



THE CERTIFICATION OF SMALLPOX ERADICATION
IN COUNTRIES WITHOUT RECENT REPORTED ENDEMIC TRANSMISSION

by

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1. Introduction

The world's last known case of smallpox occurred in Somalia on 26 October 1977. This case of Variola minor came two years after the world's final case of Variola major was detected on Bhola Island in Bangladesh. The achievement of these two milestones places before the international health community and the World Health Organization the pleasant but laborious tasks of documenting the global eradication of smallpox and establishing the safety of worldwide cessation of vaccination activities.

This process of "closing the books" on smallpox has become known as "certification of eradication", a careful and systematic process of deliberations by specially constituted International Commissions of experts convened by WHO. International Commissions have been constituted eight times thus far to certify the eradication of smallpox from specific geographic areas. Today, however, with the worldwide end of smallpox activities clearly in sight, the remaining certification procedures have been elevated in importance. The task which remains is more than the certification that one disease has been eradicated from a single country or group of countries. The steps remaining are now more clearly linked to a global scientific affirmation that smallpox has been eradicated from mankind in toto.

With such an unprecedented end in view, WHO convened a group of distinguished experts from 15 countries to join smallpox epidemiologists for a "Consultation on Worldwide Certification of Smallpox Eradication" in Geneva in October 1977. Recognizing the historical importance of their task, the Consultation declared that the imminent worldwide eradication of smallpox should be promptly certified by an extraordinary Global Commission¹ whose function should be to certify eradication in individual countries not previously certified, and also to take responsibility for setting final global certification criteria.

Those countries as yet uncertified were grouped into four categories according to procedures recommended for their certification: (a) countries requiring a formal international certification process; (b) countries requiring visits by a Commission member; (c) countries where a detailed national report would be satisfactory; and (d) those countries where formal statements by the country would be sufficient.

An important criterion for deciding upon the rigour needed for certification is how recently a country was endemic. International Commissions were constituted previously mainly to visit countries which were very recently endemic. With global eradication imminent, however, equally rigorous certification procedures were considered advisable for some countries that had been recently non-endemic. Some countries now requiring certification have been free of reported smallpox for five or more years.

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Such was the situation in the Socialist Republic of the Union of Burma, a country which had been non-endemic for a decade, when an International Commission visited that country in November 1977. A formal certification process was required because of Burma's long border with Bangladesh, the last country in the world with Variola major. The experience gained in the formal certification in Burma may be useful for the global certification efforts which remain. The purpose of this paper is to offer suggestions for planning and implementing certification measures in the remaining uncertified countries.

2. Definition and criteria for eradication

The definition and criteria of smallpox eradication was established by the 1971 WHO Expert Committee which stated inter alia:

"Recent experience indicates that, in all countries with a reasonably effective surveillance programme, residual foci can be detected within 12 months of apparent interruption. Thus, in countries with active surveillance programmes, at least 2 years should have elapsed after the last known case . . . before it is considered probable that smallpox transmission has been interrupted."²

On the basis of this recommendation, eight International Commissions have been constituted by WHO to certify the achievement of smallpox eradication in the Americas (1973), Indonesia (1974), West Africa (1976), Pakistan and Afghanistan (1976), India/Nepal/Bhutan (1977), Central Africa (1977), Burma (1977) and Bangladesh (1977).

Previous commissions have usually based certification on two criteria. First, that there has been no evidence of smallpox transmission in the last two years, and second, that there has been an active surveillance system "sufficiently sensitive to have detected smallpox should it have occurred."³ It is this second criterion which may pose problems for certifying eradication in some countries because surveillance became the cornerstone of smallpox eradication philosophy only in the last decade.⁴

In many countries which have had no reported smallpox in over 10 years, eradication was accomplished through systematic vaccination. In such countries, some of which still remain to be certified, documentation has similarly focused on vaccination coverage, vaccination scar surveys, and general health service effectiveness rather than on a particular programme of smallpox surveillance.

Indeed in some countries all specific smallpox activities ceased years ago after national authorities became convinced that smallpox was eradicated; further attention to smallpox surveillance during the past two years may have been minimal in keeping with current national health priorities.

