

## **The Challenge of Eradication: Lessons from past eradication campaigns**

Donald A. Henderson, M.D., M.P.H.  
The Johns Hopkins University

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I appreciate very much your invitation for me to participate in this conference and, as an interested and concerned observer to offer some hopefully helpful and perhaps provocative thoughts regarding the steadily strengthening tuberculosis control programs which today are so vitally important. I do so not as an expert in the disease but from the vantage point of one who spent 11 years endeavoring to eradicate a disease and more recently, from the vantage point of a policy advisor in the Executive Office of President Bush and as Senior Science Advisor in the U.S. Department of Health and Human Services.

In 1980, the World Health Assembly proclaimed the fact that smallpox had been eradicated and that vaccination everywhere could cease. Thus culminated a global campaign which began in January 1967. That year, 46 countries reported smallpox cases. Surveys were to reveal that between 10 and 15 million cases had occurred that year and that 2 million had died. A ten year goal had been proposed when the program was originally agreed upon by the World Health Assembly. The target was missed but only by 9 months and 26 days.

This was an achievement which was widely hailed because smallpox through history has been by far the most devastating of all diseases, capable of being transmitted in any country and in any season. Before a vaccine became available, everyone eventually contracted the disease and some 25 to 30% died. That threat was removed by the eradication campaign which, in international support, cost, in all about \$8 million per year over 13 years, from its launch to the certification of eradication by a

global commission. The savings are estimated to amount to perhaps \$2 000 million per year.

The immediate lesson which many drew from this achievement was that having eradicated one disease and so having demonstrated eradication to be a possible goal, other diseases should be targeted. All manner of candidates have been proposed over the past 15 years with everything from urban rabies to periodontal disease to tuberculosis receiving mention by one visionary or another. The advocates argue that even if the goal of eradication is not achieved, that substantial additional resources will be mobilized by proclaiming this goal and that, at the very least, better control of the disease in question will be achieved. This is a very attractive argument but a dangerously fallacious one as I shall describe.

Let me say at the outset that in my opinion, time devoted to debating the feasibility of additional disease eradication projects is, at this time, a futile waste of energy. In fact, it is to me an indication that the wrong lessons have been derived from past eradication campaigns. You may be surprised to know that, in fact, there have been, so far, seven global campaigns. The smallpox program was the fifth, its four predecessors which date back to the early part of this century, having failed ignominiously after the expenditure of large sums of money. They left little behind and are now largely forgotten --programs against hookworm, yellow fever, yaws and malaria. Two global eradication campaigns are operative today - programs against polio and Guinea worm. Both are behind schedule and struggling although there is hope that one if not both may eventually succeed.

Thus, I will argue the case that, at this time, our attention needs to be focused on well-structured, scientifically sound programs for disease control. Priority must be accorded to those diseases inflicting the heaviest burden globally, and, certainly, tuberculosis ranks as one of the most important..

But why not eradication? Having devoted 11 years to the effort to eradicate smallpox, I can say with feeling that it was a formidable task which only barely succeeded. Yet, all who have looked at candidate diseases would agree that the biological attributes of smallpox and the technology for dealing with it made its

eradication far more likely than for any other disease. Here was a disease which produced a severe illness with an abhorrent rash. Diagnosis was no problem. Even illiterate villagers could identify the disease and politicians and citizens alike were terrified of it. There were no subclinical cases. Thus, one could determine immediately where the virus was circulating; laboratory tests were not required. Tracing the chain of infection from one person to another permitted staff to discover unsuspected outbreaks and, with vaccination, to stop the spread by vaccinating close contacts of patients. Finally, there was a vaccine which was easily administered which protected virtually 100% of recipients with a single inoculation; which could be given at any time from birth onwards; which was so heat stable that it remained viable for 4 to 6 months even at temperatures of 40° C.; and which cost only 1 to 2 cents per dose to produce.

Despite the advantage to all countries if smallpox were to be eradicated and despite the highly favorable epidemiological and technological advantages, resources were surprisingly scarce throughout the program. Success was achieved but by only the narrowest of margins, the program having been sustained by a surprising number of fortuitous incidents in which national programs were rescued by an unexpected change in government, an opportune truce in a civil war or heroic actions by staff which were above and beyond the call of duty. Given these facts, you will understand why those of us who know the program best, question the wisdom of setting out to eradicate another disease which, at the very least, would be several orders of magnitude more difficult.

