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Guide to Preparing an Eradication Investment Case

Damian Walker[1] and Julia Lupp[2]

[1] Global Health Program, Bill & Melinda Gates Foundation, Seattle, WA, U.S.A.

[2] Ernst Strüngmann Forum, Frankfurt am Main, Germany

Contributors:

Deborah Atherly, PATH, Seattle, WA, U.S.A.
David M. Bishai, Bloomberg School of Public Health, Johns Hopkins, Baltimore, MD, U.S.A.
Lesong Conteh, Institute for Global Health, Imperial College London, South Kensington Campus, London, U.K.
Radboud J. Duintjer Tebbens, Kid Risk, Inc., Newton, MA, U.S.A.
Claudia I. Emerson, University of Toronto, McLaughlin-Rotman Centre for Global Health, Toronto, Ontario, Canada
B. Fenton Hall, Division of Microbiology and Infectious Diseases, NIAID, NIH, DHHS, Bethesda, MD, U.S.A.
Raymond Hutubessy, World Health Organization, Geneva, Switzerland
James V. Lavery, McLaughlin-Rotman Centre for Global Health, Toronto, Ontario, Canada
Jacqueline Leslie, Imperial College, London, U.K.
Ann Levin, International Health Economist, Bethesda, MD, U.S.A.
Maria W. Merritt, Johns Hopkins Berman Institute of Bioethics and Bloomberg School of Public Health, Baltimore, MD, U.S.A.
Regina Rabinovich, Global Health Program, Bill & Melinda Gates Foundation, Seattle, WA, U.S.A.
Fabrizio Tediosi, Department of Institutional Analysis and Public Management, Centre for Research on Health and Social Care Management, Università Bocconi, Milan, Italy
Kimberly Thompson, Kid Risk, Inc., Newton, MA, U.S.A.
Anna Vassall, Department of Global Health and Development, London School of Hygiene and Tropical Medicine, London, U.K.
Maya Vijayaraghavan, Global Immunization Division, Centers for Disease Control, and Prevention, Atlanta, GA, U.S.A.

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Background to the Process

This Guide is the result of numerous interactions and contributions. It began at the steering committee meeting (Frankfurt, Sept. 28–30, 2009) for the 7th Ernst Strüngmann Forum, when Regina Rabinovich stressed the need to focus discussion around the concept of an eradication investment case (EIC). At the resulting Forum, held in Frankfurt from Aug. 29–Sept. 3, 2010, a working group comprised of Lesong Conteh, Claudia I. Emerson, B. Fenton Hall, Regina Rabinovich (moderator), Peter A. Singer, Kimberly M. Thompson (rapporteur), Maya Vijayaraghavan, and Damian G. Walker endeavored to conceptualize the investment case and identify its key components. For a report of the group's discussions, see Thompson et al. (2011). At the Forum, it became clear, however, that additional work would be needed to transform this conceptualization into a usable form to ensure effective implementation.

Spearheaded by Damian G. Walker, a follow-up meeting was planned, and additional expertise brought in, to generate a guide that would assist in the actual development of an EIC. Held in Boston on Dec. 9–10, 2010, this meeting was attended by Deborah Atherly, David Bishai, Lesong Conteh, Claudia I. Emerson, B. Fenton Hall, Raymond Hutubessy, Ann Levin, James V. Lavery, Jacqueline Leslie, Julia Lupp, Maria W. Merritt, Regina Rabinovich, Radboud J. Duintjer Tebbens, Fabrizio Tediosi, Kimberly M. Thompson (moderator), Anna Vassall, Maya Vijayaraghavan, and Damian G. Walker (rapporteur). An extensive process of revision and review followed, coordinated by Julia Lupp, and has resulted in this document.

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Stephen L. Cochi served as the scientific chairperson of the Forum. The steering committee was comprised of R. Bruce Alyward, Stephen L. Cochi, John O. Gyapong, David Molyneux, Eric A. Ottesen, and Regina Rabinovich.

Stephen L. Cochi and Walter R. Dowdle were the volume editors of the Strüngmann Forum Report, and provided guidance and critical review of this Guide. Additional input was received from external reviewers and is gratefully acknowledged.

The Bill & Melinda Gates Foundation provided the financial support for the Boston meeting, and Kimberly Thompson hosted the meeting at Kid Risk, Inc.

