The GAVI Alliance (formerly the Global Alliance for Vaccines and Immunization) Vaccination Investment Strategy: Evaluative Criteria Used by GAVI in Decision-Making, A Policy Analysis

Suzanne Ceresko

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Committee:

Stéphane Verguet

Aaron Katz

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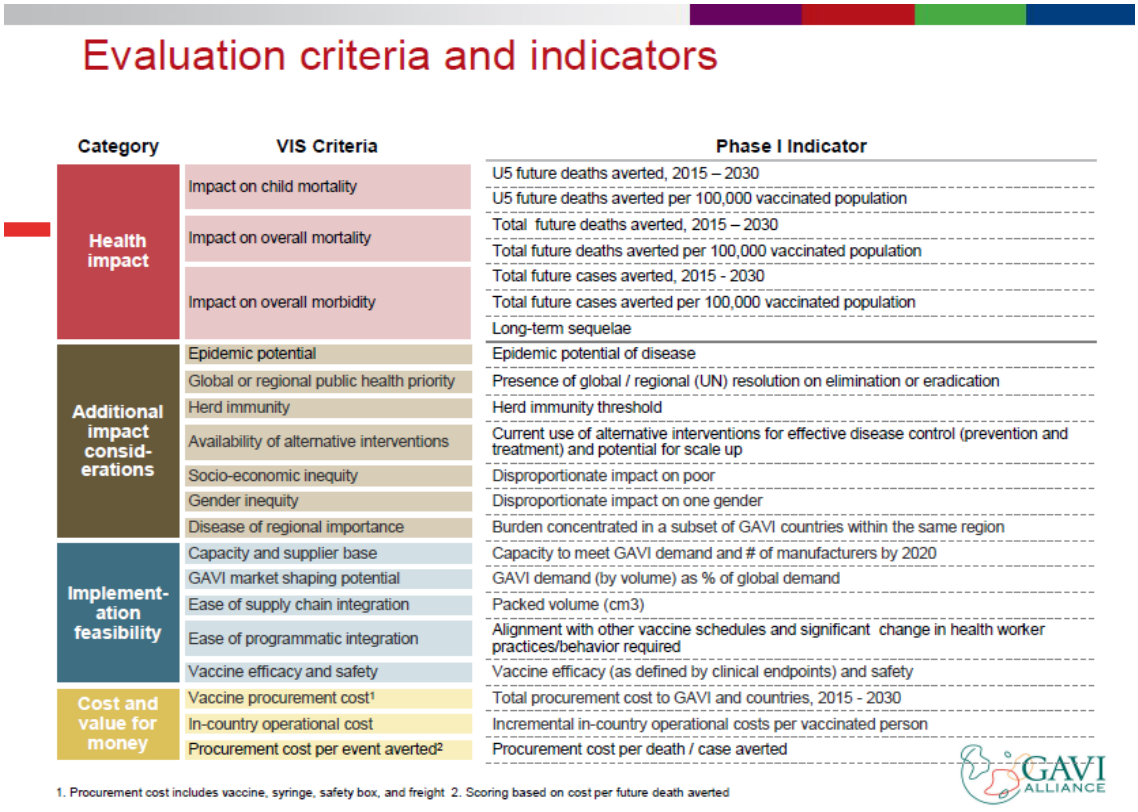
1) INTRODUCTION

Evidence-based policy is increasingly cited in academic journals as an important part of sound decision-making (Oliver, Lorenc, & Innvaer, 2014; Thokala & Duenas, 2012). The GAVI Alliance (formerly the Global Alliance for Vaccines and Immunization), has sought to develop evidence-based policies in pursuit of its goal "to improve access to new and underused vaccines for children living in the world's poorest countries" ("The partnership model - GAVI," 2014). GAVI was founded in 2000, bringing together public and private resources in a unique global coalition. From 2000 to 2006, GAVI focused on three vaccines, hepatitis B (HepB), haemophilus influenza type b (Hib) and yellow fever, and since 2006 vaccine support has expanded to 11 vaccines (see Appendix A). As GAVI's vaccine support has increased, GAVI's policy department has concurrently developed and expanded a Vaccine Investment Strategy (VIS). The VIS is an evidence-based framework used to guide the decision-making process around which vaccines GAVI should prioritize investment in order to achieve their goals. The VIS prioritization exercise helps to define which vaccines will be included in GAVI immunization programs. GAVI has programs in over 50 countries with an annual budget that reached $1.9 billion in 2014 ("Facts and figures - GAVI," 2014).

