11

Guidelines for Preparing an Eradication Investment Case

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Abstract

This chapter describes ongoing efforts to develop guidelines for the development of an eradication investment case (EIC). While a single process for the creation or updating of an EIC will likely not exist, three phases of an EIC are proposed (pre-launch, implementation, and completion) and a number of important assumptions associated with the process are highlighted. This chapter updates the list of the "critical elements" of an EIC identified at the Ernst Strüngmann Forum and summarizes a meeting convened afterward to create a template for the EIC guidelines. The intent of the guidelines is to assist analysts with respect to methodological challenges and to ensure completeness. They are an extension of the work accomplished at the Forum and have benefited from additional expertise in the areas of economics and ethics. The final product is envisioned to be practical in nature, going beyond a description of what to do, by describing how to do it with respect to some core methodological issues. This chapter summarizes the work to date and updates the list of the "critical elements" identified at the Forum.

The Process of Preparing an Eradication Investment Case

The term *eradication investment case* (EIC) was conceptualized by Thompson et al. (this volume) as the virtual counterpart of the GAVI Vaccine Investment Case (GAVI Alliance 2004), which is the body of data presented to the GAVI Alliance upon which an evaluation is based and investment commitments are made to finance the introduction of vaccines for low-income, eligible countries. Although decisions for both investment cases require donor and country financing as well as action, there are significant differences. First, while the GAVI Alliance represents the major fund for purchase of vaccines for low-income countries, no such single parallel organization exists for global eradication initiatives. Second, the decision to introduce or scale up a vaccine does not require concerted action from multiple countries, as is critical to an eradication initiative. Third, inherent in an eradication initiative is the need to reevaluate

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strategies and raise funds late into the program, when disease levels are low or nonexistent, but crucial surveillance and other post-elimination activities must be sustained.

The EIC can thus be conceived as having three phases. In the first *pre-launch phase*, it represents the business plan created with the input of the broad array of funding and implementing partners whose participation is critical to seek funding and cross the line from control to an eradication program. As such, it is a tool that formalizes the ability to analyze the strategies, requirements, risks, and management tools required for success. In the second *implementation phase*, it is transformed into a tactical and financial plan, which must be updated periodically, to address the programmatic and financial challenges that emerge. Ultimately, in the final *completion phase*, it must make a compelling and credible case for completing the task, made particularly challenging at a point when disease levels are extremely low and the disease does not itself represent a national priority based on burden of disease. In the completion phase, financing becomes hostage to donor fatigue, and the progress and costs to the final goal are most challenging.

Given the various ways that eradication initiatives are historically organized and implemented, it is difficult to conceive of a single process for the creation and updating of the EIC. It might be useful, therefore, to consider instead some assumptions regarding the process that emerged from the Forum discussions:

- The decision to create an EIC will have been preceded by a substantive body of work that compels the relevant community to envision global eradication. Thus, the length of time required to compile the EIC must allow for writing the plan, building consensus around implementation strategies, and critical review. Ultimately, however, it will depend on the robustness of the supporting database.
- The role of the champion was recognized as critical for success, but a champion is also clearly biased toward action. Thus, during the pre-launch phase, as the science base is being constructed, the EIC may benefit from being coordinated by a neutral body. However, it must engage the leadership of the community and be "owned" by the relevant experts.
- The systematic construction and evaluation of the EIC can become a powerful tool for the evaluation of competing eradication initiatives. Similarly, it can generate additional thinking around synergies with other disease control and eradication initiatives that leverage human and financial resources.
- It became clear in discussion with leaders of previous initiatives that what is new here is not the creation of a plan for presentation to global policy and decision-making bodies, but rather the attempt to systematize the elements, advance a core methodology, and ensure that appropriate review is conducted.