The Global Consultation recognized the wide differences in the history and methodology of national eradication programmes when it grouped countries according to requirements for certification (Fig. 1).

Nineteen countries^a were considered to require formal certification by International Commissions similar to those constituted in the past. Five other countries,^b recently non-endemic, were identified as requiring visits by members of the Global Commission, consultants and/or WHO staff to verify and document the eradication of smallpox. The certification criteria in these five countries may be expected to be similar to the criteria adopted by the Commission to Burma.

^a Malawi, Mozambique, Tanzania, Zambia, Sudan, Uganda, Angola, Botswana, Lesotho, Swaziland, Namibia, South Africa, South Rhodesia, Democratic Yemen, Djibouti, Ethiopia, Kenya, Somalia, and Yemen.

^b China, Iran, Iraq, Syria, and Thailand.

3. Lessons from Burma

The Commission which visited Burma found a strong health system, "unique regarding smallpox eradication".⁵ The Burmese programme, which had emphasized systematic mass vaccination supplemented by outbreak investigation, had brought an end to smallpox eight years before. The last reported case occurred in 1969. One year later, in 1970, a joint WHO/Government of Burma assessment team visited the country and declared it smallpox free. Since that visit, however, large outbreaks had occurred in neighbouring Bangladesh. Therefore when in November 1977, two years after the last case in Bangladesh, a Commission was convened to visit Bangladesh, "the time was uniquely appropriate to establish a comparable International Commission for Burma".⁵

Because of the history of smallpox eradication in Burma, the Commission members agreed that different criteria of eradication were appropriate for Burma and Bangladesh. For example, a special smallpox search programme as had been established in India and Bangladesh during the two years prior to their certification was not necessarily the sine qua non for certifying eradication in Burma. Instead, the Commission based its deliberations on documents,^a field visits, and on an independent pock mark survey conducted by Commission members themselves.

The Commission was not surprised to find that most of the country's documents centred around vaccination coverage, which the Commission verified as extremely high even a decade after the last major outbreaks of smallpox. Burma had been one of the first countries to embark on an eradication programme following the 1958 World Health Assembly decision, becoming virtually free of smallpox before the global strategy turned to surveillance and containment.

Since the disease was absent from the country, no vertical programme was felt needed although (along with cholera, plague, dengue haemorrhagic fever, and Japanese encephalitis) smallpox continued to be classified as a "principal epidemic disease under national surveillance".⁶ The effectiveness of this system was shown by the prompt reporting of the last importations of smallpox which recurred in 1968 and 1969. Both of these importations were reported within one week.

Without a vertical programme of active smallpox search to evaluate, the Commission turned to other indices of surveillance effectiveness. The geographical distribution pattern of other diseases reported in 1974-1976 for example, such as plague, cholera and dengue haemorrhagic fever cases supported the view that disease surveillance had been countrywide. During inspection visits to remote areas the Commission members found "an awareness of the necessity to report smallpox cases urgently".⁵

Further supporting data was found in a large-scale facial pock mark survey. Although vaccination scar surveys are a regular part of the immunization programme assessment, shortly before the International Commission's visit the Government added a countrywide facial pock mark survey. Nearly two million children under the age of 14 were examined by health staff. Not

^a The major documents examined by the Commission included:

(a) Smallpox Eradication in Burma, a comprehensive 60-page document⁶ prepared by the Government of Burma to acquaint the Commission with the country profile and administrative structure, the history of the smallpox programme, and the epidemiology of smallpox in Burma, as well as to provide documentation of vaccination coverage, surveillance of other communicable diseases, laboratory diagnosis, outbreak investigation, and the national disease reporting systems.

(b) Results of the Government Pockmark Survey done just prior to the Commission's visit. 1 924 095 children 5-14 years old were examined by government health staff; none were found to have facial smallpox scars.

(c) The results of laboratory examinations. Fifty-one specimens, taken between 1968 and 1975 from suspected cases of rash with fever, were all negative for Variola except for three specimens taken from the last 1968 outbreak in Arakan State.

a single child was found with evidence of pock marks, providing additional evidence that smallpox had not occurred in Burma in many years.

