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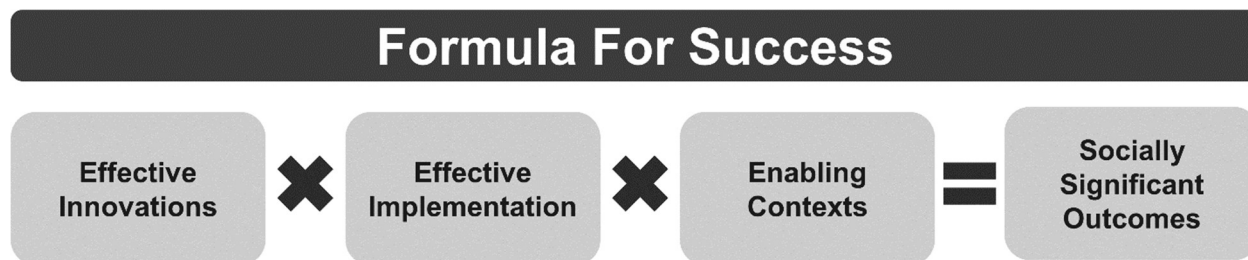
Eradicating smallpox: Through an implementation lens

Dean L. Fixsen, Karen A. Blase, Melissa K. Van Dyke

In the 1950s and 1960s mass inoculations for smallpox were aimed at accomplishing “herd immunity” by inoculating entire populations of people who might come into contact with an infected person. That is, the goal of herd immunity is to inoculate every person in a country so they will not contract the disease when encountering a person who may have the disease, especially when traveling or meeting visitors. For smallpox, mass vaccinations did not reach the last 20% of a population—the marginalized people, itinerants, beggars, drifters, migrants, and others who were less likely to be located and more likely to have smallpox and to spread smallpox. Thus, outbreaks of smallpox continued from the earliest recorded history onward.

The approaches to implementation and scaling outlined in the Active Implementation Frameworks (Fixsen, Blase, & Van Dyke, 2019) have been used to conduct a post hoc analysis of the eradication of smallpox as described by William Foege in the book *House on Fire* (Foege, 2011). Foege was a leader and innovator and fully engaged in practice as the global efforts to eradicate smallpox were planned, carried out, and adjusted in a mission-driven manner (Fenner, Henderson, Arita, JeZek, & Ladnyi, 1988). The quotes and page numbers below refer to the book *House on Fire*. We have selected this example because the book is available for further study by interested readers. In addition, it is the only example of a human service innovation that has been completely scaled globally. Thus, the example provides lessons for the field.

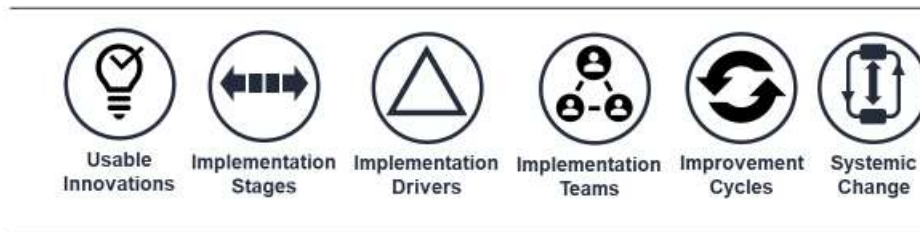
The factors in the Formula for Success are used to outline the key components that supported the smallpox eradication efforts: effective innovation, effective implementation, and enabling context.



The Active Implementation Frameworks provide an outline of the strong variables that make a difference when attempting to develop, use, and scale any innovation so that populations can benefit. The Formula for Success and the Active Implementation Frameworks are explained in the book *Implementation Practice and Science* (Fixsen et al., 2019) and on the Active

Implementation Research Network website www.activeimplementation.org. The strong implementation variables described in these sources are noted in the text below regarding the eradication of smallpox.

Active Implementation Frameworks



The content of this paper is taken from Chapter 16 of *Implementation Practice and Science* (Fixsen et al., 2019, p. 317ff).