GAVI's considerable budget and diverse recipient countries make an evidence-based approach essential to managing and achieving its mission. "Evidence-based decision-making is centered on the justification of decisions… (at) a population-policy level, the decision-making context becomes more uncertain, variable and complex" (Dobrow, Goel, & Upshur, 2004, p. 207). Identifying vaccines that can meet the needs in GAVI recipient countries is what the VIS prioritization sets out to do. GAVI revises its vaccine investment strategy every five years, and in each consecutive round its strategy has been refined to better achieve the organization's goals.

Continued revision of the VIS speaks to how GAVI has sought to keep pace with an evolving policy context. GAVI has been cited as an organization in the "vanguard" of public private partnerships that "embraces self-critique and self-improvement, evidenced in major investments in self-evaluation and subsequent efforts to act on evaluation recommendations" (Buse & Tanaka, 2011).

GAVI's most recent VIS used a new decision-making framework for the first time; this was structured around the use of new VIS scorecards. These scorecards, seen below, have four categories accompanied by eighteen criteria. See Figure 1 and Appendix B (Kallenberg, 2014):



Evaluation criteria and indicators

Category	VIS Criteria	Phase I Indicator
Health impact	Impact on child mortality	U5 future deaths averted, 2015 – 2030
		U5 future deaths averted per 100,000 vaccinated population
	Impact on overall mortality	Total future deaths averted, 2015 – 2030
		Total future deaths averted per 100,000 vaccinated population
	Impact on overall morbidity	Total future cases averted, 2015 - 2030
		Total future cases averted per 100,000 vaccinated population
		Long-term sequelae
Additional impact consid-erations	Epidemic potential	Epidemic potential of disease
	Global or regional public health priority	Presence of global / regional (UN) resolution on elimination or eradication
	Herd immunity	Herd immunity threshold
	Availability of alternative interventions	Current use of alternative interventions for effective disease control (prevention and treatment) and potential for scale up
	Socio-economic inequity	Disproportionate impact on poor
	Gender inequity	Disproportionate impact on one gender
	Disease of regional importance	Burden concentrated in a subset of GAVI countries within the same region
Implement-ation feasibility	Capacity and supplier base	Capacity to meet GAVI demand and # of manufacturers by 2020
	GAVI market shaping potential	GAVI demand (by volume) as % of global demand
	Ease of supply chain integration	Packed volume (cm3)
	Ease of programmatic integration	Alignment with other vaccine schedules and significant change in health worker practices/behavior required
	Vaccine efficacy and safety	Vaccine efficacy (as defined by clinical endpoints) and safety
Cost and value for money	Vaccine procurement cost[1]	Total procurement cost to GAVI and countries, 2015 - 2030
	In-country operational cost	Incremental in-country operational costs per vaccinated person
	Procurement cost per event averted[2]	Procurement cost per death / case averted

1. Procurement cost includes vaccine, syringe, safety box, and freight 2. Scoring based on cost per future death averted

GAVI ALLIANCE

Figure (1): GAVI Vaccination Investment Strategy scorecard

GAVI chose the criteria in the VIS scorecards to facilitate evidence-based decisions to further its organizational goals. The focus of this thesis is to evaluate the VIS framework criteria and make policy recommendations to potentially strengthen these VIS criteria. This evaluation was possible with cooperation from GAVI that provided access to internal documents to facilitate a review of the VIS process.

GAVI's internal decision-making process has enabled rapid policy and context analysis to drive sound health programming and address complicated challenges in health policy and programming in low- and middle-income countries (LMICs). Developing succinct frameworks is an important part of being able to make sound decisions amidst a context that calls for agile and actionable policies. This policy analysis looks at GAVI's VIS framework in the context of decision-making, and then compares the VIS to other vaccine prioritization frameworks. The comparison was done to analyze the strengths and weaknesses of the VIS process, and look for potential ways to improve the VIS criteria in the future. Three policy options to improve the VIS framework were identified:

1. Keep the status quo
2. Adopt a new framework
3. Expand the VIS framework by adding additional criteria

The third option, which adds more criteria to GAVI's existing framework, was selected as a recommendation for policy improvement. This option utilizes the VIS scorecards and adds criteria from existing vaccine prioritization frameworks, which will help GAVI better reach its overall goals. This recommendation is made to strengthen the VIS framework using the following measure for improvement: vaccine affordability.

