

SWOT Analysis: Strengths, Weaknesses, Opportunities and Threats of the Israeli Smallpox Revaccination Program*

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Abstract

During September 2002, Israel began its current revaccination program against smallpox, targeting previously vaccinated “first responders” among medical and emergency workers. In order to identify the potential strengths and weaknesses of this program and the conditions under which critical decisions were reached, we conducted a SWOT analysis of the current Israeli revaccination program, designed to identify its intrinsic strengths and weaknesses, as well as opportunities for its success and threats against it. SWOT analysis – a practical tool for the study of public health policy decisions and the social and political contexts in which they are reached – revealed clear and substantial strengths and weaknesses of the current smallpox revaccination program, intrinsic to the vaccine itself. A number of threats were identified that may jeopardize the success of the current program, chief among them the appearance of severe complications of vaccination. Our finding of a lack of a generation of knowledge on smallpox vaccination highlights the need for improved physician education and dissipation of misconceptions that are prevalent in the public today.

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During September 2002, Israel began its current revaccination program against smallpox, targeting previously vaccinated “first responders” among medical and emergency workers. The conception and planning of the Israeli revaccination strategy coincided with similar undertakings in the United States, but the decision to actually commence with revaccination was achieved only after much deliberation within the Israeli medical and national defense communities. The process of deliberation and planning brought to light various arguments in favor of and against initiation of revaccination. These arguments can be broadly categorized as pertaining either to intrinsic characteristics associated with the vaccine itself, or to extrinsic conditions associated with the prevailing sociopolitical environment.

Identifying the potential strengths and weaknesses of a new program, especially one as ambitious as a national revaccination effort, is critical for success. Programs should be tailored to exploit their inherent strengths, and contingency planning should address weaknesses so that their effects can be minimized. Business administrators have long recognized the necessity of understanding

strengths and weaknesses before implementing decisions, and commonly use an effective, intuitive and simple tool for conducting such analyses. This tool, known as SWOT analysis, identifies the intrinsic **strengths** and **weaknesses** of the organization and its proposed program, as well as **opportunities** and **threats** that exist in the external environment and must be utilized or avoided, respectively, in order to achieve success. SWOT analysis is a subjective tool, in that the administrator categorizes the strengths, weaknesses, opportunities and threats as they are perceived, rather than basing them on objective, quantifiable measures. The product that SWOT analysis provides is a map of pros and cons that can assist in assessing the likelihood that the proposed program or product will, in fact, succeed. We can use the SWOT model to conduct a cross-sectional assessment of the current smallpox “first responder” revaccination program in Israel. Mapping the relative strengths and weaknesses of this program, as well as the opportunities for its success and threats of its failure, can help understand the conditions under which critical decisions were reached and the environment in which the program is currently being carried out.

As of January 2003, 17,000 doses of smallpox vaccine have been administered in Israel in the context of the current revaccination program (unpublished data, Department of Epidemiology, Israel Ministry of Health). This is an ongoing process, and we have not finished learning from the collective effort of these last months. Nonetheless, performing a SWOT assessment at this time will provide an opportunity to discuss what we have done so far, to learn from our successes and shortcomings, and to teach others of our experience.

Strengths

Proven track record

There is no vaccine in history with a more prominent achievement record than the smallpox vaccine. The global program for integrated and concentrated widespread use of smallpox vaccine led to the first and only instance of global eradication of a disease [1]. Never before, and never since, has man succeeded in such a drastic step towards the improvement of global public health.

Two centuries of experience

Vaccination against smallpox was first used by Edward Jenner in 1796. Jenner's technique was crude by today's standards, involving scarification of the human subject with pus obtained directly from a bovine cowpox lesion [2]. Nonetheless, this technique proved

* This recommendation – SWOT analysis – regards preparedness for vaccination during peacetime. In emergency situations an alternative policy should be considered. *Editor.*

effective, and despite initial public skepticism and non-acceptance evolved to become a crucial element of preventive medicine. Vaccination continued to develop, with the vaccinia virus eventually replacing the cowpox virus for purposes of scarification. Several vaccinia strains were developed for use in vaccination and industrial production techniques improved over time. The scarification technique itself was also modified – with the more vigorous and penetrative methods used in the past due to low vaccine potency being replaced by the milder multiple punctures method widely accepted today [3].