Effective innovation

After observing the apparent immunity of milkmaids and then purposefully injecting cowpox, then smallpox, in a young boy, in 1798 Edward Jenner published his findings that cowpox immunizes people against smallpox. Despite the 175-year history of knowing “what works,” the production of the smallpox vaccine in the 1960s still was a “cottage industry” with inconsistent quality and uneven distribution.

Vaccine

As a first step toward reducing the incidence of smallpox, a World Health Organization (WHO) panel was convened to set standards for production and for preservation via freeze-drying to allow for reliable transport. Consultants then were sent out to help countries convert production to meet the new standards, and reference centers (fidelity assessors) were established to assure consistent high quality. By 1969 an effective process had been established, and by 1973 over 80% of the vaccine was being produced by the countries where the vaccine was being used (pp 48-49).

Injection

The inoculation method initially involved manually injecting the vaccine via multiple needle pricks through a drop of vaccine on the skin, a method that required time and skill and was difficult to teach. “Take rates” (successful vaccination) varied within and across vaccinators (high or low fidelity practitioners). In the 1960s other methods were developed to consistently deliver measured doses of vaccine via a mechanical injector. With this method, one vaccinator could inject about 1,000 people per day with high take rates (pp 49-52).

As field experience accumulated, the injector was replaced by a bifurcated needle. Use of this method of injection “was easy to teach, provided take rates of 98% or higher, and required only about 20% of the vaccine” used with other techniques (p 101). The needles were inexpensive and could be cleaned and reused. Supplies were lightweight and suited to use by mobile teams. Vaccinators could vaccinate up to 500 people a day, fewer than the 1,000 people using the previous injector. But, the ease of training meant that more vaccinators could be deployed with the expectation of greater take rates in the population while conserving the supply of the vaccine (p 102).

Surveillance

In a country a search network was organized with reporting by “block” (roughly 100,000 population in a block; a scalable unit for surveillance). The block data were summed up by district, state, and nationally. “What exactly was a search?” (p 107). For six days each month, every available health worker employed in the system was mobilized to find cases of smallpox in their block. At the end of six days, they would go back to their regular jobs in malaria prevention and treatment, family planning, and other programs. If more workers were needed, day laborers were employed and taught to be searchers. A search protocol was developed with operational guides for each area. The team for each block searched 20–25 villages a day for six days and reported the results using standard protocols and forms.

Containment

Separate teams were deployed for containment. In India, for example, each of the 386 districts had one vaccinator per 25,000 population, one supervisor for every four vaccinators, and one medical assistant per “block” of 100,000 people. In addition, each district had a mobile team of five vaccinators that could be sent anywhere at any time. Containment teams were taught to adhere to a protocol for vaccinations (fidelity). “A single-page instruction sheet was developed on vaccination techniques, use of the bifurcated needle, the preferred site of vaccination, and the sterilization of bifurcated needles after use” (p 109).

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Effective implementation

“The objective may be global, but implementation is always local. The strategy for smallpox eradication did not change from country to country, but the local culture determined which tactics were most useful. Only the specific locality can provide information on who is sick, who is hiding from the vaccinators, when people are available for vaccination, how to hire watch

guards, or how to secure the cooperation of the community. In all cultures, an approach of respect for local customs is needed” (p 192).

The targeted surveillance and containment strategy became the focus of implementation in each country. There were impediments to the new and effective strategy. First, the Center for Disease Control and Prevention (CDC) and WHO staff had been trained to do mass vaccinations. The surveillance and containment strategy was counter to their training and thinking. The CDC workers who were “too young to realize they couldn’t do it” were most successful. Second, it was commonly accepted that smallpox spread rapidly with minimal contact with an infected person. The assumption of rapid transmission was not supported by evidence from practice that it often took multiple exposures to transmit the disease (p 73-74). Third, the WHO expert panel favored mass inoculations for herd immunity and was not prepared to support the new strategy. The evidence accumulated as the surveillance and containment strategy expanded into all 20 CDC-related countries with equal success as smallpox was eliminated in each of those countries after only a few years (e.g., 3.5 years from the beginning to the last case in Nigeria). Based on this practice-based evidence, WHO and CDC then supported surveillance and containment as the strategy for eradicating smallpox globally. The biggest test was in India where smallpox was endemic and accepted as part of life in a large, diverse, and mobile population.