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- Evidence-based external review is critical for credibility and can be achieved through open and blinded review, publication in peer-reviewed literature, and analysis by stakeholders. Some of the key groups capable of evaluating substantively include the technical advisory groups for disease initiatives: the World Health Organization (WHO) expert review, the Carter Center's International Task Force for Disease Eradication, and special commissioned reviews.
- There are a number of potential customers for such an analysis and versions of the final document. These include disease experts, Ministers of Health of affected countries, particularly as embodied by the WHO, regional offices, and advisory groups, and its World Health Assembly; donors (countries, bilaterals) and other funders (philanthropy); civil society and other local implementing partners; and, finally, the people in affected countries who must ultimately be willing to engage in such an endeavor.

As envisioned, the EIC would become the basis for subsequent advocacy, but it does beg the question as to how financing for an eradication initiative can be facilitated. Leadership, technical consensus, and a clear business plan are all necessary components, but would ideally align against the ability to raise funds of the magnitude required for such a program. The Forum considered some innovative approaches to accomplishing this (Thompson et al., this volume), and if such a mechanism were to be created, we believe its effectiveness would be facilitated by having a clearly laid out, reviewed and accepted EIC.

The Boston Meeting

At the Forum, Thompson et al. (this volume) recommended that "efforts should be undertaken to develop specific guidelines for EICs that may help to standardize the process, assist analysts with respect to methodological challenges, and ensure completeness." With the goal of creating a template for the EIC, a subsequent meeting was convened in Boston, Massachusetts, on December 9–10, 2010, to begin the process of standardizing the methodology required to prepare an EIC in support of the decision-making process involved in launching an eradication initiative. The final product, *Guidelines for Preparing an Eradication Investment Case*, is envisioned to be a practical document that describes what needs to be done and, in a few instances, delineates how to do it (e.g., discounting future benefits). To ensure that the development of the EIC guidelines met the expectations expressed at the Forum, additional expertise was brought into the process (Box 11.1). To structure the meeting, we began with the provisional list of critical elements necessary for an EIC identified by Thompson et al. (this volume). Participants were assigned a selection of these elements to develop in advance of the Boston meeting. Small groups were

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Box 11.1 List of participants to the EIC methodology workshop held in Boston, MA, December 9–10, 2010.

Kimberly Thompson* Kid Risk, Boston, MA, U.S.A. (Moderator)
Damian Walker* BMGF, Seattle, WA, U.S.A. (Rapporteur)
Debbie Atherly PATH, Seattle, WA, U.S.A.
David Bishai Johns Hopkins School of Public Health, Baltimore, MD, U.S.A.
Lesong Conteh* Imperial College, London, U.K.
Radboud Duintjer Tebbens Kid Risk, Boston, MA, U.S.A.
Claudia Emerson* McLaughlin-Rotman Centre for Global Health, Toronto, Canada
Lee Hall* National Institutes of Health, Bethasda, MD, U.S.A.
Raymond Hutubessy World Health Organization, Geneva, Switzerland
Julia Lupp Ernst Strüngmann Forum, Frankfurt, Germany
James Lavery McLaughlin-Rotman Centre for Global Health, Toronto, Canada
Jacqueline Leslie Imperial College, London, U.K.
Ann Levin Independent consultant, Bethesda, MD, U.S.A.
Maria Merritt Johns Hopkins School of Public Health, Baltimore, MD, U.S.A.
Regina Rabinovich* BMGF, Seattle, WA, U.S.A.
Fabrizio Tediosi Centre for Research on Health and Social Care Management, Bocconi University, Milan, Italy
Anna Vassall London School of Hygiene and Tropical Medicine, London, U.K.
Maya Vijayaraghavan* Centers for Disease Control and Prevention, Atlanta, U.S.A.
* Member of the discussion group at the Ernst Strüngmann Forum
Peter Singer, a member of the original discussion group, was unable to participate

assigned on the basis of each participant's area of expertise, recognizing that all participants were expected to provide feedback on other elements not assigned to them at the meeting.

