Smallpox shows the way

Given programmes with clear objectives, the mutual understanding of national and international staff and good surveillance methods, the pace of development of health care in the developing world could be measured in months or years instead of only in decades.

by Donald A. Henderson

In just ten years, smallpox has been transformed from a disease problem which afflicted more than 10 million people annually, and was a threat to countries throughout the world, into a disease soon to be confirmed as extinct. Was this disease and the campaign which eliminated it of such a unique character as to have no applications in the control of other important health problems? Or are there lessons to be learned in the principles and strategy employed?

Many diseases can be effectively and expensively controlled by immunization, although the global eradication of any other disease is unlikely during the recent century for technical and practical reasons. Since vaccination was the principal tool in the smallpox campaign and eradication is no more nor less than the ultimate in control, the principles utilized and the strategy employed are, I believe, directly relevant to the development of other immunization programmes.

Major problems such as those of obtaining sufficient funds and vaccine and the difficulties involved in designing programmes appropriate to countries of widely differing characteristics may be anticipated in the development of immunization programmes. They were no weaker in the smallpox eradication campaign. Funds for smallpox eradication from international sources were always limited, an average of US$ 8 million in 1973 forms of international assistance having been made available each year. The provision by whatever means of adequate supplies of potent, stable vaccine, until very recently, a constant concern. Also, it was apparent from the beginning that no single plan, however brilliantly conceived, could possibly be replicated in the different countries. The endemic countries exhibited marked differences in the quality and extent of their health services as well as a diverse range of geographical problems and socio-cultural variations. Inevitably, programmes in the different countries had each to be differently constituted in order to derive the maximum possible utilization of existing systems of health care and to adapt to social patterns of behaviour.

The essential elements of the smallpox programme were: (1) a planned systematic programme of vaccination designed to be as inexpensive as possible, and (2) the development of a reporting-surveillance scheme which, by providing current data on smallpox incidence, served as a quality control measurement of progress. For immunization programmes of whatever type, these would seem, likewise, to be essential features.

The availability of vaccine which meets acceptable standards is a sine qua non for any immunization programme. When the intensified smallpox eradication programme began, little of the vaccine then in use in the endemic countries met accepted standards. Some of this substandard vaccine was produced locally but some was produced in reputable laboratories in developed countries. In consequence, considerable resources were being expended in the endemic countries in conveying ineffective vaccine to millions of people. Reliable, independent WHO reference testing centres, able and willing to routinely test large numbers of batches of vaccine, were obviously essential and these started work the same year that the eradication programme began. All vaccine for use in the programme from whatever source was subject to test at no cost to the producer or the recipient country. Vaccine quality quickly improved.

It was estimated that 250 million doses of smallpox vaccine would be required annually. Some countries could afford to buy vaccine but for most it
was difficult because of shortages of foreign currency. WHO decided to try to make vaccine available to all countries at no cost in foreign exchange through a mixture of local production and donation. The plan was to provide assistance in the form of equipment and consultants to those countries which had sufficient basic expertise to be able to undertake production and a sufficiently large population to make vaccine production economically feasible. For smallpox vaccine, a minimum country production of 500,000 vials, approximately 12 million doses annually, was considered necessary. Virtually all countries requiring this quantity of vaccine eventually did become self-sufficient although it took several years to achieve full production.

Requests for WHO assistance in developing vaccine production laboratories came in from many additional countries, but all but a few were successfully discouraged: very few of the smaller countries which endeavoured to establish their own production laboratories were successful. As an alternate approach for the smaller countries, some people initially advocated the development of "regional" vaccine production centres. Although many countries were willing to serve as a host for the regional centre, it proved impossible to work out a satisfactory mechanism whereby the costs of production could be shared on a regional basis.

To facilitate development of vaccine production, a group of producers met in 1968 to prepare a detailed step-by-step manual and, in the course of doing so, simplified and streamlined vaccine production methodology. There were other advances. For example, improved instruments for scarification, which were not commercially available, were produced in quantity on special order from WHO. Blueprints were reproduced for constructing animal-holding tables and stalls and, through WHO, research began to compare vaccine strains and to develop more efficient methods of production.

Donations of vaccine, either as bilateral contributions or as donations to WHO's newly established vaccine bank, were solicited and WHO headquarters in Geneva coordinated the quality testing of samples.

During the first two years of the eradication programme, WHO's headquarters staff spent considerable time and effort in rationalizing the vaccine supply problem and in trying to match this with the increasing needs of developing programmes. In retrospect, it was time an effort which could not have been better spent.

When the programme began, vaccination was conventionally performed by some form of scratch technique after first cleansing the skin with alcohol, acetone or soap and water—a technique basically not different from that employed by Dr Edward Jenner, more than 150 years ago. Soon after the programme began, vaccination technique was radically changed through the introduction of the bifurcated needle which produced more frequently successful vaccinations while using far less vaccine. Further simplification was possible when it turned out that cleansing of the skin could be abandoned without change in the incidence of bacterial complications. The evident lesson was that any technique or procedure, however traditional, should be questioned to see whether there is not a better, simpler, faster, more efficient approach. Is there not now something better than the cumbersome and expensive syringe and needle?