Competency Drivers: Selection, Training, Coaching, Fidelity

In India, training was provided for staff at each level: state, district, and block. In one state, “preparations for the first search required over 60 training sessions simply to get down to the district level, and an additional 930 training sessions at the district and [block] levels” (p 108; linked Implementation Teams). Supervision (coaching) followed the same pattern with training for supervisors to follow quality control protocols (fidelity) to assure surveillance was carried out as intended in each block. The preparations paid off with searchers in the first month contacting 99% of the 140,000 villages in one state.

In India there are 29 states, 386 districts, and more than 25,000 blocks. Competency development for many thousand health workers had to be done well and be repeatable in several thousand training sessions provided at the block level across India where surveillance and containment was carried out each day (p 103; 108).

The incidence of smallpox discovered by the surveillance teams far exceeded expectations. The expectations were based on the existing passive reporting system where medical staff in a block reported the number of smallpox patients who came to them. The active surveillance method detected far more cases than imagined. For example, in one month the passive reporting system in one state reported 437

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cases of smallpox while active surveillance found 5,989 new cases in that state (p 115). Given the overwhelming need that was detected, the first response by some was to end surveillance and devote all the resources to containment. However, the decision was: “Our first response should be to improve containment, not dumb down surveillance” (p 116). It is best to know the truth and deal with it, even when the truth is daunting.

Given the overwhelming need detected by surveillance teams in India, the number of teams was increased and the containment strategy was changed (Improvement Cycles). To use the teams more efficiently, only those living in adjacent houses were inoculated instead of the previously required 20-30 nearby houses. Experience from the first searches found that school children were the best informants so they became the initial focus of future searches (p 117; Improvement Cycles). The astounding number of cases detected each month led to difficult decisions. Was it more important to fully contain each outbreak or to reach as many outbreaks as possible? The optimism attached to the proponents of each option found their “optimism was trumped by reality” (p 118; fidelity and outcomes). Either option left people unprotected and smallpox continued. And, given the shortage of high quality serum, “It was tempting to consider diluting the vaccine so we could vaccinate more people.” (p 56; fidelity). A WHO study found that diluted vaccine resulted in ineffective prevention and treatment of smallpox. Thus, the focus was on assuring an adequate supply of high-quality serum when and where it was needed and to deploy enough teams to fully contain each outbreak by injecting the full dose of undiluted vaccine.

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“Containment, as well as surveillance, improved when it was supervised and evaluated” (p 153; coaching and fidelity). In 1974 the program developed evaluation teams. The containment teams were asked to make a mark on the door of each house they visited. The mark changed each month. The evaluation team then could visit houses to record the number visited and ask a sample of households about what the containment team had done. The evaluation results along with key indicators in the data (e.g., percentage of outbreaks reported within 21 days of the first case in an outbreak) enabled program leaders to “quickly spot deficiencies in searching, investigating, and containing outbreaks; such weaknesses could be related to particular [blocks], districts, or even individuals” (p 155; Improvement Cycles; recursive Practice-Policy Communication Cycles). The evaluation program (Decision Support Data System) “became an indispensable management tool and the driver for quality improvement” (p 155; fidelity).

“Every new refinement in search and containment methods required training, new procedures for reporting, and new forms which had to distributed on an ongoing basis to thousands of [blocks] and districts” (p 155; Implementation Drivers; linked Implementation Teams).

In India where smallpox was endemic and the population was dense and mobile, the demand for vaccination far outstripped the ability to respond. “The marketplace took over, less careful operators proliferated, entire villages were no longer inoculated at the same time, and outbreaks of smallpox resulted.” (p 91; fidelity). The advance of surveillance and containment methods threatened the livelihood of the operators and produced resistance to the strategy. To the extent they were willing, local operators were hired to be trained as vaccinators as part of the program (selection).