The Commission decided to supplement this national pock mark survey with its own smaller independent survey conducted not only on children, but on adults as well to provide a rough estimate of the historical pattern of smallpox in the country. International Commission members examined approximately 58 000 persons (of whom 5000 were pre-school children) during visits to 10 of Burma's 14 states and divisions.^a Whenever pock marks were detected, a history of disease onset was elicited.

Pock marks were identified in a total of 399 persons. The data of onset as determined by interview indicated a high percentage of cases dating from the late 1950s, which correlated well with Government reports (Fig. 2). More importantly, of course, the Commission found no evidence of smallpox dating after the last reported case.

Although the Commission's rapid pock mark survey would clearly be inadequate (in any statistical sense), for confirming the absence of the disease, still the correspondence between smallpox trends as calculated from pock mark prevalence and the official reported smallpox figures helped the Commission affirm the strength of the Burmese reporting system.

4. Efficacy of pock mark surveys

Foster⁷ has reviewed the history of smallpox facial scar surveys, citing Keja⁸ in Indonesia as the first to use such surveys to assess smallpox eradication programmes. Additional surveys have been done in many states of India,³ Nepal⁹ and Bangladesh.¹⁰

Pock mark surveys have two important roles in the certification of eradication. First, by establishing the absence of detectable pock marks in children born after the last reported case of smallpox, surveys provide some evidence against significant recent transmission. Secondly, a correlation between the pattern of smallpox calculated from the survey results and the smallpox history as officially reported over the years provides an indication of how well the health services were able to find smallpox when it did exist.

Fig. 3 displays the results of several recent pock mark surveys in Asia. Sample sizes, survey methodology, as well as the prevalence of pock marks detected vary considerably, in part because each survey was designed to serve a different objective. Some of these surveys were done by WHO epidemiologists visiting a small area (Nos. 1, 2, 3, 8, 11 and 12 in Fig. 3) while others were done by government health staff for the declaration of eradication (Nos. 3, 5, 6 and 9).

The most extensive survey was done in Bangladesh in 1976 on one per cent. of all houses in the country.¹⁰ This survey was done in order to assess yearly smallpox surveillance efficacy by correcting observed rates of pock marking for mortality and pock mark fade to make a retrospective estimate of smallpox incidence. Because of its rigorous statistical design and careful implementation it may be considered the reference standard for pock mark surveys.

^a Foreign members of the Commission were not able to visit all areas of Burma. The problem of inaccessible areas was carefully addressed by the Commission, which was satisfied that such areas were being visited by government health staff. As an additional measure, simultaneously with the Commission's pock mark survey in areas accessible to foreigners, Burmese national Commission members conducted pock mark surveys in the four states and divisions which the foreign members of the International Commission could not visit. Results of these studies supported the feeling that there had been no transmission in these four states in more than 12 years. The Commission noted that "by and large such areas were sparsely populated and any lingering focus of smallpox would have burnt itself out during the course of years . . . (or) . . . with continuous to and fro movement of the population it would have spread to big cities and towns and thus brought to the attention of health authorities."⁵

Other less rigorous studies may still be useful for certain purposes. Thus a survey such as the Ladakh study³ - which found a high overall prevalence of pock marks (2.7%) but no pock marks after 1955 - was helpful to the India Commission seeking data about that remote and inaccessible area. Likewise, the active search for pock marks conducted by health staff in the Andaman and Nicobar Islands³ was also persuasive even though it elicited one of the lowest pock mark prevalences (0.1%), because nearly 15% of the population was examined. It is apparent that, for the purposes of certification of eradication, several different types of pock mark surveys can make persuasive contributions.

Another pock mark survey was carried out among nearly six and a half million persons in 15 countries of West Africa.¹³ This survey detected 4168 people with pock marks:

	Total	Pre-school age	Primary school age	Above primary school age
Population surveyed	6 497 250	1 631 918	3 696 932	1 168 400
Persons with pock marks	8 390	0	4 222	4 168
Pock mark prevalence (per 10 000 surveyed)	12.9	0	11.4	35.7

Age-specific pock mark prevalence rates drop markedly, at primary school age and below, indicating that smallpox had been historically decreasing in the decade preceding the survey. If this were not the case, one would have expected about 2000 pre-school age children to be found with pock marks.