But I believe there are important lessons to be derived from smallpox and other eradication campaigns, both from their successes and their failures. These I will discuss under six headings: 1) Political commitment; 2) Program leadership; 3) A technically sound and feasible plan ; 4) Surveillance as a strategic; 5) Quality control of materiel and program execution; 6) The importance of a closely linked research program.

Political commitment is critical to a major disease control program but experience shows that it is neither easily obtained nor readily sustained under the

best of circumstances. Politicians and heads of state world-wide have many problems on their minds and countless distractions; health issues are seldom high on their agendas. Dr. Fred Soper, a formidable international figure of a half century ago and one who led on of the early eradication campaigns, made the point best when he said that in public health fully half the job is in selling the program and half is in implementing it. That I find to be a reality which our public health colleagues often ignore and resent to the detriment of the program.

As a generalization, one can say that no program will garner needed support without a visible, proactive educational and lobbying effort at many different levels and it needs to be a continuing one. Descriptive materials are critical, including data which quantify the problem, the trends and the program needs. But I offer the caution that the data must present the problem honestly. Dishonest or selective analyses are all too soon identified as such and, in consequence, the credibility of the program is thrown into question. Unfortunately, the tuberculosis program has not been without fault in this regard, although recent WHO and CDC publications which I have seen are substantially better balanced than they were a few years ago.

A national commitment is more readily obtained if there is first an international commitment such as in a World Health Assembly resolution. Such a resolution, however, does not provide a guarantee of national commitment as it is well known that the Assembly each year passes all manner of resolutions and, it is said, if even half were honored, we would be living in a latter day garden of Eden.

I would offer the cautionary note that there are those who would argue that no serious national or international commitment can be obtained short of proclaiming eradication or elimination of a disease to be the goal. This, I believe, is absurd and would suggest that significant progress could not be made in public health without eradicating the condition, whatever it might be. If that were so, it would not portend well for efforts to deal with such as family planning, environmental pollution and a host of other conditions. Yet, major progress has been made in all these fields.

Experience shows that effective program direction requires individuals with both leadership skills and technical knowledge of the subject. The adage that nothing

more than a master's degree in business administration is required to manage any public health program has been thoroughly tested and found wanting. This is not to say that all managers need to be physicians or nurses but it is clear that every manager does need some level of professional expertise. What the successful eradication campaigns have shown is that a surprisingly small number of dedicated, knowledgeable and dynamic individuals can transform even some of the largest and most arteriosclerotic bureaucracies. In my experience, I have found that even the most apparently inept organizations have substantial numbers of talented people who will respond to positive intelligent leadership.

With imaginative program leadership, one soon discovers that there is an incredible wealth of underemployed health staff in every country who generally welcome involvement in a dynamic program. Likewise, there are all manner of organizations and people at community level who are more than prepared to pitch in and surprising numbers of teachers, militia, police and religious workers who usually respond with remarkable enthusiasm to a health program challenge.

A sound and feasible plan would appear to be a *sine qua non* for any public health program but, in fact, all of the earlier eradication programs failed this test. Simple logic suggests that in embarking on a campaign, one would need a plan which is soundly grounded in a scientific understanding of the disease, of its ecology and of the practical realities of undertaking field programs. Logic would also suggest that programs begin on a modest scale and develop progressively through ever expanding operations which subject the methods and technologies to the acid test of field experience.. Indeed, anyone who has worked in the field knows all too well that nothing works in practice as it was designed on the drawing board.

Strange as it may seem, the earliest eradication programs began with an evangelistic fervor, an incomplete knowledge of the disease's ecology, unrealistic expectations, less than optimal technology and with field experience which was minimal and uncritically evaluated. Each program lasted approximately 15 years before being terminated as being unworkable. In the case of the malaria campaign, more than US\$ 2000 million was spent world-wide but it left little behind except for

transient disease control in a few areas. The debacle of malaria eradication left, as well, a determination by UNICEF and bilateral assistance agencies to have nothing more to do with another eradication campaign. Thus, the inherent risk in proclaiming unrealistic and untested eradication or disease elimination goals is a real one.