Decision Support Data System

“Numbers consumed our days, became our compass, and guided our actions” (p 146). New outbreaks continued to be the key statistic. New data were developed to track contained outbreaks. A contained outbreak was defined as a previously infected area that went four weeks without a new case of smallpox. Despite the efforts of increasing numbers of containment teams, the number of new outbreaks continued to increase in part because surveillance techniques improved each month. Surveillance evolved from asking school children and other informants, to going house to house in high-risk parts of a village, to going to every house in a village. The quality of searches improved from some workers just “filling out a form” to nearly all workers taking pride in finding and reporting cases because every “missed case” provided an opportunity for an outbreak to continue.

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The data from surveillance led to a conclusion that the number of outbreaks (not individual cases) was the best indicator of the containment work required. “The surveillance and containment strategy was a learning program” where the attempts at shortcuts provided evidence of what did not work. After three months of experience, it was clear that “the smallpox workers were learning and improving every month while the smallpox virus, for all of its evolutionary success, could not respond with the same agility” (p 121; Improvement Cycles).

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Based on the location and density of missed cases, secondary searches were initiated to augment the standard monthly six-day search. Markets, fairs, religious ceremonies, and areas of high risk were searched by trained smallpox workers between the monthly searches. Protocols were developed for secondary searches. Smallpox workers would go through the crowds and use recognition cards to see if anyone had seen a person with smallpox, a highly visible disease. Additional searches were conducted among groups of itinerant workers, beggars, and others who were mobile and difficult to find in any given location. By January 1974 the monthly searches were occurring in all 100 million homes in the entire country. Quarterly data on new outbreaks

helped to track the location of the disease and decide on the allocation of resources for surveillance and containment (p 149).

The soaring numbers of outbreaks, the labor-intensive work of containment, and the difficulty of continuing to train more teams meant the program constantly was behind in developing containment capacity. “The ideal was always ahead of the actual” (p 151). In addition, in 1974 the protocol was changed to have a supervisor visit each outbreak to evaluate the work of the containment team (Competency Drivers). And, the program returned to the original plan of vaccinating 20 households around each house with smallpox (fidelity). Without enough containment teams, the next monthly search produced evidence of more outbreaks before the containment teams had visited all of the previous outbreak sites. “The amount of work, record keeping, and supervision for one outbreak was prodigious,” and visits had to continue for four-six weeks (i.e., the incubation period) to be certain no new cases had developed before containment could be declared. Visits by supervisors monitored workers to be sure they followed the protocols for containment and to detect reasons for continued outbreaks in “contained” areas (Competency Drivers).

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“It was soon discovered that people from outside the immediate family and even outside the neighborhood were expected to visit a person who was sick with smallpox” (p 152). This led to the addition of watch guards at each patient’s house with instructions to vaccinate every visitor day or night. “Hiring, training, and employing watch guards at each house was added to the work of the containment teams” (p 152). An additional problem was then discovered when outbreaks occurred in previously contained areas because some people had been missed. They had contact with an infected person but were working in the fields, or out shopping, or hidden when the containment team was vaccinating villagers. The containment teams countered this by asking an informant to list all the members of a household. Then the team and the watch guards spent extra time and effort to locate and vaccinate every person (Improvement Cycles).

“Effective evaluation allowed us to redeploy resources with confidence that the highest priority needs were being addressed” (p 174). Following a monthly search, ten villages in a district were randomly selected for evaluation (e.g., marks on doorways, interviews with household members: fidelity). With the evaluation teams in place, the key indicator of “outbreaks reported within 21 days of onset” reached 100% reporting and sustained at that level (fidelity). For any unexpected outbreaks, an “outbreak autopsy” (debrief session; Improvement Cycles) was performed to discover the reasons why. Delayed or incomplete containment actions (low fidelity) were the

primary reason (p 175). As the number of new outbreaks declined, resources were freed up to devote more attention to containing each new outbreak.

