. It is emphasized that at this stage laboratory diagnostic services will become an essential part of the programme. If in the early stages of the maintenance phase the incidence of disease remains high, a reassessment will be required and the attack phase may have to be repeated.

6. Evaluation

The success of the campaign will be indicated by the disappearance of the disease. The percentage of each section of the population vaccinated in each area will give an indication of the adequacy of the coverage. Teams must, however, check the efficacy of their work and the potency of the vaccine in the field (which may differ from the potency at the time of production because of deterioration during storage or transportation). Checks should be made by observing and recording the vaccination reactions in representative samples of persons primarily vaccinated and revaccinated by each vaccinator.

Information on the population in the area in which the team is working, the percentage vaccinated by age-groups (and if necessary by other groupings e.g. occupation), the numbers of vaccinations and of revaccinations which are read and the numbers successful should be collected weekly by the team and reviewed by a responsible medical officer. This should be transmitted weekly to the campaign headquarters for consolidation, analysis and periodical distribution to those concerned in the campaign including the vaccination teams.

At the same time, an independent evaluation should be carried out concurrently by a separate team responsible directly to campaign headquarters so that the efficacy of the work will be independently checked.

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Annex I

During the maintenance phase evaluation by an independent team has to be continued and should include assessment of the level of immunity by challenge revaccination of random population samples, checks on the proportions of new entrants into the community who are vaccinated successfully, and on the methods of control of the spread of infection from imported foci.

7. Commitments of the government and WHO

WHO normally provides, subject to its budgetary limitations, personnel, equipment and supplies and technical advice during all the phases of the campaign.

A short-term consultant can be provided for some months by WHO before the campaign begins or when it is inaugurated to advise on planning or he may be recruited to help in some specific problem, such as local preparation of freeze-dried vaccine or the development of epidemiological studies on smallpox.

In some cases WHO may provide a medical officer for a longer period (one or more years) to assist the national campaign director throughout the whole of the campaign.

The help which countries usually ask from WHO is the supply of freeze-dried vaccine. The amount of vaccine available depends on the donations received by WHO from different countries. So far it has always been possible to supply vaccine to approved eradication campaigns.

In addition to vaccine other supplies, especially refrigeration and freeze-drying equipment may be provided.

The government is expected to provide all the personnel - medical officers, inspectors, vaccinators, car-drivers - and supplies and equipment not provided by WHO. The government is also expected to arrange for the transportation and storage of the vaccine and to provide any other facilities necessary for the successful execution of the campaign including assistance to WHO personnel.

8. Agreement between WHO and the country concerned

After a plan of operations has been agreed upon by both parties it has to be signed by the government and WHO. The main points to be included in the agreement are listed in Annex II.

Annex I

Techniques of Vaccination

(As recommended by the Expert Committee on Smallpox)

In the multiple pressure technique a small drop of vaccine is placed on the skin and a series of pressures are made within the smallest skin area (not over 1/8" or 3 mm in diameter) with the side of a sharp needle held tangentially to the skin. The pressures are made with the side of the needle, not the point. For revaccination, 30 strokes are completed in a few seconds, using an up and down motion perpendicular to the skin. For primary vaccinations, not more than 10 strokes are necessary. Immediately after the pressures are made, remaining vaccine is wiped off the skin. No signs of bleeding should occur. No dressing should be used.

The scratch technique consists of a single linear scratch not more than 1/4" or 6 mm in length performed through the lymph with a needle or another suitable instrument. The scratch should not be too superficial. The needle should not draw blood but the scratch should be deep enough so that slight oozing occurs after a few seconds. The vaccine is rubbed into the scratch with the side of the needle, and no dressing is necessary.

SUGGESTED FORM OF AGREEMENT BETWEEN THE GOVERNMENT AND WHO
FOR THE SMALLPOX ERADICATION PROJECT

The Government of . . . and WHO being desirous of obtaining mutual agreement concerning a smallpox eradication project in . . . , particularly with reference to the purposes of the project and the responsibilities which shall be assumed by each of the parties, and declaring that the responsibilities will be fulfilled in a spirit of friendly co-operation,

HAVE AGREED as follows:

PART I. Basis of relationships

This Basic Agreement concluded between the Government and WHO on (date) provides the basis for relationships between the Government and WHO in this project and the following articles are to be interpreted in the light of the Basic Agreement.

PART II. Objectives

The Government with assistance from WHO aims to eradicate smallpox from the country by the vaccination of the entire population within as short a time as possible and if at all possible in less than three years (the attack phase). The Government will, thereafter, continue a maintenance phase for as long as may be necessary.

PART III. Area

(In this Part it should be stated that the area of operation will cover the whole country but, if necessary, the country may be divided into different regions with a timetable of vaccinations for each region to fit the estimated duration of the attack phase for the whole country. Details of the regions and of the timetable for each should be set down.)

PART IV. Methods

The parties agree to implement and develop activities according to the technical methods and procedures recommended by WHO. These methods are:

Annex II

1. House to house visits to carry out the vaccinations.
2. Use of freeze-dried vaccine.
3. Use of the multiple pressure or short scratch methods of inoculation or other methods shown to be practical and efficient and causing a minimum of trauma.