Expanding criteria around vaccine affordability provides needed transparency around vaccine pricing and profit, to help GAVI better reach their goals. Adding additional criteria that address vaccine affordability will create a more robust decision-making framework. This policy analysis provides GAVI with valuable feedback for future revisions of the VIS framework. It also responds to the urgent need for more health policy literature about evidence-based decision-making (O'Grady, 2014).

2) SPECIFIC AIMS

The broad aim of this thesis is a policy analysis of the GAVI Alliance Vaccine Investment Strategy (VIS) prioritization process as a tool for decision-making. Specifically, the analysis focuses on the criteria GAVI uses to guide its decision-making process. The research question has two parts:

1. How does GAVI's Vaccine Investment Strategy (VIS) prioritization exercise use criteria to determine policies that accomplish the organization's goals?

2. How might the evaluative criteria used in the VIS process be improved upon in the context of GAVI's mission and goals?

3) SIGNIFICANCE OF RESEARCH

Making sound and reasonable decisions on a global scale with so much inherent complexity is essential and makes reviewing the VIS a timely and important exercise. Further, there is a call in health policy literature for more studies around decision-making in health policies and systems; this thesis aims to contribute to this literature by looking into GAVI's process (Gilson et al., 2011). The body of academic literature around global vaccine decision-making frameworks and their use as decision-making tools is small. The VIS process is complex: it starts with a broad review of the global vaccine landscape and then uses a prioritization exercise to narrow the broad list of vaccines for GAVI to support (Chopra et al., 2013). Globally, GAVI operations are growing. At the upcoming January 2015 pledging conference, GAVI is requesting $7.5 billion, their largest ever replenishment from donors, in order to meet their goals of saving an additional 5-6 million lives by 2020 (*GAVI presentation: Healthy Children, Healthy Future*, 2014). Better understanding of the VIS decision-making process is pertinent, not just for this thesis, but for other organizations engaging in similar processes (de Leeuw, Clavier, & Breton, 2014; Dieleman et al., 2014).

4) BACKGROUND

4.1. GAVI Background

GAVI is a young and influential organization. The GAVI partnership was only founded in 2000, but GAVI has made a significant impact in a short amount of time. From GAVI's initial launch, the partnership scaled up rapidly and dispersed program funds to recipient countries within the same one-year period (Brugha, Starling, & Walt, 2002). In fifteen years, GAVI has

grown from a five-year start-up pledge of $750 million from the Bill & Melinda Gates Foundation into a multi-billion dollar annual budget and became an important and influential actor in controlling infectious diseases (Sandberg, Andresen, & Bjune, 2010). If donors positively answer GAVI's upcoming replenishment request for $7.5 billion, the organization will be equipped with its largest operating budget to date.

GAVI has a structure based on collaboration between the public and private sectors, "with the shared goal of creating equal access to vaccines for children, wherever they live" ("The partnership model – GAVI," 2014). Since GAVI's founding, they have immunized "more than 440 million children, saving 6 million lives" ("Facts and figures - GAVI," 2014). Their unique partnership structure employs diverse assets to operate on a global scale and solve global problems to meet their recipients' needs. GAVI's broad partnerships and use of existing distribution platforms like UNICEF for vaccine procurement and country ministries of health for program implementation has extended their reach. The partnership model is an important part of how GAVI is structured. GAVI articulates this as, "Rather than duplicate the services of the many players in the field of health and vaccines, GAVI relies on country-based systems and works with partners with widespread field presence to deliver its programs" ("The partnership model - GAVI," 2014).