In Israel, production of Lister-strain vaccine was shifted to embryonated chick eggs, while in other countries it continued to be harvested from calf lymph preparations [1,4]. In all, much practical experience in vaccine production and administration has been amassed over 206 years since Jenner's first use of vaccine. No other vaccine can claim such a vast body of experience in its use.

Usage

Routine smallpox vaccination of infants was initiated in Israel in 1918 with the occupation of Palestine by British forces, and continued uninterrupted at coverage rates at or near 90% until 1980 [5]. Routine vaccination of soldiers recruited to the Israel Defense Force continued until 1996. Thus, in 2002, the vast majority of the Israeli-born population over the age of 24 has been previously vaccinated against smallpox at least once, and in many cases twice or more. Institution of a revaccination program in Israel represents the reintroduction of a clinical practice routinely performed in Israel until quite recently.

Residual population immunity

Although the efficacy of vaccinia vaccine has never been measured in controlled trials, epidemiologic studies demonstrate that an increased level of protection against smallpox persists for less than 5 years after primary vaccination, while substantial but waning immunity may persist for 10 years or more [6]. There is some evidence implying the presence of vaccinia antibodies for as long as 30–35 years after vaccination [7,8]. As stated above, vaccination was routinely and effectively carried out in Israel for decades, with nearly all Israeli-born infants receiving at least two vaccines up to 1980, and most young adults receiving an additional dose upon induction to the IDF until 1996. Although the level of vaccine coverage among immigrants to Israel remains widely unknown [4], as do the significance and dynamics of waning immunity over time, it stands to reason that a substantial level of residual immunity to smallpox still remains in the overall Israeli population.

While certain subgroups of the population, such as children born after 1980, remain entirely susceptible to smallpox, the population as a whole could be therefore hypothesized to be somewhat immune, although to what extent is unclear. This residual immunity may likely decrease the risk of vaccine side effects associated with a revaccination program, as the rate of serious complications from vaccination is known to be lower in persons vaccinated in the past [9–12]. Furthermore, the existence of residual immunity may serve

to increase the robustness of the revaccination plan: even if 100% revaccination coverage is not attained, as can be expected, a certain proportion of the non-covered population would, in essence, be unaffected due to preexisting immunity.

Weaknesses

Non-existent disease

On 9 December 1979, the World Health Organization Global Commission declared the world free of smallpox. The conclusions and recommendations of the Global Commission included discontinuation of vaccination in all countries. These recommendations were accepted without change by the 33rd World Health Assembly on 8 May 1980, and by 1985 no country was carrying out routine vaccination against smallpox [3].

Despite certain concerns about the possibility of officially sanctioned variola virus falling into the hands of rogue organizations, the information available is vague and no evidence exists to prove this concern. Thus, a decision to revaccinate the population, or segments of the population, against smallpox translates into taking active preventive steps against a non-existent medical entity. Can the risk of a vaccination program, however small, be justified to the public when launched against a disease that ceased to exist some 20 years ago? This single point is most likely the leading weakness in any pre-event revaccination program against smallpox.

Anti-vaccination sentiment

Smallpox vaccine has historically endured a notorious reputation for poor safety and quality. Its earliest detractors voiced their objections at the time of Jenner's first use of cowpox vaccination, ridiculing the use of bovine pus in a medical procedure. Even today, scarification amounts to grafting what is essentially a bovine disease onto a human recipient. In 2002, smallpox vaccine is regarded by many as outdated, obsolete, sub-standard and perhaps even dangerous. The risks involved in its administration are not universally acceptable in the post-eradication age. Smallpox vaccine is associated with serious and life-threatening side effects such as encephalitis, eczema vaccinatum and generalized vaccinia. Even moderate and mild side effects associated with vaccinia vaccine, such as auto-inoculation and lymphangitis, are encountered at a rate and severity greater than that observed for other vaccines. The relative and absolute contraindications to vaccination among the household contacts of children, pregnant women and the immunosuppressed [6] serve to further focus attention on the issue of safety of the smallpox vaccine.

While the inherent risks of smallpox vaccination were unavoidable and thus acceptable in the pre-eradication era, they may not be justifiable in the post-eradication era, when vaccinees are exposed to risk without any measurable benefit.

Lack of VIG for treatment of complications

Vaccinia immune globulin is the only product currently available in Israel for treating the complications of vaccinia vaccination [13,14]. It has been estimated that even after the exclusion of candidates with known contraindications for vaccination, 250 vaccinees would

IDF = Israel Defense Force

subsequently require VIG for the treatment of unforeseen vaccine complications for every 1 million doses administered [15]. At the initiation of the revaccination program there were insufficient stores of VIG in Israel to treat the number of complications anticipated from a widespread vaccination campaign.