PART V. Plan of action

The plan of action for this project shall be divided into three phases - preparatory, attack and maintenance phases, as follows:

Preparatory phase

(The following items have to be considered for insertion in this section:

1. Background information. All the information about smallpox epidemiology, availability of staff and facilities for transport and refrigeration.
2. Recruitment of personnel (medical officers, vaccinators and supervisors) and their training, including, if convenient, studies on the methods of vaccination; organization of vaccination teams.
3. Provision of freeze-dried vaccine of good potency and equipment for its storage and distribution.
4. Provision of transport facilities.
5. Preparation of a programme of health education.
6. Preparation of special legislation and quarantine measures (if needed).
7. Preparation of a detailed plan of operations for the attack and maintenance phases according to a target time schedule and the background information available (see Annex I).

If a pilot project is to be carried out it should be carried out as a part of the preparatory phase and details given here.)

Annex II

Attack phase

(The following items should be considered for insertion in this section:

1. Composition of the vaccination teams and groups.
2. Targets to be attained in the different regions or areas according to the timetable described in Part III and detailed plan of this timetable.
3. Proportion of persons primarily vaccinated or revaccinated to be examined to estimate the result of the campaign.
4. Brief description of the system of distribution of vaccine.
5. Recording and reporting system.
6. Plans for mopping-up operations.
7. Consultation between the Government and WHO.)

Maintenance phase

(The main point to be borne in mind in the description of this phase is that it will last for some years after the attack phase has finished.

The following items should be considered for insertion in this section:

1. When this phase will begin and end.
2. Staff requirements and organization of meetings for general discussion among the persons responsible for the campaign.
3. Vaccination of newborn children, immigrants and floating population.
4. Continued revaccination of the whole population at intervals.
5. Arrangements for the epidemiological investigation and rapid control of any outbreak or sporadic case of smallpox which occurs.
6. Diagnostic laboratory services.

Annex II

7. Where necessary, measures for the prevention of importation of cases from contiguous countries.
8. Independent evaluation.)

Evaluation

(In this section it should be made clear that the Government and WHO jointly assume responsibility for evaluation of this project throughout its operation and the Government must continue evaluation after the period of international co-operation has ended. On the basis of this evaluation of the project, the plan of action should be reviewed and modified by mutual consent whenever such action is considered necessary.

The following items should be considered for inclusion in this section:

1. Continuous evaluation of the potency of the vaccine in the field.
2. Insistence that vaccination teams should be specifically charged with the evaluation of their own work.
3. The creation of an independent team (or teams) for concurrent independent assessment of the success of the campaign.)

PART VI. Administration and assignment of responsibilities

(The following items should be considered in the preparation of this section:

1. The project will be the responsibility of the Government with technical advice and material assistance from WHO. It is usually under the direction of an experienced senior medical officer designated by the Government.
2. The smallpox eradication campaign may be set up independent of existing health services or, in suitable circumstances, may be incorporated into the existing health services. Its activities must be very carefully co-ordinated with those of other departments even when it is administered as an independent campaign.
3. An efficient administrative and financial organization is required to be responsible for the supply of vaccine and other equipment; transport; statistics and maps; propaganda; training and staff welfare.

Annex II

4. At local, provincial or district level an officer, preferably a medical officer, should be in charge of the campaign under central direction.
5. WHO should be represented by its Regional Office (or, by delegation, by the local WHO representative) in carrying out all functions, activities, rights and duties of WHO, as provided for in the plan of operations.)

PART VII. WHO Commitments

(In this section WHO may agree to provide the following, subject to its budgetary limitations:

1. Personnel - a short-term consultant for a few months before or at the beginning of the campaign to advise on planning or some specific problem; or a medical officer for a longer period (one or more years) to assist the national campaign director.
2. Supplies and equipment, principally freeze-dried vaccine; sometimes refrigeration and freeze-dried equipment.
3. Printed material as may be needed.)

PART VIII. Government commitments

(The Government have to provide all personnel, materials, supplies, equipment and local expenses necessary for the project, in addition to those supplied by WHO (Part VII). The following items should be considered in particular:

1. Personnel: medical officers, supervisors, vaccinators and drivers.
2. Supplies and equipment not provided in Part VII.
3. Transportation and storage of the vaccine.
4. Transport for personnel.
5. Publications and reports agreed between the Government and WHO.
6. Facilities for WHO personnel as decided upon.)

Annex II

PART IX. Final provisions

(These should be on the following lines:

1. This Plan of Operation will come into effect upon signature by the parties and will remain in effect until the international assistance provided by WHO is withdrawn, including such period of time as may be necessary for winding-up arrangements.
2. This Plan of Operation may be modified by mutual consent of the parties.
3. Upon termination of this project, supplies and equipment furnished under Parts VII and VIII of this Plan of Operation to which WHO has retained title shall be disposed of in accordance with the appropriate rules and policies and as mutually agreed between the Government and WHO.)