The composition of the board represents the diversity that GAVI has tapped to achieve its mission. Board seats are filled by developing country governments, industrialized country governments, research and technical health institutes, developing country vaccine industry, industrialized country vaccine industry, civil society, the Bill & Melinda Gates Foundation, the

WHO, UNICEF and the World Bank ("Board members - GAVI," 2014). Board allocation is shown in Figure 2 below:

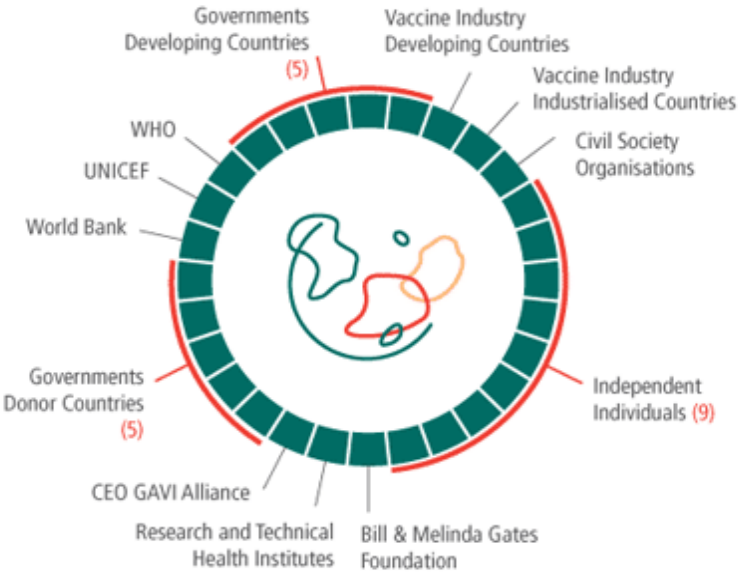


Figure (2): GAVI board composition

("Board members - GAVI," 2014)

The board and GAVI's complex structure are well described by the Center for Strategic and International Studies white paper on the organization: "…the GAVI Board comprises a contentious mix of prominent independent opinion leaders, the pharmaceutical industry, GAVI grant recipients, foundation and government donors, international organizations and civil society; and GAVI has remained principally a finance mechanism, an operation whose visible, on-the-ground achievements are implemented by ministries of health, nongovernmental organizations, and technical partners like UNICEF, WHO, and the World Bank" (Carty, Glassman, Morrison, & Reeves, 2011, p. 2).

GAVI's link with the vaccine industry is a unique aspect of how the partnership approaches its mission. Public-private partnerships (PPPs) are growing in the field of public health, but there is not an extensive amount of academic literature about how PPPs make decisions internally. PPPs, like GAVI, are increasingly being used as an approach to problem-solving in the field of global health (Buse, Samuels, & Pearson, 2008). The term PPP is widely used and does not have a formal classification. However, the World Bank describes them as follows: "Public-Private Partnerships (PPPs) mobilize private sector resources—technical, managerial, and financial—to deliver essential public services such as infrastructure, health and education" (World Bank Institute, 2012, p. 3). Large donor governments and private foundations have advocated for finding public-private solutions; USAID has invested nearly $4 billion in PPPs since 2000 (Ingram & Biau, 2014). GAVI's partnerships with vaccine manufacturers have been important in guiding and deciding policies and programs, in part because affordability and pooled purchasing are key components of GAVI's mission.

Working directly with vaccine manufacturers has also been an essential part of the GAVI partnership model, as is the Advanced Market Commitment (AMC). In 2007, the AMC was introduced with a push to accelerate a comprehensive pneumococcal conjugate vaccine (PCV) for children in developing countries and has since been expanded. The AMC has worked to pool country government vaccine purchasing to secure more competitive pricing and limit risk for manufacturers by guaranteeing a product market. "GAVI has made market shaping a centerpiece of the alliance's strategy moving ahead. The market-shaping goal is ambitious, with the intention to influence both the supply and demand sides" (Carty et al., 2011, p. 4). Other centerpieces of GAVI programs have been: co-financing country vaccine purchase, immunization services support to help build country immunization programming and health systems strengthening

programs. Health systems strengthening programs include support for logistics, human resources and health information systems.