Enabling context

Given the scope of the problem, it was difficult to convince leaders that smallpox could be eliminated. “As more geographic areas became free of smallpox, it became easier to transmit this belief ... Once this [belief] was shared by a critical mass of people, no barrier was insurmountable” (p 53).

Transformation Zone

In one area of Nigeria in 1966, “Serendipity provided a chance for us to rethink the eradication strategy” (p 54) and move from a herd immunity approach to a surveillance and containment strategy. Given the limited supply of high quality vaccine in a remote area of Nigeria, the decision was made to vaccinate the person with smallpox and inoculate the family members, neighbors, and others who had contact with the infected person and were susceptible to the disease. The difficulty with this strategy is surveillance; how to find each person who has smallpox in a district, region, and country. Taking advantage of an existing network, the program leaders contacted missionaries in villages who then reported any cases of smallpox to the team. The person with smallpox was inoculated, and those who had contact with that person were located and inoculated to contain the spread. If any one of them already had smallpox, the containment strategy of locating and inoculating was repeated. This targeted approach conserved the supply of vaccine while effectively eliminating smallpox from a region of a country (p 59).

The decision was made to vaccinate the person with smallpox and inoculate the family members, neighbors, and others who had contact with the infected person and were susceptible to the disease. The difficulty with this strategy is surveillance; how to find each person who has smallpox in a district, region, and country.

Given the early indications of success, the team began training other health workers from Nigeria. They used stopwatches to see how fast the trainees could set up an immunization site, attach ropes for crowd control, set up the supplies, clean the injectors, and so on until they provided the first injection. The surveillance and containment strategy then was replicated in another region of Nigeria that reported an outbreak of smallpox. The success of the replication with newly trained staff provided sufficient confirmation that the targeted surveillance and containment strategy was more effective and efficient than the herd immunity mass inoculation strategy (p 59).

The experience in Nigeria led to the development of separate teams for surveillance and for containment. It was discovered that “there was a decided tendency to underreport cases if positive reports meant more work for the searchers” (p 110).

Developed out of necessity and replicated on purpose, the surveillance and containment strategy was established, and methods for developing the competencies of health workers were established in other regions in Nigeria. Smallpox was eliminated in Nigeria. The strategy did not rely on local health systems or providers. It had its own structure of teams to create teams (capacity to develop capacity) to promptly engage villages to contain outbreaks that were detected by the surveillance system. The surveillance and containment strategy developed and operationalized in Nigeria became the goal of implementation and scaling globally.

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Systemic Change

India already had made a substantial commitment to eliminating smallpox with an intensive campaign to vaccinate at least 80% of the population in three years (pp 98-99). A central organization was developed at the national level and in each state. District operating units were developed and provided with vehicles, vaccine, and other supplies. District units supported mobile teams that each included 72 vaccinators, 12 sanitary inspectors, two health educators, a paramedical assistant, and a medical officer. There were 152 mobile teams that employed over 13,000 staff. Even as these teams reached 80% coverage in an area, smallpox outbreaks continued unabated as the remaining 20% continued to contract and spread the disease. “The euphoria of starting a new program already had run into the brick wall of reality” (p 99). The first policy response was to increase the goal from 80% to 100%, an impossible and demoralizing goal for mobile team members who knew how difficult it was to achieve the 80% goal. A government study found that, for a variety of reasons, the vaccination-take rates varied greatly by district, and perhaps only 50% of the population had been vaccinated effectively (fidelity). In 1967, 830,000 new cases of smallpox occurred. At the policy level, there was the growing realization that “the number of vaccinations given is a meaningless figure.”

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By 1973 “everything was falling into place: government commitment, increased national and international resources, increased vaccination staff, sufficient vaccine of good quality, and easy system for vaccinating using bifurcated needles, a timely reporting system, and cross-notification of cases between districts to provide a national approach. However, smallpox still was not disappearing.” (p 104).