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Preface

The sustained eradication of an infectious disease agent, in which humans are the primary or sole host, was achieved for the first and only time in 1980 when the World Health Assembly declared the world free of smallpox. This declaration followed a campaign that began in 1959 and involved the tireless efforts and commitment of many people and institutions around the globe. Building on the experiences from this program, concepts and definitions associated with disease eradication were subsequently subjected to intense examination (Dowdle and Hopkins 1998; WHO 1998; CDC 1999), and attempts have since been made to develop general as well as specific criteria to guide the decision-making process inherent in evaluating future candidate diseases (e.g., Cochi and Dowdle 2011).

Because an eradication initiative is a major societal investment, nothing short of a systematic, comprehensive analysis of feasibility and impact is needed to support the decision-making processes involved in launching an eradication initiative. Such an analysis must include a full examination of the challenges and opportunities of a decision to move forward as well as the factors associated with the likelihood of success or failure.

The *eradication investment case* (EIC) has been conceptualized as the body of data upon which evaluations will be based and investment commitments made when new eradication initiatives are established (Thompson et al. 2011; Walker and Rabinovich 2011). As conceived, an EIC consists of four phases:

1. The *prelaunch phase* analyzes the strategies, requirements, risks, and management tools required for success, and it delineates the rationale for moving from disease control to disease eradication. A multidisciplinary approach is necessary to develop this analysis and requires the expertise from wide-ranging fields (e.g., epidemiology, ethics, economics, health systems).
2. The *implementation phase* transforms the results of the prelaunch phase into tactical and financial plans. These plans must be updated periodically to ensure that emergent programmatic and financial challenges are addressed.
3. The *completion phase* focuses on completing the task of eradication. Here, a compelling and credible case is set forth, and challenges specific to the "last mile"[1] are addressed (e.g., when the burden of disease no longer is viewed as a national priority, when financing becomes threatened by donor fatigue, when progress and costs to achieve the final goal are most challenging).
4. The *post-eradication phase* describes those activities which must be sustained in the post-eradication world, and the commitments required.

Several assumptions and guiding principles were identified regarding the EIC process:

- The decision to create an EIC will have been preceded by a substantial body of work that compels the relevant community to envision global eradication.
- The length of time required to compile an EIC must allow sufficient time to write the plan, build consensus around implementation strategies, and enable critical review. A robust, supporting database is critical.
- A complete EIC should be prepared during the prelaunch phase. Thereafter, during the implementation and completion phases, the EIC should be revisited in light of new and better data, and greater detail should be provided for certain elements (e.g., challenges, risks, and constraints, as well as estimating the costs of reaching the last mile). Similarly, if eradication is achieved, the post-eradication phase of the EIC will also need to be revisited.
- Although the role of the champion is recognized as critical for the overall success of the eradication initiative, in the prelaunch phase as documentation is prepared, an EIC may

[1] "Last mile" refers to all of the issues involved in reaching people who are hardest to access: those living in remote or inaccessible areas as well as those who resist or decline interventions. These individuals or communities are the hardest and therefore most expensive to reach.

benefit from being coordinated by a neutral body. Engaging the leadership of the community as well as relevant experts is crucial during this stage.

- The systematic construction and evaluation of an EIC can become a powerful tool to assess competing eradication initiatives. Similarly, the process may serve to generate additional ideas (e.g., synergies with other disease control and eradication initiatives) and thus enable human and financial resources to be more effectively utilized.
- An EIC 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 *before* such presentations are made.
- External review is critical for credibility and can be achieved through open and blinded review, publication in peer-reviewed literature, and analysis by stakeholders. Examples of key groups capable of substantive evaluation 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.

Since eradication initiatives have historically been organized and implemented in various ways, it is difficult to conceive of a single process that can create and update necessary information for all diseases. Equally so, the creation of a template capable of addressing all possible circumstances has been a challenge. This Guide must therefore be considered a work in progress. As experience is gained in using an EIC, it is hoped that feedback from these efforts will inform future improvements to this Guide.

This Guide is organized around the critical elements that should be addressed in an EIC. In the main document, an overview of each element is given. Guiding questions that should be considered for each element are listed in Appendix A.