Key elements in the development of the smallpox programme were: (1) the recognition that because of the divers...
characteristics of the different endemic countries, no two programmes could or should be identical; and (2) the realization that, because of the limitation of WHO funds—$2,500,000 each year for campaigns in 50 countries—maximum use would have to be made of existing health services. At the same time, the programme required a coordinated international effort.

To provide coherence and direction to the programme, three important measures were taken. Firstly, an operational manual was developed and distributed within six months after the programme began. The manual set forth two broad objectives for execution of programmes: (1) each programme should ensure vaccination of at least 80 per cent of the population in a two- to three-year campaign and should incorporate an independent sample-assessment mechanism to validate, on a continuing basis, that this was achieved in fact and not simply on paper; (2) a reporting-surveillance system should be developed which could monitor, on a concurrent basis, the success or failure in diminishing smallpox incidence, ultimately to nil cases. The manual provided illustrative alternative examples of approaches which it was labelled as a “draft” in recognition of the fact that much was yet to be learned and to encourage national and WHO staff to explore new and different approaches.

Secondly, considerable time and effort was expended in endeavouring to recruit WHO advisory personnel who exhibited characteristics of self-reliance, intelligence, and an ability and willingness to innovate, and who were agreeable to spending not less than one-third of their time working in the field. Not surprisingly, the WHO advisory smallpox staff were, on average, considerably younger and less academically minded than most WHO advisers.

Thirdly, recognizing the need to learn constantly from experience and to adapt and to change accordingly, a variety of mechanisms were employed to keep both national and WHO staff currently informed regarding overall progress in the programme and to advise them of developments or strategies found to be of value in one area which might be adapted and used elsewhere. Regional Smallpox Advisers and Headquarters staff met annually for planning sessions; at least one inter-country seminar for national and WHO staff took place annually. Regional Advisers were expected to spend at least one-third of their time on field visits, visiting each country programme at least once and preferably twice each year to learn and to advise. Furthermore, every two to three weeks, in WHO’s Weekly Epidemiological Record, a summary of the status of the programme appeared which frequently included notes of findings and differing approaches being used in various countries. Coinciding with publication and distribution of the surveillance report in the WER, one or more special papers were edited and distributed which dealt with operational methods, interesting observations from one or another programme, results of special research programmes, and so forth. As a practical indication of the concern that staff at all levels function as a team, requests for help or advice received from the field were accorded absolute priority, requiring immediate response.

Although the programme as a whole developed in a surprisingly coherent manner, it is gratifying to note that no two national programmes were identical—some, in fact, bearing so little resemblance to others that a transfer of advisers or national staff from one
Moreover, some national programmes evolved so rapidly from year to year that repeat visits by consultants after only one year also demanded a degree of reorientation. The objective of the programme, in its simplest terms, was to reach zero cases of smallpox—"with full confidence that the zero was valid. It mattered little how many vaccinations had been performed how complete the coverage was if smallpox cases were still occurring. ends in the incidence of smallpox were thus regarded as the principal indices of progress. Moreover, it was felt by continual scrutiny of the age, vaccination status and geographic distribution of cases, available resources could be more precisely focussed in places or on groups of the population where the problem was greatest.

The decision was made to try to gradually improve reporting simultaneously at all levels and to obtain "the best possible" count of cases. Repeated contact with government health officials can only improve the frequency and regularity of reports to WHO. A manual was written and published setting forth a philosophy of surveillance and outlining the methods for improving case detection and notification. At the basic level, it was suggested that each health service unit (health centre, dressing station, hospital and so on) be identified as a reporting site, that each should report each week indicating the number of smallpox cases detected that week (irrespective of date of onset), and that a "no" report be sent if no cases were found. Eventually, a system such as this proved to evolve most rapidly when each reporting unit was visited regularly by a mobile surveillance team. Two persons and a vehicle for a population of 2-5 million persons was usually sufficient. The teams served to instruct village staff on the need for case reporting, to remind them when they were in excess of submitting reports, to investigate cases and outbreaks and to reassure health units to undertake vaccination both among patients visiting them and in their geographical area of possibility. The fact that someone was actively concerned in receiving reports and, moreover, took action on basis of such reports was a new and unique experience for local health staff in many countries.

The surveillance system proved ultimately to have been the key to the eradication programme. Time and again, smallpox was found to persist in communities in which more than 95 per cent bore vaccination scars. Only by detecting and containing the remaining outbreaks was it possible to eliminate the disease. Moreover, where surveillance was intensively and aggressively pursued, smallpox was frequently eliminated when less than half the population had been vaccinated.