Similar findings were also reported from a pock mark survey in nine countries of Central Africa.¹⁴ As in the case of the Commissions which reviewed data in Burma, parts of India, and West Africa, the Central African pock mark survey results were also used to support that Commission's conclusion that smallpox transmission had been interrupted more than five years earlier. Although the International Commission does not usually have the time or resources to do a full national sample, the results of some Commission's studies are reasonably close to the results obtained by more carefully designed survey methodologies.

An interesting example of this can be seen by looking at two Bangladesh pock mark surveys (Nos. 9 and 10 in Fig. 3).^{10,12} The International Commission which assessed the smallpox eradication programme in Bangladesh carried out its own independent pock mark survey. Subjects were selected by Commission members as they travelled, which often meant that faces were simply scanned for evidence of facial scars. Since the Commission was not interested in a retrospective estimate of reporting efficacy, but only in any smallpox which might have occurred since 1975, the selection bias was skewed in favour of children less than 2 years old. Although the numerator (cases with pock marks) was carefully recorded, the denominator (the number of people looked at) was only roughly estimated. Fig. 4 displays the results of the Commission's findings and compares them to the reported^a annual smallpox incidence in Bangladesh.

Table 1 below compares pock mark prevalence (per 10 000) from the rapid survey done by the International Commission with the more elaborate Bangladesh/WHO countrywide pock mark survey referred to earlier.¹⁰

^a The interpretation of this correspondence is complicated by the fact that the completeness of reporting in Bangladesh increased dramatically towards the end of the eradication effort. Hughes et al.¹⁰ estimates that the national surveillance efficacy in Bangladesh increased from 11.8% in 1972 to 83% in 1975.

TABLE 1. COMPARISON BETWEEN TWO POCK MARK SURVEYS SHOWING RATES OF PREVALENCE OF POCK MARKS (PER 10 000 PEOPLE SURVEYED) BY YEAR OF SMALLPOX ONSET

	Survey No. 9 (a one per cent. countrywide sample)	Survey No. 10 (spot assessment by the International Commission)
Pre-1971	93	83
1972	6	12
1973	5	8
1974	2	4
1975	1	8
1976	-	-
1977	-	-
Total all years	107	115

Each survey defined pock marks as "5 or more round depressed scars one or more millimetres in diameter". The survey by Hughes et al.¹⁰ was carefully statistically designed with a sampling frame that included all of Bangladesh, except the Chittagong Hill tracts. Villages were chosen randomly, weighted for size. Cluster sampling (which may cause errors in the estimation of a communicable disease incidence, since the disease itself clusters) was chosen for logistical reasons. 465 892 people aged 0-19 years were examined by surveillance team members especially trained for pock mark reading, and supervised by epidemiologists with much smallpox experience.¹⁰

In spite of the different goals and markedly different statistical rigour of these two pock mark surveys, both produced similar pock mark prevalence rates (107 v. 115 pock marked faces per 10 000 persons screened), although data by year of onset did not correlate as well. It is interesting to compare the results of such a rapid pock mark survey against what might be considered a reference standard because future Commissions to China or the Middle East may be unable to examine a carefully designed countrywide random sample of the population, yet they will have the same data needs as the Bangladesh Commission. It is also important to note that though the statistical value of surveys casually conducted is always very limited, in the case of both Bangladesh and Burma, such relatively casual surveys did provide important supporting evidence to the Commissions which certified eradication in those countries.

5. Conclusions and recommendations

A major lesson from the Burma Commission is that certification of eradication in a country which has not reported smallpox in many years is a more complex procedure than in countries where recent smallpox epidemics have made it necessary for the health services to establish special eradication projects. In recently endemic countries, certification of eradication becomes a form of programme evaluation, while in countries without a clearly visible current smallpox surveillance programme, the assessment duties of the Commission involve a wide range of activities.