Commensurate with the multidisciplinary input required to prepare an EIC, it is envisioned that many different groups will benefit from the ultimate product: disease experts; Ministers of Health from affected countries, particularly as embodied by the WHO, regional offices, and advisory groups and its World Health Assembly; multilateral and bilateral funding agencies as well as other contributing institutions (e.g., philanthropies); civil society and other local implementing partners. Most importantly, however, an EIC is intended to aid the very people who stand to benefit from eradication efforts: those from affected countries, who must ultimately be willing to engage in such an endeavor; people from non-affected countries, who will benefit in numerous ways from an improved global health landscape; and, of course, future generations.

Section I: The Proposed Investment

I.1 The disease and its global health significance

Current information should be provided on disease incidence, prevalence, case fatality or mortality rates, morbidity, as well as social and economic burden in the target environments, groups, or regions of the proposed eradication initiative. Host reservoirs or aspects of transmission should be identified that are relevant to the design and effectiveness of the proposed eradication initiative.

I.2 Current state of control efforts

Describe current disease control efforts, including vaccines, therapeutics or other prophylactic measures, interventional strategies, and other relevant activities. Include graphic representation of how cases and coverage of interventions have evolved over time: where control efforts stand today versus where they might be in the future. Assumptions regarding the future trajectory of the current control efforts (disease and coverage of interventions) should be clearly stated. Include a discussion of the relative success of current efforts in achieving coverage and limiting the disease burden as well as a discussion of the major issues that limit current efforts. Examples of the latter include: problems of demand; not seeking available interventions because of a lack of resources, information, political will, or other causes; not reaching those in need because of poorly equipped logistics or delivery systems in the most remote regions; difficulty in targeting key populations; weak management, inadequate training capacity/or technology.

I.3 How can eradication be achieved?

Specify the plan for achieving eradication. Describe the activities to be carried out and outline how the project will conform to different implementation environments. Provide a timeline for the entire scope of the eradication plan (i.e., prelaunch, implementation, and completion phases as well as post-eradication activities) and delineate critical dates for project implementation of the work plan. Include a discussion of the ability of implementers to adapt the plan to differing implementation environments.

I.4 Post-eradication scenarios

The impact of reemergence or emergence of the pathogen is a complicated issue, thus motivating the careful consideration of appropriate alternative scenarios to inform judgments and subsequent evaluation. Various factors should be critically evaluated, including the proposed period of time required to confirm or certify eradication and the proposed period of time, post-confirmation, that post-eradication activities must be sustained. These factors fall into two general categories: (a) the economic, public health, and social impact of a reemergence scenario and (b) the determinants (biological, public health, and organizational) of a post-eradication scenario.

Section II: Rationale for Investing

II.1 Biological and technical feasibility

The basis for eradication is critically dependent on the premise that transmission of a pathogen can be effectively interrupted and reduced to a non-sustainable level. This demands a thorough understanding of the natural history of the pathogen. Here, evidence of biological and technical feasibility must be provided.[2]

When evaluating the feasibility of eradication, it is important to ascertain whether current diagnostic tools are sufficiently capable of identifying symptomatic as well as asymptomatic, latent, or dormant cases or infections which might serve as reservoirs to reinitiate transmission. Similarly, it may be important to have diagnostic tools that can provide an accurate assessment of transmission potential during periods of apparent epidemiologic vulnerability (e.g., low seasons of transmission) so that optimal timing of interventions can be determined.

Thus, the performance of interventions and diagnostic tools during the different phases of an eradication effort should be considered. In situations of high incidence, a diagnostic tool with high specificity is critical to avoid misclassification, which in turn could lead to overreporting of the burden and under-reporting of the potential impact of interventions. In contrast, in situations of low incidence and as successful eradication efforts proceed, diagnostic tools with high sensitivity are needed to obtain high confidence in eradication in the absence of detected cases and to identify and manage potential cases quickly and appropriately to prevent reestablishment of transmission.

II.2 Health, social, and economic burden of disease

Provide an analysis that will predict the level of improvement in the health, social, and economic outcomes by comparing eradication with one or more control scenarios. The outcomes to be assessed for both the comparator and eradication plans should include the number of cases, deaths, and DALYs as well as the use of health services and economic productivity. Discuss the social implications of the disease (e.g., stigma) and the extent to which these compound the economic burden (e.g., by limiting productivity). Analysis should include appropriate stratification to allow for different paths to eradication in different settings (e.g., by income level and/or region).[3]

Since the choice of comparator scenario(s) fundamentally impacts projections of disease burden and costs, and hence the interpretation of overall findings, the comparator scenario(s) and eradication plan under evaluation must be clearly described.