Surveillance data also reshaped the vaccination programme. In one country, a cumbersome and expensive programme designed to vaccinate women isolated by purdah was dropped when it turned out that cases among adult females were all but unknown. The discovery in Africa and South America that more than 95 per cent of all cases were occurring among individuals who had never been vaccinated resulted in a shift to programmes which focussed on primary vaccination. There were many additional examples of the value of surveillance data. The essential principle, however, and indeed the heart of any management process was precise definition of the objective, the creation of methods to monitor progress in reaching this objective, and a constant review of programme practice in the light of these findings.

Experiences and observations in the vaccination component of the programme are perhaps most instructive in considering future approaches to the delivery of health care to rural populations. Systematic vaccination programmes varied in character from country to country but, in general, they incorporated three principles: (1) provision of vaccination as near as possible to the home of the vaccinates; (2) independent assessment to determine weekly the extent of coverage and the proportion of successful vaccinations; (3) involvement of such people as village leaders and school teachers in motivating the population and in assisting in vaccination.

In most countries, mobile teams, or individuals moved systematically throughout the country to offer vaccination at collecting points as close as possible to the homes of the villagers. In some programmes, it was anticipated that there would be adequate coverage of all within a radius of ten kilometers. Within this system and adequate publicity, coverage of adults and babies proved satisfactory but for young children, too large to be carried and unable to walk easily such a distance, the coverage was poor. By trial and error, three to four kilometers was found to be the maximum. Health workers obtained the best cooperation when they employed an "advance man" to work with each team. He preceded the team by several days and in each village or area discussed with local health staff, village leaders and school teachers the extent of the programme, decided with them the best location for the team to work and enlisted their support for such activities as publicity, organization and keeping records. Quite possibly, villagers could have also been trained and utilized to perform vaccination, thus further reducing manpower requirements for health staff. This was done in outbreak containment operations toward the close of the campaign and, in such circumstances, worked reasonably well. With an effective "advance man" and the cooperation of village leaders, vaccination coverage of more than 90 per cent was readily achieved, the lowest coverage inevitably being among children under five years of age; but even in this group, more than 80 per cent coverage was the norm.

The number of vaccinations that could be performed each day by each vaccinator varied according to the terrain and the efficiency of the teams. In Africa an average of 500 vaccinations per vaccinator per day was a minimum standard but the average ranged as high as 1,200 vaccinations per man per day in one country. This level of productivity required comparatively few health staff. For example, in Kenya with a popula-

Just one more little victim of smallpox—a sight the world will never see again. (Photo WHO/N. Willard)
of 13 million, only 70 health staff were employed and, in Zaire, with a population of 25 million, 220 health staff. But even with this small number, in both countries, it was possible to give anti-tuberculosis BCG as well as smallpox vaccine.

Considerable efforts were made to persuade health staff at all health centres, hospitals, MCH centres and so forth to report smallpox cases and to perform vaccinations, if not throughout the area in which they worked, at least among patients presenting themselves at the health unit. Such units worked reasonably well in those areas where mobile smallpox teams visited regularly to encourage them and to assess their work, although nowhere did health centre staff alone achieve satisfactory coverage. When responsibility for supervision was left entirely to the basic health service structure, curative activities quickly predominated and vaccinations often ceased entirely. Most remarkably, in one WHO-supported "model health centre" in an epidemic area, I was informed that there were so many to be treated that my sort of preventive vaccination was out of the question.

Independent assessment teams who checked the work in 5 to 20 per cent of the villages proved to be one of the most valuable components of the vaccination programme. In most countries, there was resistance to the assignment of reliable senior staff to assessment, a task which appeared to contribute nothing to increased vaccination coverage. In some areas, statistically-minded health officials unless the sample were a carefully worked out, statistically valid sample. In fact, however, knowledge on the part of the teams that their work was being regularly checked invariably and dramatically improved performance; occasional faults in technique or vaccine handling were detected; and sometimes areas were discovered which had been omitted from the programme due to faulty planning. The selection of the sample of villages for checking was done by crude random sampling with a bias toward evaluation of the less accessible villages on the premise that if coverage there was satisfactory, this would also be true of the more accessible ones. The statisticians were eventually placated when assessment was discussed in terms of an "operationally valid" sample.

The essential principles in the vaccination campaign, as we saw them, were careful planning with established goals; the maximum possible involvement of the local population; and a continuing system of assessment through special teams for quality control of what was being done.

Can the lessons learned be applied to other programmes? In 1967, a great many experts had carefully explained to those of us embarking on the smallpox eradication programme how impossible and technically unsound it was; they provided us with a remarkable litany of reasons why reasonable control, let alone eradication of smallpox, was quite out of the question. Today, paradoxically, we hear from many of the same people that the task was, after all, not so

Closing stages: a health team questions villagers in a rugged landscape of Ethiopia, as the last remaining pockets of infection are sought out and contained.

(Photoby WHO/D. Henrioud)