Participants were sent a copy of the *Guidelines for Preparing Proposals for GAVI/Vaccine Fund Investment*, because they were perceived to be a useful starting point (notwithstanding a number of important differences in the nature of the investment decisions noted above; see also Thompson et al., this volume). In addition, an example of a submitted investment case, *Accelerating the Introduction of Rotavirus Vaccines into GAVI-Eligible Countries* (PATH's Rotavirus Vaccine Program 2006), which had been worked on by Deborah Atherly, one of the participants, was provided. For the sections of the EIC that focus on the economic evaluation of eradication compared to the status quo, the EIC builds on the WHO's guide for standardization of economic evaluations of immunization programs (WHO 2008a) adding to that framework to account specifically for eradication-related issues (e.g., discounting and intergenerational equity, costing the "last mile"). Participants also referred to their own work on eradication (see, e.g., Emerson and Singer 2010; Duintjer Tebbens et al. 2011) as well as recent efforts to examine the technical feasibility of measles

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(WHO 2010a) and malaria eradication (e.g., work of the Malaria Eradication Research Agenda and the Malaria Elimination Group). Participants sent drafts of their sections to Damian Walker, in advance of the meeting, so that a first complete draft of the EIC document could be prepared. In Boston, the participants then worked through this document together, discussing in detail each section and sub-section. As a result of these deliberations, the list of critical elements was revised (Box 11.2).

Structure of the EIC Guidelines

The EIC guidelines are structured around the revised list of critical elements (Box 11.2). To provide requisite guidance, each element begins with a brief description of what the section should cover and why. Where appropriate, recommendations will be made to promote standardized methods (e.g., discounting and intergenerational equity, type of modeling). For example, the choice of discount rate is particularly critical when evaluating the cost-effectiveness of an eradication program. Whereas most general guidelines recommend that health effects be presented as both discounted and undiscounted values, in the context of an eradication program, a zero discount rate for health effects would lead to an intractable analysis due to the infinite benefits arising from a successful eradication program. Therefore, a near-zero discount rate for health effects, lower than the rate for costs, could be considered. An alternative approach to recognizing the intergenerational benefits of successful eradication of a disease is to apply a nonconstant discount rate (declining or "slow") when presenting results (Jamison and Jamison 2003). The EIC guidelines will provide guidance on this core methodological issue.

Each section will also be accompanied by a series of questions to ensure that the group developing an EIC for a specific disease addresses each issue in sufficient detail. These questions will also form the basis of a checklist designed to help promote complete submissions and assist external review of submissions. To illustrate this approach, the preliminary text from Section I.4 is presented in Box 11.3. This section addresses the issue of public goods obtainable by eradication.

In general public health represents a *public good* in the sense that the "benefits to one person cannot readily be individuated from those to another" (Faden and Shebaya 2010). In economic parlance, public goods are collective goods (e.g., disease prevention) that resist efficient market allocation because they can be provided for some people only through efforts that will inevitably benefit others ("free riders"). The prospect that free riders will benefit from a public good without assuming the burdens of producing it is likely to reduce the motivational power of self-interest as an incentive to assume those burdens. For this reason, some public goods may be obtainable only through nonmarket actions (Powers and Faden 2006:144–145). Some public goods in the economic

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Box 11.2 Revised structure of the EIC Guidelines.

Section I: The Proposed Investment

- I.1 Description of the disease and its global health significance
- I.2 Characterization of the status quo
- I.3 Articulation of a specific plan for achieving eradication,
- I.4 Discussion of the public goods obtainable by eradication
- I.5 Discussion of the need for cooperation to obtain the public good

Section II: Rationale for Investing

- II.1 Documentation of biological and technical feasibility and review of evidence related to proof of concept
- II.2 Indications that stakeholders do or do not want eradication
- II.3 Projection of burden of disease expected over the time horizon for analysis: status quo vs. the eradication effort
- II.4 Anticipated ethical, social, and political challenges and constraints associated with eradication
- II.5 Discussion of how the global plan integrates with and strengthens health systems
- II.6 Identification of risks associated with eradication
- II.7. Discussion of the "critical" risks over the entire time horizon of the plan, including the post-eradication stage
- II.8 Assessment of total costs associated with an eradication plan
- II.9 Assessment of health outcomes associated with eradication plan
- II.10 Transparent discussion of broader social impacts
- II.11 Assessments of cost-effectiveness and benefit-cost
- II.12 Discussion of projected impacts on demand and supply of the interventions and the effect on prices and availability
- II.13 Discussion of capacity of qualified staff and technical resources
- II.14 Discussion of assumptions about post-eradication plans