Use of current control efforts for the comparator implies that the current policies and levels of control would continue indefinitely and that the burden follows from extrapolation of the current burden, correcting for projected population growth and commitments of current policies. The level of control, however, may increase even in the absence of a coordinated eradication effort. Thus, analysis should consider any credible scenarios for the comparator.

For the eradication intervention, the analysis should project the burden of disease until global eradication occurs and include the post-eradication era covered under the analytical time horizon (Section I.3). Even after eradication has been achieved on a national level, risk of importing the causative agent from countries with continued transmission remains until global eradication has been achieved. The consequences of such an introduction will depend on the population immunity levels maintained after national eradication. Thus, projections of the disease burden under the

[2] Hinman and Hopkins (1998:20) identified three criteria for the scientific feasibility of eradication: (1) availability of an effective, practical intervention (e.g., vaccine or other primary preventive, curative treatment, and means of eliminating the vector); ideally, the intervention should be effective, safe, inexpensive, long-lasting and easily deployed; (2) demonstrated feasibility of elimination (e.g., documented elimination from island or other geographic unit); and (3) epidemiologic vulnerability (e.g., existence of a nonhuman reservoir, ease of spread, natural cyclical decline in prevalence, naturally induced immunity, ease of diagnosis, and duration of any relapse potential).

[3] The path toward eradication in each country depends on the projected level of intensity of efforts (i.e., routine vaccination coverage and frequency and coverage of supplemental campaigns for vaccine preventable diseases, or intensity of measures for nonvaccine preventable diseases) over time. Modeling the impact of various control levels on transmission typically involves a herd effect of reducing individuals' ability to participate in transmission, which requires some form of dynamic modeling.

eradication scenario require realistic assumptions about the level of effort required after national eradication. In addition, risks of reintroduction of the causative agent may exist, and the consequences of these rare events should be modeled.

II.3 Assessment of total costs

Provide estimates of the total financial and economic incremental costs of the eradication plan compared to current control efforts. Include a summary of the expected resource use and unit costs for each alternative. The estimation of the costs of scaling up interventions and covering the "last mile" are features unique to eradication programs. If feasible, particular attention should be paid to the derivation of cost functions used for these estimates.

II.4 Cost-effectiveness and cost-benefit analyses

Describe the costs and effects obtainable through eradication during the pre- and post-eradication period, and include endgame activities required to sustain eradication of the disease. Due to the long time horizon involved in eradication, alternative approaches to discounting may be justified. Both costs and effects occurring in the future should be evaluated according to a standardized scenario (e.g., discounted using a 3% discount rate). However, it is recommended that a sensitivity analysis be provided using discount rates of 0%, near-zero, and 10% to reflect the (probably) higher, real risk-free cost of capital in developing countries. The analysis should compare incremental costs and effects and specify the incremental cost-effectiveness threshold below which eradication will be considered an efficient use of resources. Options may include the use of multiples of GDP per capita or other commonly funded investments in global health.

Because successful eradication programs produce an infinite stream of health benefits, constant discounting may appear to undervalue the future; any constant rate much above zero will then give benefits to future generations almost no weight. Conversely, a zero discount rate for health effects could lead to undesirable implications, such as infinite benefits arising from successful eradication programs. Therefore, a discount rate for health effects that is lower than the rate for costs, but above zero, should be considered when presenting results. Analysts are encouraged to check the sensitivity of their results to the application of a nonconstant discount rate (declining or "slow" compared to exponential discounting; i.e., discounting at a constant rate).

Cost-benefit analysis requires monetary estimates of effects. An objective and careful cost-benefit analysis can demonstrate the returns on investments (RoI) in an EIC compared to investments in other sectors. In cost-benefit analysis, productivity gains and externalities can be taken into account as benefit increases or cost decreases. The pathways through which eradication can affect economic activity, both at the individual household and population level, are numerous (e.g., the RoI in vaccinations may be captured by improvements in cognitive development and worker productivity but may also have macroeconomic consequences in sectors of the economy other than the health sector). Demonstrate the mechanisms through which health can affect income (e.g., productivity, children's education, savings and investments, and demographic structure) (WHO 2009).

Examine the cost-effectiveness and cost-benefit analyses for sensitivity to possible variations in the values of critical parameters. Discuss the implications of the sensitivity analysis for project design and provide a summary of the analysis in table form and graphical representations.