4.2. The Vaccination Investment Strategy

The Vaccination Investment Strategy (VIS) is GAVI's internal process to determine which vaccines they should support. The VIS has been an evolving process at GAVI. In 2007 the GAVI board asked the policy department for a "comprehensive long-term strategy" for vaccine investments (Kallenberg, 2008). The board wanted a VIS that made the best use of resources, maximized investments and was transparent for countries, stakeholders and the vaccine industry (Kallenberg, 2008). From 2000 to 2008, the support of vaccines was decided on the basis of investment cases, using classic business models that were quantitatively based (Kallenberg, 2008). Following the 2007 board request for a new strategy, the policy department began work on a new methodology. The creation of the new VIS was a consultative process with members of the GAVI partnership and external experts. The consultative process resulted in a revised evidence-based framework to guide decision-making, the VIS scorecards (Figure 1 above).

The criteria and indicators used in the VIS scorecards are a kind of scale that weighs the strengths and weaknesses inherent in selecting a certain vaccine for use. The new VIS scorecards use both quantitative and qualitative criteria for an evidence-based mixed-methods approach. The criteria used by GAVI are tied to indicators that provide an evidence-base. For example the criterion "impact on child mortality" is linked with the quantitative indicator "U5 (under age five) deaths averted per 100,000 vaccinated population" (Kallenberg, 2014). The criterion "socio-economic inequity" is tied with the qualitative indicator "disproportionate impact on the poor" (Kallenberg, 2014). GAVI's application of the criteria in the VIS scorecards

is as a tool in the "assessment of vaccines against criteria" (Kallenberg, 2014). Both quantitative and qualitative criteria provide direction in an evaluative process used for policy decision-making. The VIS scorecards help to frame conversations for policy decisions that serve GAVI's beneficiaries (Brearley, Eggers, Steinglass, & Vandelaer, 2013).

In 2013, the new VIS scorecards were used for the first time in setting GAVI's five-year investment strategy for 2016-2020. Using the new VIS methodology, the policy department coordinated with the World Health Organization (WHO) to collect information from the field of vaccines available and in various stages of development. The pilot use of the VIS scorecards was done with committees from the GAVI board and a group of external experts to fine-tune the process. These groups were composed of vaccine industry experts, academics, country representatives and funders. These expert groups and GAVI's policy department used the VIS scorecards to review the broad field of vaccines GAVI could support. From the VIS process a narrowed selection of vaccines were recommended for board consideration. The investment strategy the board approved for 2016-2020 continued ongoing investments and expanded support of both new and existing vaccines. Vaccine investments included ongoing support for measles, meningitis A, inactivated polio virus, pentavalent, pneumococcal, rotavirus, human papilloma virus (HPV), Japanese encephalitis, rubella and typhoid, additional yellow fever campaigns and the global cholera stockpile. Also planned were studies of rabies vaccine, maternal influenza immunization and a review of malaria vaccine readiness slated for 2016 ("Vaccine investment strategy - GAVI," 2014).

The VIS prioritization exercise instigates an evaluative process in an extremely complex environment, which includes a range of infectious diseases in LMICs. The country contexts where GAVI funds programs have numerous variables impacting decisions about health, and

many face under-developed health care systems and infrastructures. Country setting can vary the type of vaccine needed and its application. For instance, cholera vaccine can be relevant in a country context with poor sanitation systems, and measles immunizations are critical in densely populated areas (Luquero et al., 2013: Cutts et al., 1991). Further complexity comes from a diverse field of pharmaceuticals with many different antigens and vaccination strategies. In the last VIS, GAVI decided that funding additional yellow fever campaigns made sense in sub-Saharan Africa (GAVI, 2013a). More variables enter the decision-making process with the complex structure of GAVI's partnership and the global scale on which GAVI operates. In the previous VIS, the investment case framework allowed for less consideration of specific country contexts and focused more on global costs related to lowered morbidity and mortality rates.

The current VIS scorecards are systematic, weighted and fact-based but also contextualized. The scorecards try to be both broad and specific to meet GAVI's goals. The VIS looks at broad factors like GAVI's market shaping potential when making global wholesale vaccine purchases, and they also look specifically at factors like diseases of regional importance. Flexibility was designed into the GAVI framework (GAVI, 2013a, 2013b, 2013c, 2013d) and is a smart way to manage a complex field. Flexibility is identified in academic literature about effective policy making as a way to add value in an evaluative framework measuring a heterogeneous field (Bardach, 2005; Lavis et al., 2012). Heterogeneity and changeability are good words to describe the complicated context of disease and vaccines that GAVI has to contend with.