Given the pathogenesis of tuberculosis, notably its ability to persist in man for decades in a dormant state and later to exhibit recrudescent infection, global eradication of tuberculosis, short of at least two generations is simply not possible and especially unlikely given the fact that the span of attention of national health authorities for any defined program seems to be not more than about 15 years. Recently, a new phrase has begun to be used - "elimination of a disease as a public health problem". In the U.S. the national program has set TB "elimination" as its goal - more specifically, the achievement of less than one case per million population. Establishing some sort of achievable, specifically quantified goal for the conduct of a disease control program makes good sense. However, as has become apparent with several diseases for which such a disease elimination target has been set, overenthusiastic program directors and supporters have regularly shortened the phrase to "disease elimination" without qualification in order to argue for added program support. This has invited both skepticism and questions about the credibility of the organizations concerned - and with good reason. Accordingly, there are increasing numbers who are calling for the eradication of the phrase "disease elimination as a public health problem". Indeed, at a recent international conference in Germany, this decision was unanimously accepted. Why cannot the phrase, "effective disease control", be used? Certainly, it has served us well for many years.

Surveillance has proved to be the most critical element, by far, for all eradication programs with programs succeeding where ever it has been effectively employed and failing consistently where ever it has not. Surveillance is defined in terms of disease reporting for action. Specifically it is the routine, systematic collection of morbidity and mortality data; its compilation, interpretation and dissemination; and, finally, the implementation of necessary action based on these data.

Only three eradication programs began with surveillance as a key component - smallpox, Guinea worm and poliomyelitis in the Americas. All three made extraordinary progress and, utilizing the data received, each progressively modified and changed its strategies and tactics over time.

Surveillance provides the ultimate outcome measurement. Fewer cases due to the disease is, after all, the ultimate objective of a control program, not the numbers of persons treated nor the numbers of persons vaccinated. Predictably, not all cases will be reported. Reporting is always incomplete to some degree, better in some areas than others, but the aim is to steadily improve surveillance and to continue to follow the trends nationally, by geographic area and by special risk groups. Each new case should be seen as representing, in some way, a failure of the program. By analyzing the cases by age, by geography, and by such as occupation, patterns will be seen which will suggest that more resources are needed in one area than in another; or that more appropriate programs may be needed for specific groups or situations. This is what is meant by surveillance being, in fact, public health in action.

An important component of surveillance is the reporting back of information to all who have reported cases of disease and others with a need to have such data for policy or research purposes. Most useful are monthly or sometimes biweekly surveillance reports documenting numbers of cases by geographic areas, an analysis of trends of the disease and information about new developments. This closes the loop, if you will, so that those who report information can see that the data are being used and this, in turn, improves

We used other measures to assess progress in the smallpox campaign - process indicators, if you will, and other measurements to assure "quality assurance" for such as vaccines and drugs. The latter would appear to be so perfectly obvious that one wonders why it should be mentioned at all. Would you believe that as smallpox eradication began, 90% of the vaccine then in use was substandard and some contained no protective virus at all? Some was from what were believed to be reputable producers in the industrialized countries. In the smallpox program, there were a number of operational standards, process measurements which we regularly

employed. For example, we routinely assessed the performance of vaccination teams by arranging for an assessment team to sample 10% of villages. Coverage of 90% with 95% successful vaccinations had to be achieved or the vaccination team was sent back without per diem to repeat the work. Seldom did they fail twice. We required for each district, each province and for the country as a whole that at least 90% of all health units report each week as to whether cases were or were not present. For outbreak investigation, it was stipulated that 90% of all cases had to be investigated within 48 hours and that no case should occur in an outbreak more than 21 days after vaccination and containment measures were taken. With explicit targets and regular reporting, staff in every geographic area could assess their own performance and compare their success to that of others.

A word of caution, however, should be said about goals. We endeavored to keep the number to not more than 5 operational ones. Obviously, there were hundreds of possible measurements of progress that could have been requested and compiled. Our experience, however, was that when the number got beyond 4 or 5, key staff became so involved in submitting and compiling data that few used the data for the purpose for which it was intended -- in monitoring the strengths and weaknesses in program implementation.