II.5 Public goods obtainable through eradication

Here the focus is on the *unique* contribution(s) that eradication can make to public goods.[4] For any candidate disease for eradication, current control efforts can be expected to already contain

[4] Public health, in general, 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 those collective goods, such as 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,

concerted efforts to promote multiple public goods (e.g., public confidence, global security). Thus the relevant question is: How will eradication provide, protect, and promote public goods in ways that current and projected control efforts cannot?

Highlight contributions to public goods that will be achieved through eradication and which are otherwise unlikely to be pursued (e.g., international cooperative financing mechanisms). To the extent that these contributions may remain in place post-eradication (based on realistic expectations), include a discussion of whether such contributions can be obtained *solely* as a part of an eradication effort.

II.6 Strengthening health systems

Delineate how the eradication effort will complement (or conflict with) ongoing operations compared to the control scenario. Where applicable, explain how work in a new eradication initiative would coincide with other eradication efforts. Two goals should constitute the minimal starting point: (1) an eradication effort should do no "net" harm, and (2) where possible, an eradication effort should strengthen the existing health system. Clarify how these goals can be achieved.

Particular attention should be given to countries with fragile health systems, where eradication efforts may stress limited resources. Disease-specific interventions implemented as parallel activities in fragile health services may potentially weaken a health service's ability to respond to its community's needs, especially when several global health initiatives operate simultaneously (Cavalli et al. 2010). Explore positive synergies to couple disease-specific eradication efforts with nontargeted health services in fragile health systems. Examples of useful frameworks for categorizing the various health system influences include the WHO's health system building blocks (WHO 2007) as well as the recent *Lancet* series on malaria elimination, which focused on the technical, operational, and financial challenges to elimination (Feachem et al. 2010).

some public goods may only be obtainable through nonmarket actions (Powers and Faden 2006:144–145). Some public goods, in the economic 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).

Section III: Issues to Consider When Moving From Control to Eradication

III.1 Stakeholder involvement

Describe how commitments will be shared among international, regional, national, and local actors to realize eradication goals. Determine the nature and extent of the real-world commitments from all actors and the forms of cooperation that will be necessary and sufficient for the success of eradication. That is, without these specific shared commitments, the effort cannot possibly succeed, and with them, it is realistic to expect that the effort will succeed. After identifying the necessary and sufficiently shared commitments and forms of cooperation among actors for the success of eradication efforts, provide evidence of these commitments and willingness of all actors to cooperate.

The evidence of demand for eradication (or at least openness to supporting eradication) on the part of all affected populations is a point of particular concern. Experience with prior and ongoing eradication efforts has demonstrated that indifference, fatigue, or outright hostility by members of affected populations—especially when basic infrastructure and primary health care services are lacking—can emerge and pose critical barriers to success (Arora et al. 2010; Bhattacharya and Dasgupta 2009).

III.2 Challenges, risks, and constraints

To encourage active development of appropriate monitoring and contingency planning, analyze the anticipated challenges, risks, and constraints (e.g., economic, epidemiological, biological, technical, environmental, ethical, social, political, and others) associated with moving from the control scenario to eradication.

Ethical, social, and political challenges must be expected over the entire analytical time horizon (Section I.3). Delineate the broad social impacts of eradication and acknowledge both positive and negative impacts. Do not assume that only positive impacts will result; an eradication plan may divert resources that could be used to achieve other public goods, whose value may be equal to, or greater than, the public good achieved through eradication.

Discuss the likely implications of maintaining a strategy of control (e.g., likely costs and challenges) as well as potential impacts upon the interests, rights, and liberties of individuals and communities (Kass 2001; Childress et al. 2002).

Consider the existence and development of effective strategies to address the challenges associated with maintaining the control scenario versus pursuing eradication. This discussion will be pivotal in justifying the selection of one option, as the move from a control scenario to eradication will depend on ensuring that no challenge proves insurmountable to the success of an eradication initiative.

Highlight key elements of the market dynamics associated with products involved in the eradication efforts (e.g., product profiles, supplier landscape, and forecasts of demand, supply, and pricing). For example, if an adequate, affordable, secure, and acceptable supply of products is perceived to be critical to the success of an eradication initiative, it is important to understand how current and future market dynamics will influence the project, and to identify key challenges and uncertainties.