Many Commissions have given a great deal of weight to facial pock mark surveys, whether done by government staff or by Commission members. Surveys have ranged from casual observations in single markets¹⁵ to elaborate studies with carefully designed sampling methodology.¹⁰ Most previous International Commissions have been satisfied with a sample sufficiently large to detect enough old smallpox cases to give a reasonable picture of transmission in the country and which, of course, revealed no disease more recent than the last reported case. Such studies can be expected to provide important supporting data for the International Commissions which will visit China, Iran, Iraq, Syria and Thailand.

Countries which have not yet been certified should be encouraged to do their own national pock mark surveys^a before being visited by a Commission. Such surveys are especially useful in countries where certification is being done more than five years after the last known cases occurred. In all remaining uncertified countries, national surveys should cover geographical areas which may not be accessible to the International Commission when it visits. Adults as well as children should be included to estimate prevalence rates by year of onset, which in turn give some historical evidence of the transmission pattern in the country. The standard definition of pock marks should be used ("five or more round depressed facial scars with a base of one millimetre or more").

In addition to such national surveys, International Commission members may desire to do their own supplementary surveys, subject to limitations of time and manpower. The experience of the Burma Commission indicates that such studies may play an important role in the Commissions' decisions.

In order to establish the scope of such pock mark surveys, a preliminary country visit by WHO smallpox specialists is advisable. During such a visit, a methodology for assessment may be prepared. The length of time required for such a visit is proportional to the size of the country and the complexity of the assessment.

In the case of China, such a visit would be extremely useful in order to assemble records in a form most useful for the Global Commission's visit. Like Burma, China has an unusual position regarding smallpox. No cases have been detected since 1959, and it is understood that an outstanding health system has been developed within the general context of which smallpox has been conquered. The same WHO Expert Committee which established guidelines for worldwide eradication, however, also commented specifically on China:

"It is most important to obtain detailed information regarding the smallpox situation in continental China. China was reported free of smallpox following an intensive programme more than 10 years ago, but confirmation of this fact is critical, particularly now that the goal of eradication in other parts of the world is within reach."²

The global certification of smallpox eradication may come as early as October 1979, two years after the last case of Variola minor in Somalia. At that time, there will be a call for worldwide cessation of vaccination, an action which may save an estimated \$ 2 billion annually.¹⁶ It is important that all other countries are certified before that date, since many health authorities will continue to insist on vaccination until eradication is certified worldwide. Continued unnecessary vaccination deprives all countries of one of the major economic benefits from global eradication. Each day's delay, beyond the earliest date that global certification could be announced, consumes scarce health resources. Preparation should begin now for documentation, data collection, and pock mark surveys in those countries still requiring certification.

^a Pock mark surveys are useful for areas where Variola major or Variola intermedia were prevalent, but would not be good for areas where Variola minor was found. For the latter areas, a chickenpox survey with systematic scab specimen collection could substitute for the pock mark survey.