Vaccine production technology

As stated above, the first smallpox vaccines involved scarification of the human subject with pus obtained from bovine cowpox lesions. Although industrial production techniques developed over time, they continued to be based on the infection of calves with vaccinia virus and harvesting of virus from calf lymph for vaccine production [16]. In the 1960s, vaccine production in Israel shifted to culturing vaccinia virus on embryonated chick eggs. These *in vivo* production techniques allow for the possibility of unintentional contamination of the vaccine product by additional microorganisms of animal origin. Furthermore, the conditions under which the vaccine is produced, although proven satisfactory for decades, do not meet the standards of modern industrial production known collectively as “good manufacturing procedures” that are required today by manufacturers of other vaccines. Whether or not smallpox vaccine (the production of which started long before the introduction of GMP into the pharmaceutical lexicon) should be held to the GMP standard is debatable. There are those who claim that the semantic differentiation between “vaccination” (against smallpox) and “immunization” (against other diseases) is crucial: “immunization” describes the introduction of purified killed or attenuated human pathogens or their antigens or toxins into the human subject in an effort to stimulate a symptom-free immune response, while “vaccination” involves the grafting of a bovine pathogen onto the human subject in an effort to intentionally cause local signs and symptoms of a non-human disease (vaccinia). Unlike immunization, the endpoint of successful vaccination is the appearance of a visible sign of disease, namely the pustule of vaccine take. Thus, according to some, GMP – a standard appropriate for the manufacture of other vaccines – is *a priori* inappropriate for judging smallpox vaccine production.

While smallpox slept for nearly 25 years, vaccine technologies for other diseases leapt forward in great bounds, leaving the smallpox vaccine, suddenly reawakened in 2002, far behind its peers on the technology trail. Irrespective of whether GMP is the preferred measuring stick, the fact remains that smallpox vaccine is produced today under conditions inferior to those considered prerequisite for other preparations.

Professional isolation

Israel, so far, is alone in the arena of widespread smallpox vaccination. Its revaccination effort was planned and undertaken parallel to similar preparations in the United States, but Israel reached the vaccination stage before other countries. The Israeli campaign is under scrutiny of the U.S. and other countries, which view it as a “dry run” for their own strategy in terms of finding

undesirable side effects and transmission to immunodeficient contacts [17]. There are few if any data available with which to compare our initial results, and we cannot benchmark our achievements relative to those of others. Furthermore, difficulties that arise during the Israeli campaign must be addressed anew since it is impossible in certain matters to learn from the experience of others.

Opportunities

Global war on terrorism

The attack on the World Trade Center and the Pentagon on 11 September 2001 has changed the way the world interprets risk. Suddenly all theoretical threats have become conceivable, however remote the likelihood of their actual occurrence. Homeland security and defense against bioterrorism and weapons of mass destruction have become key issues for most developed countries, chief among them the United States. The discovery of envelopes containing anthrax in Florida, Washington and New York served as a catalyst to further intensify this reaction. Smallpox had always been considered a candidate for use as a weapon by terrorists, but very few states could be said to have an adequate response plan to cope with its intentional release.

The overall global concern about bioterrorism provides a unique and convenient opportunity to promote a smallpox vaccination campaign. A smallpox vaccination plan, which would have been deemed irrational before 9/11, has suddenly become prudent, perhaps even critical and urgent.

Dedicated proponents

The presence in 2002 of influential, vocal and persuasive proponents of pro-active smallpox vaccination has contributed to the overall design and speed of implementation of the Israeli vaccination plan. While this plan had both proponents and detractors, the former tended to be better voiced than the latter. Key proponents of vaccination, such as an organized group of former IDF Surgeons-General, were highly dedicated and motivated to protect the population from potential bioterrorist use of smallpox, and employed their collective influence and persuasion to promote various vaccination strategies. In their absence, it is possible that planning and implementation would have proceeded on a different course or at a slower rate.

Threat of war in Iraq

The looming threat of a U.S. attack on Iraq, together with the possibility (real or conceived) of deliberate retaliatory use of smallpox against Israel, set the stage for the immediate drafting of an emergency response plan to such an event. Although smallpox is considered to be a weapon of bioterrorism rather than a weapon of war, and thus in some way irrelevant to the imminent U.S.-Iraqi confrontation, the unfolding of events between the U.S. and Iraq cast a halo effect on Israeli preparation efforts, blurring the technical distinction between bioterrorism and biowarfare. The overall concern about encountering biologic agents in general served to transform smallpox preparation from a bottom-drawer contingency plan to an immediate-action plan.