III.3 Critical risks and risk management plan

From the risks discussed in Section III.2, identify those considered to be critical over the entire time horizon of the eradication plan (Section I.3). Delineate the criteria for determining the criticality of risks, and present, describe, and quantify the risks considered critical. Specify risk mitigation plans for each of the critical risks identified. This analysis should attempt to quantify risks to the greatest extent possible and to develop strategies and contingency plans to manage them.

Section IV: Management and Governance

IV.1 Partnerships and governance

Detail the management structure for the proposed eradication plan. Identify the managing agency and provide a description of the organizational arrangements. Include a schematic of the project management structure to pinpoint the main partners involved in the global and regional management and country-level support. Describe the responsibilities of the partners (e.g., technical support, monitoring and evaluation, decision making, fundraising) and assess their capacity. Provide a table of all partners expected to participate and include the following information: type of organization of the partner, location, responsible contact person, specific role in this eradication effort, and past project experience.

IV.2 Critical milestones and monitoring

Specify how success will be measured and how the proposed eradication effort will be monitored and evaluated during implementation and post-eradication phases. In particular, include the following information:

- Definition of success and milestones by which progress can be measured.
- Specification of the data required for monitoring and evaluation.
- Specification of the monitoring and evaluation processes.
- Identification of monitoring and evaluation responsibilities.
- Timetable for monitoring and evaluation.

Set out the milestones for the levels of achievement that will be expected at different times and stages in the eradication effort. These milestones need to correspond to the timeline (Section I.3) and should describe explicit levels of project performance required for project continuation, modification, or discontinuation. It is expected that both qualitative and quantitative measures will be needed to measure success and milestone achievements.

Describe the data required for monitoring and evaluation as well as the steps needed for data collection, compilation, and processing. Outline the resources and processes needed to monitor and evaluate the project, and designate the partner(s) responsible. Routine monitoring and reporting by country administrators as well as periodic supervision and final evaluation by supporting agencies and partners are required. The monitoring process should include a feedback loop to critical personnel at all levels. Identify and address all possible issues related to the assurance of data quality.

IV.3 Operational research plan

Delineate the operational research (OR) plan in terms of how it will be organized, how it will function, and which resources and process are required to ensure that OR planning and implementation is participatory and includes stakeholders from all levels; see, for example, the approach used by the GPEI (WHO 2010b; sections 4.5–4.7), WHO (2010c), and the newsletter "Polio Pipeline" (WHO 2008, 2010a), which describes the work of the Polio Research Committee.

Provide an outline of the stakeholders involved and the process that will be used to develop and manage the OR plan. Explain what structure and mechanisms are in place, or will be developed, to exact agreement and target a global OR agenda. Take key themes and the alignment of stakeholder interests into account to meet national, regional, and global research needs as appropriate. Outline the process for targeting research at all levels of the program. Identify the anticipated funding required throughout the entire eradication plan and explain how these estimates have been derived. Describe the source and amounts of OR funding currently available to the plan as well as the process by which future funds will be allocated.

IV.4 Evaluating impacts on health systems

In the past, the evaluation of disease interventions have commonly concentrated on estimating impact(s) directly associated with that disease. Eradication may, however, require a substantial health system effort, and this is likely to have wider impacts on the provision of other, nontargeted, health services. Thus, an evaluation of potential impacts on health systems must be provided and include a description of:

- The scope of the evaluation: Particular attention should be given to evaluating the key assumptions or risks identified in Sections II and III.2. Priority should be given to countries with weak or fragile health systems.
- A broad specification of the types of data and methods required: Given the lack of routine reporting of health systems performance in many countries, a prioritized selection of indicators, measured using a combination of approaches, may be required. Care should be taken to ensure that measurement of impact is based on clear and unbiased indicators that relate directly to the factors being evaluated.
- The time frame for evaluation: this must link with the broader eradication management and governance plan outlined in Section IV.1.
- The evaluation process: Outline plans, resources, and processes needed to evaluate health systems impact. Identify the key individuals and agencies responsible for funding, preparing, collecting data, and acting on the evaluation reports.

The evaluation of health systems impact may involve tailored methods and processes. It is integral, however, to the overall evaluation of an eradication plan. Describe clearly how the health systems impact evaluation will align with the broader evaluation, both in terms of actors and processes. Ensure that the design of the evaluation allows for input from lessons learned at local, national, and international levels.

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