Section III: Leadership, Management, and Governance

- III.1 Discussion of proposed eradication initiative partnerships and the plan for governance
- III.2 Establishment of critical milestones and the plan for monitoring, oversight, and evaluation of milestones
- III.3 Assessment of diagnostic tools for monitoring
- III.4 Discussion of the risk management plan for critical risks
- III.4 Discussion of the operational research plan and the proposed strategy for how operational research would be supported
- III.5 Discussion of the proposed process for active evaluation of any impacts on health systems

Section IV: References

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Box 11.3 Preliminary text to one section of the EIC Guidelines.

Section I.4 Discussion of the Public Goods Obtainable by Eradication

This section should describe why eradication would contribute uniquely to the attainment of public goods. It should thus answer whether eradication is necessary to provide, protect, and promote the public good in question. It should define what economic public goods would be obtained through eradication, and how these benefits can be captured quantitatively. In doing so, it may be helpful to answer the following questions:

- What public goods are already served by the status quo?
- Are there unique public goods that arise from eradication that do not arise from the status quo? What is special/different about zero incidence as compared with status quo
- Are there incremental gains in public goods to which eradication will contribute?
- Are there any failures in the provision, protection, or promotion of public goods that can be remedied, if at all, only by eradication? Addressing this question will require making the case that eradication remedies the failure.
- What is the nature of the economic public goods?

sense also contribute to aspects of the *common good* as understood in political philosophy. To serve the common good is to serve the interest held in common by all members of the public in "self-protection or preservation from threats of all kinds to their welfare" (Beauchamp 2007).

The investment case for eradication should focus on its *unique* contributions to public goods. For any eradication candidate, we expect that the status quo already incorporates concerted efforts to promote multiple public goods. For instance, the status quo should already promote public confidence and global security; eradication activities should continue to do so. The relevant question then becomes: How does eradication provide, protect, and promote public goods in ways that the status quo cannot? For purposes of this comparison, the EIC may also consider contributions to public goods that are necessary means to achieving eradication and are unlikely to be pursued otherwise (e.g., international cooperative financing mechanisms). To the extent that these contributions may remain in place post-eradication (based on realistic expectations), can they be obtained *only* as part of the eradication effort?

Conclusions

Although it is unlikely that any one single process can support the creation or updating of an EIC, we propose three general phases:

- A *pre-launch phase* enables an analysis of the strategies, requirements, risks, and management tools required for success. It is the "business

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plan," developed through the input of a broad array of partners, whose participation is critical in crossing the line from control to an eradication initiative.

- The *implementation phase* transforms the business plan into a tactical and financial plan—one which must be updated periodically to address emerging programmatic and financial challenges.
- The *completion phase* focuses on work necessary to complete the task (e.g., donor fatigue or challenges that result when disease levels are extremely low and the disease does not represent a national priority based on burden).

Efforts are underway to develop guidelines to support this process. These EIC guidelines are intended to assist analysts with respect to methodological challenges and ensure completeness when preparing the EIC. The development and finalization of the guidelines requires, however, its own process of review and revision. Once a final draft has been prepared, it will be subjected to rigorous, open and transparent review.[1] In addition, the guidelines will also be revised in light of feedback received from groups who submit EICs, and over time, as an EIC moves through the phases of pre-launch, implementation, and completion.

As efforts continue to confront the incalculable misery caused by scourges of disease, it is our sincere hope that the EIC will prove to be a useful tool to the many different stakeholders involved. We look forward to seeing the first applications of the guidelines.

[1] For current information on the EIC guidelines, see www.eic-guidelines.org

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