VIG = vaccinia immune globulin
GMP = good manufacturing procedures

Unexpected vaccine supplies

While the Israeli vaccination plan was in its formative stages, the rate-limiting factor was perceived to be the number of available doses: there were simply not enough doses warehoused to permit vaccination of the entire population. The non-availability of a sufficient number of doses significantly limited the options of planners and decision makers in drawing up the Israeli smallpox response plan. It was at this stage that a fortuitous error was discovered: there had been a miscalculation of the size of the vaccine droplet necessary for effective vaccination. The miscalculation was of such an order of magnitude that in fact the stock on hand would suffice for the vaccination of a tenfold number of vaccinees. The problem of limited resources was eliminated, and the possibility of initiating a national smallpox vaccination plan became real.

Threats

Dissent within the medical community

The lack of a single harmonious message from the medical community is a major threat to the success of the Israeli smallpox preparedness plan. This lack of agreement can be seen on two levels – the first at the level of senior officials within the public health establishment, and the second at the clinical patient-oriented level.

Senior policy makers found it difficult to choose a vaccination strategy, and disagreed on whether to proceed with a preemptive, pre-release, population-based strategy, or to expectantly wait for a smallpox release event, utilizing the time until such an event to prepare for rapid, post-release vaccination. Disagreement still remains as to whether a future post-release response should proceed as focal trace vaccination or as mass, population-wide vaccination [18,19], and at what speed post-release response must proceed. According to some, the answer to these questions depends on the level of residual immunity in the general population and on the successful implementation of the “first-responder” revaccination campaign [19].

On the clinical level, physicians, untrained and inexperienced in smallpox prevention and uninformed by the formal medical establishment on current issues of vaccine strategy, are likely providing their patients with incomplete and possibly inaccurate information on vaccine safety and efficacy and on future plans for its use before, during or after a smallpox event. The public has been exposed to – and at times misinformed about – these issues by the press, and their physicians have not been provided to date with enough information to answer their questions. Furthermore, physicians who lack authoritative medical information on smallpox disease and vaccine tend to behave as laymen. It is our impression that physicians are among the leading detractors of smallpox vaccination today, as evidenced by an especially low rate of compliance for revaccination in the context of the current program (personal communication, Department of Epidemiology, Israel Ministry of Health). Thus, not only are physicians unavailable as a resource to promote smallpox revaccination, they may in fact be a hindrance to the success of the program. This will continue to be the case until physician education is successfully achieved.

Side effects

As mentioned above, the risk of serious vaccine side effects poses one of the major weaknesses of a pre-release smallpox vaccination plan. Accordingly, the actual occurrence of such a side effect poses a major threat to the success of such a plan. The expected rate of theoretical side effects is currently deterring a certain proportion of the target population from consenting to revaccination, but this effect can be considered minor compared to the deterrence to be expected after the actual appearance of severe complications. The publicized occurrence of encephalitis or death in even a single vaccinee will suffice to transform the potential energy of unease currently present in the public into kinetic energy of refusal. This threat has significantly shaped the current vaccination policy, which favors aggressive disqualification of potential vaccinees with questionable contraindications at the cost of a lower vaccination rate, instead of a more aggressive vaccination coverage at the potential cost of even a single severe vaccine-associated complication.

Conclusion

SWOT analysis is not designed to determine whether the situation is “good” or “bad.” It is a tool used to map the different forces acting at a given moment. This SWOT analysis shows that there are clear and substantial strengths and weaknesses in the current smallpox revaccination program, intrinsic to the vaccine itself. There are also a number of threats that may jeopardize the success of the current program, the most important being the appearance of severe complications of vaccination. Clearly, a generation of knowledge on smallpox vaccination is lacking, as evidenced by the advances in immunization made for other diseases over the last three decades while smallpox was essentially frozen in time. Routine smallpox vaccination was easy to stop in 1980, but it is proving quite difficult to restart 22 years later. In order to reintroduce smallpox vaccination more successfully, we must improve physician education and dispel misconceptions that are prevalent in the public today. This can be done only through open communication both within the medical community and without. Finally, the gap in vaccine production technology must be bridged to adapt Jenner's eighteenth century innovation to twenty-first century vaccine-production standards.

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