Executive leadership and management

India's top health officials and over 600 high level leaders were deployed from federal and state governments as well as universities, hospitals, and private industry. The federal leaders set monthly goals, had monthly meetings with state leaders and teams that "provided a rapid exchange of information and obligated program directors at central and state levels to be involved in the field." (p 124). Their task was to identify and overcome any obstacles and to assure good working conditions for those doing the work of surveillance and containment (Practice-Policy Communication Cycle). Leadership teams were established to reach shared objectives that superseded competition for turf among represented units. Once the management structure was in place, it provided a platform for making adjustments to assure the work was done at all levels.

When the surveillance and containment strategy was fully functional in India, the Indian government employed over 150,000 surveillance and containment team members and nearly 100,000 watch guards (p 152).

The management system included special teams of epidemiologists who were highly mobile and could go to unusual or intensive outbreaks to provide additional expertise and support. The special teams provided a way to incorporate outside experts into a country sensitive to intrusion by outsiders. Eventually, 30 countries contributed 235 consultants who served on the special teams, each bringing "fresh energy and new eyes" to the work during their three months in India. (p 136). Before doing any work in India, each consultant had three days of training on the technical components of surveillance and containment, procedures they were expected to follow, forms required for reporting, and the role of the monthly meetings to review data and make adjustments. Not all consultants were able to adapt and contribute. Over time the leaders learned to look for qualities that "are not found in the usual résumé or recommendations by supervisors." The qualities they began to look for were integrity, cultural sensitivity, and optimism (selection).

Recursive Practice-Policy Communication Cycles

The Executive Management Team in each state had a monthly meeting of 50 to 100 people for one day. The goal of each meeting was to review the work of the previous month and plan the goals and tactics for the next. Attendees included representatives of the federal government agencies, the state smallpox officer, state health and political leaders, district medical officers,

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special team members, urban health officers, and people from the blocks that were of special concern. The meetings were used to “get real-time feedback from field workers, pursue scientific inquiry, evaluate what was working and what was not, replenish funds and provide payment, and recharge the field-workers enthusiasm” (p 141). At the meetings, field workers shared innovations, and the effective innovations were quickly replicated and evaluated by others. Lessons from practice were identified and used to help meet targets that were set for the next month. The monthly meetings in each state and nationally kept leaders and others “looking for clues regarding what was working and what needed to be changed” (p 145).

At the meetings, field workers shared innovations, and the effective innovations were quickly replicated and evaluated by others. Lessons from practice were identified and used to help meet targets that were set for the next month.

In May 1974, for the first time, the number of contained outbreaks exceeded the number of new outbreaks in India. Even so, the number of new outbreaks was still large, over 800 new outbreaks per week. In that same month railway workers went on strike. This required planning for how supplies could be moved and distributed to outbreaks. The vaccinators in one state also declared their intention to strike for higher wages. Then India detonated its first nuclear device which led to global criticism and scrutiny of India, including criticism of the unacceptable incidence of smallpox. The political response was to abandon containment and surveillance and reinstate mass inoculation. “Whether effective or not, the known was preferred over the unknown” (p 169).

On May 27 the decision to return to mass immunization was to be announced at the monthly meeting of the smallpox group. After the Minister announced his intentions to the group, a young physician stood up and pointed out that if a house is on fire, no one wastes water on the nearby houses, they pour water where it will do the most good—on the house that is burning! This, he said, is the difference between mass immunization and the surveillance and containment methods. The Minister thought about this and decided on the spot to give them one more month. Coincidentally, on that same day the railway strike was settled and the other groups withdrew their threats to strike. The next month the data showed a decline in new outbreaks, and more dramatic declines occurred in new outbreaks in the following months—data that convinced the politicians and Minister to allow the program to continue beyond June 1974.

By May 1975 the last smallpox case was treated in India, 20 months after the surveillance and containment strategy was put in place. In late 1978 the last known case of smallpox in the world was treated and contained. Smallpox had been eliminated globally.

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