FIG. 1. COUNTRIES REMAINING FOR GLOBAL CERTIFICATION OF SMALLPOX ERADICATION

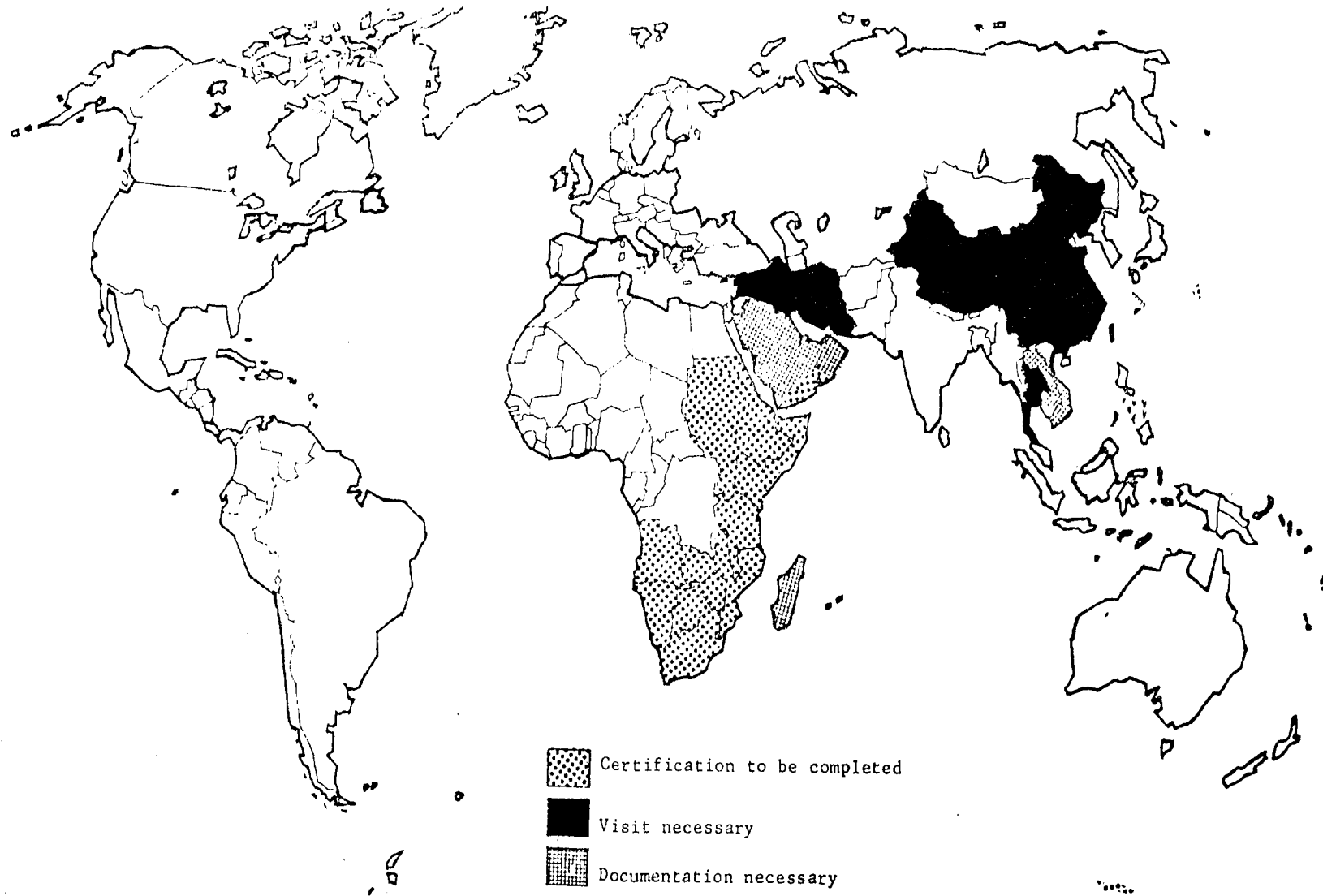


FIG. 2. BURMA: COMPARISON BETWEEN ANNUAL INCIDENCE OF SMALLPOX CASES REPORTED BY HEALTH STAFF AND RESULTS OF POCK MARKS SURVEY CONDUCTED BY THE INTERNATIONAL COMMISSION