The character of the goals were important; five criteria were used to test the appropriateness of goals:

- 1) Specific -- that the goals be stated with specific numerical expectations
- 2) Measurable -- that they be able to be measured without undue effort
- 3) Adaptable and adjusted to need - that the goals be regularly reviewed for relevance and, as necessary, altered to address unforeseen circumstances
- 4) Reasonable - that staff who use these yard sticks perceive them as being achievable within reason. One approach in smallpox eradication was to ask staff themselves to propose their own goals, say 3, 6 and 12 months ahead. More often than not, they set more rigorous goals than would their supervisors and surprisingly often they were achieved.
- 5) Time limited - Without a reference point in time, the goal is meaningless.

I've focused at length on surveillance and goals for quality control because these were the most difficult to establish. Primarily, this seemed to be because both governments and our own staff looked initially upon this exercise as being simply a diversion of resources from what they initially perceived to be their reason for working -- specifically, the delivery of as much vaccine to as many people as they possibly could. And, indeed, they regarded surveillance itself as a diversion from their duties. However, until surveillance and quality control measures were established, programs drifted. The staff could tell how many vaccinations had been performed but they had little notion as to whether they were making progress. As we had to repeat again and again, the aim of the program was not to vaccinate children, it was to prevent disease.

A major area which has been neglected in most public health programs with disastrous consequences is research. Most of the older eradication campaigns and, to a degree, the contemporary ones, spurn research while reciting what almost appears to be a mantra; "We have the tools; we know what to do; it is simply a matter of diligently applying what we know". For the malaria eradication program, research activities were terminated deliberately as the program began and the same can be said with respect to each of the other failed eradication campaigns. For the smallpox program, we launched research activities from the very beginning. Always a concern was the question as to how the task could be accomplished more efficiently, more readily, more certainly. The bottom line was that we tested and introduced world-wide a new vaccination device which was easier to use and required one-fourth as much vaccine; we found better ways to produce and test vaccine; we discovered that the usual protection conferred by vaccine was far better than the textbooks said -- so good, in fact, that we could suspend efforts in routine revaccination. We discovered that the disease spread very much less rapidly than the textbooks stated, making it far easier to find and control outbreaks than we had at first believed and this dictated a major shift in our entire strategy. and, even as the program moved toward its conclusion, we were testing a new vaccine which would have found wide-spread use had smallpox not been eradicated.

There is no question in anyone's mind but that without the better tools and

better understanding of smallpox epidemiology which was acquired through research, that eradication would never have been achieved.

I am no expert in tuberculosis but as I review the tools that appear to be most widely used, I note that BCG continues to be used in many countries; sputum smear, X-rays and PPD testing all have roles in surveillance-assessment; and for disease treatment, there is DOTS. As others have pointed out., all these tools are at least 25 years old. None are fully satisfactory for a variety of reasons. Is this the best we can do? Of course not but one will not get better tools without investing in research! It seems to me that research in TB prevention has only begun to command the interest and attention it deserves.

In conclusion, let me say that I, for one, share your belief that we need to do far more in the prevention and treatment of tuberculosis, especially in this era of AIDS and drug resistance. The problem is certainly serious enough to command far greater support from the international community. Much can and should be done with the tools and the technology now available but, from this vantage point, it seems to me that a far higher priority should be assigned to applying contemporary biotechnology to improve diagnostic methods for better surveillance; for the development of a vaccine which actually prevents infection; for the development of drugs which don't require 6 months of administration. For effective global control of tuberculosis, I see no validity in the assertion that "we have the tools, it is simply a matter of applying them well". No effective disease control program, let alone one for eradication, has had to rely on measure for surveillance and prevention which are as cumbersome and uncertain as those for tuberculosis. I have no doubt, however, that that situation could change dramatically within the decade if sufficient support were given to a well-constructed effort.

Meanwhile, it is clear that the program has already gathered remarkable momentum and far more support than I would have thought possible within the short time real efforts have been made to place this major problem high on the public agenda where it belongs. With the increased infusion of leadership and skill which is also apparent, I am confident that bright victories lie ahead - but not eradication.