Dobrow et al. argue that context can be more important than evidence at the population-policy level, noting that "While both evidence and context are fundamental to evidence-based decision-making, there will always be grey zones blurring a clearly definable relationship

between evidence and context" (Dobrow et al., 2004). In some instances context can be the strongest form of evidence, for instance in some LMIC's poor water and sanitation systems can provide the strongest evidence for choosing a certain public health intervention. In other country contexts the efficacy of a certain vaccine over another vaccine may be a stronger form of evidence. It is important that vaccine decision-making frameworks allow for some flexibility to consider the setting in which they operate. Since GAVI operates in a global setting, and needs to be effective within so many country contexts with such different vaccines, they have had to find a proper scale to measure all these factors. The VIS scorecards strive to achieve the proper balance of considering many variables to make the best possible decisions. The discussions about a proper balance between vaccine needs in diverse countries, the proper use of funds, and best medically based decisions are reflected in many of the meeting notes from the VIS creation process (GAVI, 2013c, 2013d; Zuber et al., 2011).

5) METHODS

To frame this policy analysis of the VIS process, Eugene Bardach's formative book *A Practical Guide for Policy Analysis, The Eightfold Path to More Effective Problem Solving* (Bardach, 2005) was used as a broad organizing methodology. Following Bardach's guide to policy analysis, this thesis began with a literature review and structured evaluation to understand challenges and problems. Following the definition of problems, options for possible policy solutions were sought and a solution was selected from the policy options to recommend a course of action. Bardach succinctly describes the methodology as "Defined problems are problems of choice between alternative means to realize a given opportunity" (Bardach, 2005, p. 52).

The broad steps were:

1. A review of evidence-based health policy analysis literature
2. A review of GAVI data
3. A review, followed by a comparison of vaccination decision-making frameworks
4. An assessment of options
5. Recommendations

All of these steps helped to answer part one of the research question:

-How does GAVI's Vaccine Investment Strategy (VIS) prioritization exercise use criteria to determine policies that accomplish the organization's goals?

Steps 3, 4 and 5, which included the analysis and discussion of results and recommendations, helped to answer part two of the research question:

-How might the evaluative criteria used in the VIS process be improved upon in the context of GAVI's mission and goals?

Step 4, an assessment of options, used the following three options as recommendations:

OPTION 1:	OPTION 2:	OPTION 3:
Status-Quo Keep VIS Framework as Built	Change to the Expanded IOM Framework	Expand the VIS Framework by adding additional criteria

Option 3 was selected as smart practice for policy recommendations, using Bardach's definition of "smart practice" and identifying improvements based on specific criteria additions to better

reach GAVI's goals. Improvements were based on the identified measure: vvaccine affordability.

The broad research design is illustrated in Figure 3:

Research Design

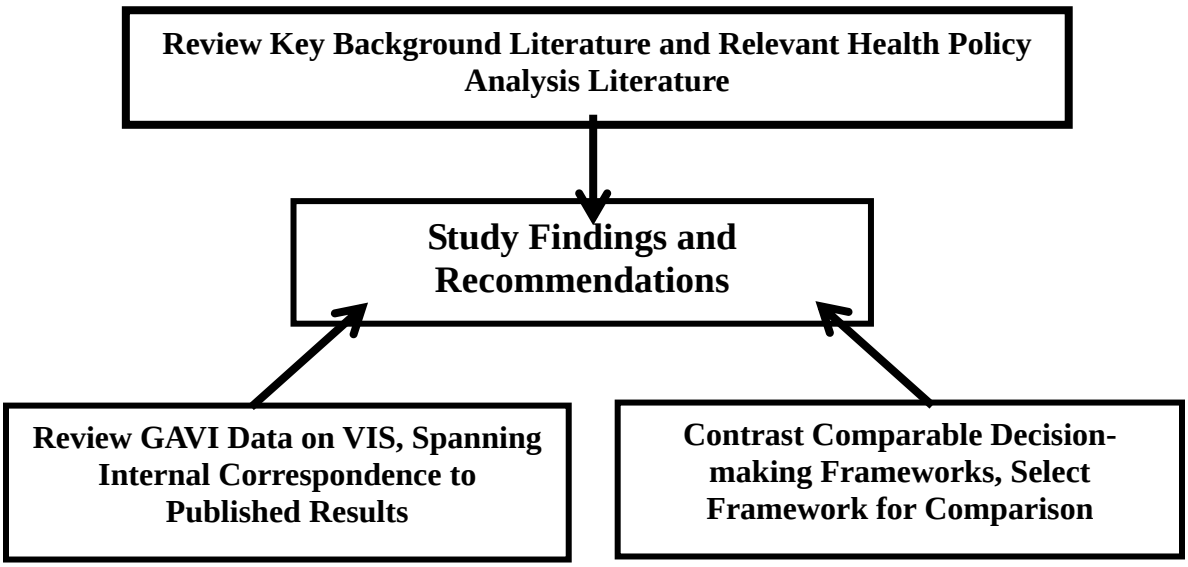


Figure (3): The research design, showing steps that led to the study recommendations

6) LITERATURE REVIEW

6.1. Literature Review Methods

As the literature review in this thesis is part of the policy analysis methods, a formal approach was organized. Three main databases were selected as sources for references. First, PubMed (attached to the US National Library of Medicine) was selected since it is the standard database authority used in public health academics. The second database used was Web of Science (which aggregates many global databases) to locate any relevant articles from outside of the United States. Lastly, the University of Washington digital library catalog was used as needed to search sources outside of scientific journals. In total, 381 articles were collected as

research for this thesis. The following search terms were used: “health policy analysis frameworks”, “evidence-based frameworks”, evidence-based policy, decision-making frameworks, LMIC health policy analysis, LMIC decision-making frameworks, vaccine frameworks, evidence-based vaccine policy, vaccine frameworks, vaccine decision-making and evidence-based immunization policies. The words vaccine and immunization were cross-searched with key words or terms in all databases as the two different words were found to lead to unique results. Of the 381 articles collected 48 journal articles in total were used as sources for this thesis.

GAVI assisted with this research by providing literature and information for review. GAVI provided internal data and documentation about the VIS process. The primary source literature and data used for analysis in this thesis were the VIS scorecards available on the GAVI website, public and private GAVI meeting minutes on the VIS process, board meeting minutes, public and internal presentations and internal documentation regarding the evaluation criteria considered for the VIS scorecards. Other sources on GAVI were located in searches conducted in PubMed and Web of Science. The following search terms were used to research GAVI: GAVI history, GAVI VIS process, GAVI strategy, GAVI policy, GAVI evidence-base, GAVI success, GAVI failure, GAVI strength, GAVI weakness and GAVI criticism. Of the 381 articles collected for this research 85 of those articles took GAVI as their topic of research. From the 85 identified articles 16 journal articles on GAVI were selected for use in this thesis. The GAVI website was also used as a source for facts and figures about GAVI, and new GAVI press releases were followed to keep current in the course of this research.

6.2. Seeking Smart Practices

Health policy analysis looks at problems of decision-making in complex circumstances, seeking to evaluate and recommend the best options for health care in complicated settings with many variables. Reviewing health policy analysis literature was approached with a two-fold purpose: first to understand the thesis topic in the context of existing literature and secondly, to find a conceptual model that could serve as a guide. The article *'Doing' Health Policy Analysis: Methodological and Conceptual Reflections and Challenges* (Walt et al., 2008) spoke to how "little guidance" exists on health policy analysis in LMICs. Walt's article reviewed many existing frameworks and theories; the reviewed frameworks included the stages heuristic (Lasswell 1956, Brewer and deLeon 1983), network frameworks (Thatcher 1998) and the policy triangle framework (Walt and Gilson 1994). The stages heuristic speaks of four steps in policy analysis: agenda setting, formulation, implementation, and evaluation. However, the stages heuristic did not have the level of detail sought to approach the VIS methodology. Both the network framework and the policy triangle framework address context and stakeholders, and both frameworks have been used with success in LMICs, but many of the applications described were more focused on stakeholders than an evidence-based process analysis.