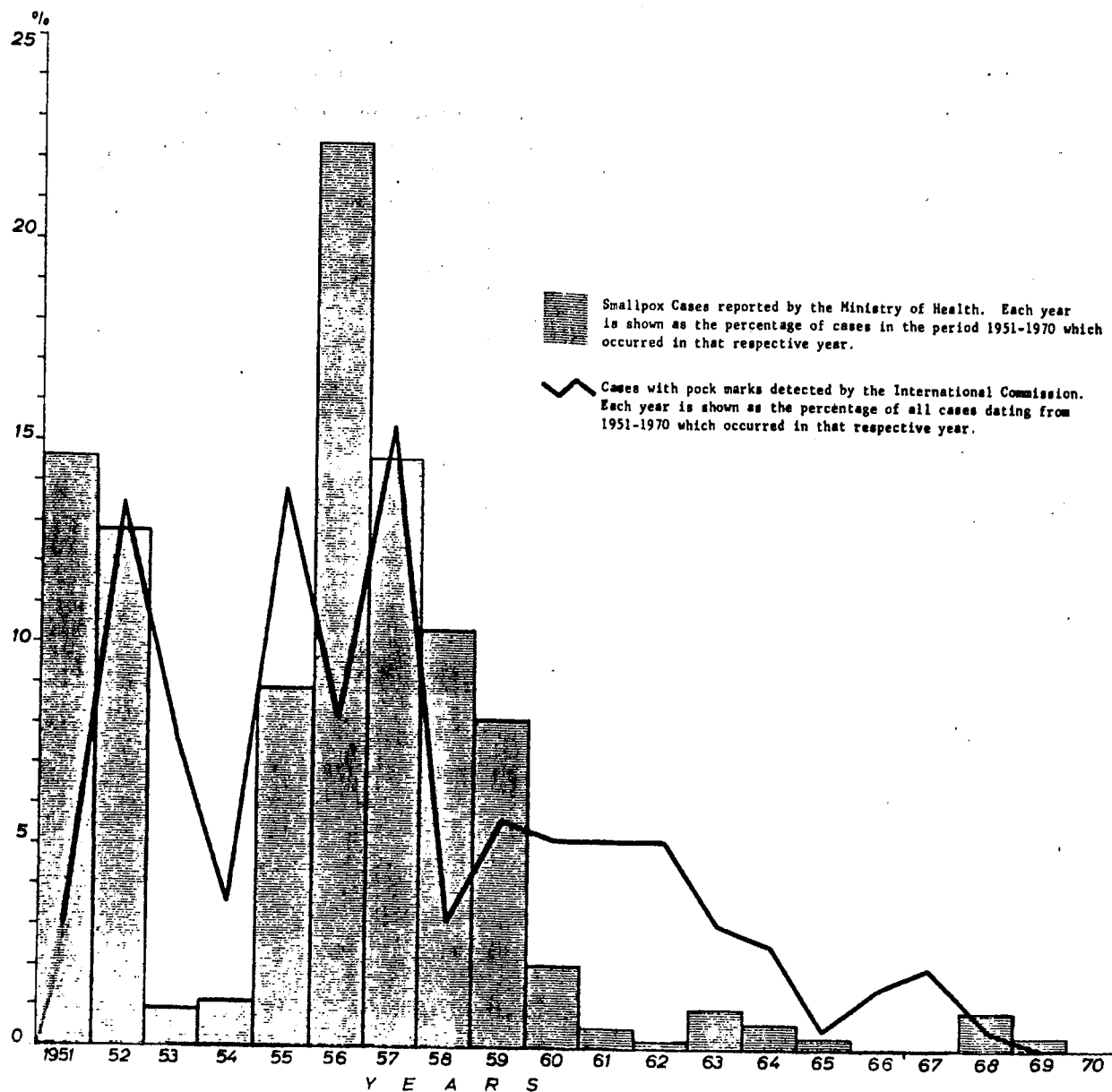


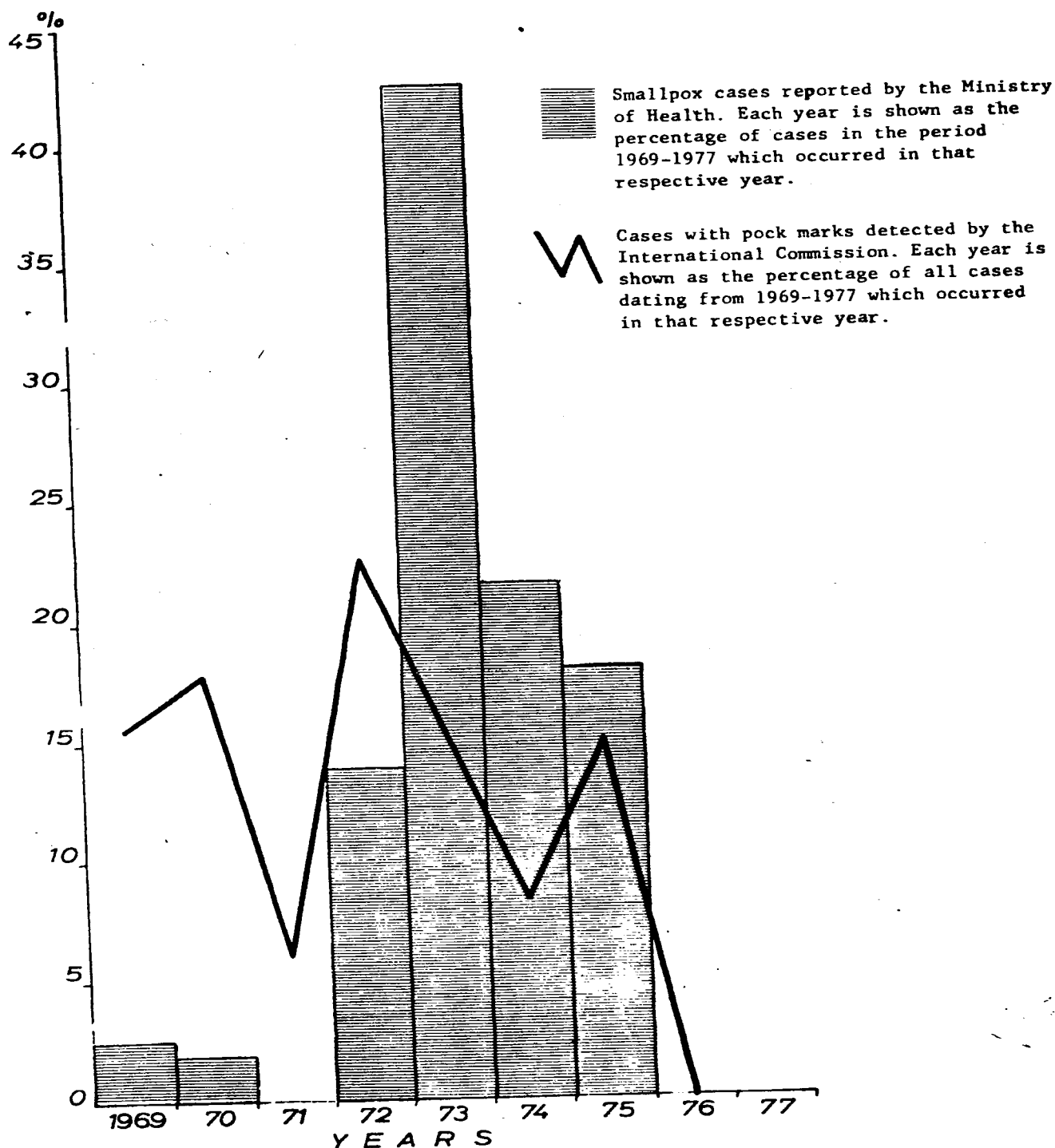
FIG. 3. SUMMARY OF RECENT POCK MARK SURVEYS

Country or area	Population	No. of people surveyed	% sample	% of population found with pock marks	Date of last case found with pock marks	Year of survey
INDIA						
1. Ladakh ³	104 250	1 010	1.0	2.7	1955	1976
2. Mizoram ³	332 390	1 420	0.4	0.7	1968	1976
3. Andaman and Nicobar Islands ³	115 113	17 000	14.8	0.1	1971	1976
4. Sikkim ³	255 497	1 495	0.6	2.8	1973	1975
5. Bastar M.P. ³	1 514 000	8 736	0.6	3.8	1971	1976
6. BURMA ⁵	31 420 000	1 924 095 ^a	6.2	0	-	1977
7. Areas visited by International Commission ⁶		58 000	0.2	0.7	1968	1977
8. Arrakan ¹³		3 000		1.0	1966	1975
9. BANGLADESH ⁷	80 000 000	465 892	1.0	1.1	1975	1977
10. Areas visited by International Commission ¹²		50 000	0.1	1.2	1975	1977
11. NEPAL ⁹		2 350 ^b	-	1.8	1964	1976
12. INDONESIA						
South Sulawesi		459	-	0.9	1966	1974

^a Survey among school children under 14 years of age.

^b Tibetan refugees surveyed at camps.

FIG. 4. BANGLADESH - CORRELATION BETWEEN ANNUAL INCIDENCE OF SMALLPOX CASES REPORTED BY HEALTH STAFF AND RESULTS OF POCK MARKS SURVEY CONDUCTED BY THE INTERNATIONAL COMMISSION



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