The health policy literature review next led to Eugene Bardach's formative book *A Practical Guide for Policy Analysis, The Eightfold Path to More Effective Problem Solving* (Bardach, 2005), which was also selected as a concept model for this research. Bardach's path for problem solving fits the goals of this thesis to identify and recommend, "…smart practices (that) are internally complex, context-sensitive, and can be used by different parties to pursue slightly different bundles of goals..." (Bardach, 2005). The term 'smart practice' aligns with GAVI's iterative approach to the VIS. Bardach's nuanced term 'smart practice' refers to smart

rather than best practice. Pragmatically, this highlights the difficulty in identifying a 'best' practice; smart practices are easier to identify. A single best practice sets a high bar to define and surmount, whereas smart practices are pragmatic and achievable. Smart also speaks to the revisions in well-practiced 'smart' policy analysis, revisions based on new knowledge and lessons learned from experience. Bardach's useful term 'smart practice' was adopted for this research, particularly in the context of policy recommendations for GAVI. Bardach's pithy and practical book was used to guide the methods used in this research, the details of which are elaborated on below.

6.3. Literature on Evidence-Based Policy

A reoccurring thread in the literature on evidence-based health policy analysis is the importance of considering the setting in which policy decisions are made. *Guidance for Evidence-Informed Policies about Health Systems: Linking Guidance Development to Policy Development* (Lavis et al., 2012) focused on health systems and the importance of understanding the decision-making context in policy decisions. GAVI's board sought to evolve the VIS process from investment-case based decisions to a "comprehensive" decision-making framework for the VIS (Kallenberg, 2008). The resulting VIS framework adopted qualitative indicators that consider many factors in LMIC like socio-economic inequity, the availability of alternative interventions, and the feasibility of an intervention to scale-up (GAVI, 2013d). The argument made in *Expanding the Evidence within evidence-based healthcare: thinking about the context, acceptability and feasibility of interventions* (Shaw, Larkin, & Flowers, 2014) argues for more policy decision-making processes using mixed-method decision-making frameworks.

In the review of evidence-based decision-making framework, a better understanding of how GAVI approached the topic was sought. In the VIS scorecards, indicators are specific

evidence linked to broader criteria categories. However, in describing the scorecards GAVI stated that flexibility was also important in looking at LMIC and a diverse field of vaccines (Kallenberg, 2014). From the policy literature, the description of GAVI's use of criteria and indicators in policy decision-making was closest to Dobrow's description in *Evidence-based health policy: context and utilisation*. Dobrow writes "The *practical-operational* orientation to what constitutes evidence *is* context-based, with evidence defined with respect to a specific decision-making context." Dobrow et al. argue that context can be more important than evidence at the population-policy level. He writes, "…while both evidence and context are fundamental to evidence-based decision-making, there will always be grey zones blurring a clearly definable relationship between evidence and context. Therefore it may be less critical how these fundamental components are *defined*, and rather more critical how the decision-making context impacts on how evidence is *utilised* in the development of evidence-based decisions" (Dobrow et al., 2004, p. 212).

6.4. Other Evidence-Based Vaccine Models

Literature on other evidence-based vaccine decision-making models were more directly comparable with the VIS scorecards model, but also pointed to how new and unique GAVI's mixed method model, and models like it, are in the field of vaccines. The body of work in this field is small; the search term vaccine frameworks yielded 74 records, and 19 of those records had relevance for this research. Literature searches in PubMed and Web of Science did not locate any academic literature on the VIS process; however, GAVI is writing articles describing the process that will be published soon. Currently, the available public materials on the VIS are those available on the GAVI website. Vaccine decision-making frameworks are understudied and require more in-depth academic review. A literature review with the search term vaccine

decision-making frameworks yielded only 17 records. These searches revealed how little academic work on these frameworks exists, and that what does exist is recent. Although the body of work is small, there were some notable items.

The literature on vaccine frameworks led to three other decision-making frameworks working on a global or multi-country level. The first framework investigated was the Institute of Medicines (IOM) of the National Academy of Sciences Ranking Vaccines Strategic Multi-Attribute Ranking Tool (SMART) for decision-support system, which yielded only two records, and both were for the two books on the IOM SMART tool published by the IOM. The second vaccine framework found in a literature review was the Pan American Health Organization (PAHO) ProVac tool. For the PAHO ProVac tool, thirteen academic articles reviewing the framework were located in PubMed and Web of Science. The last similar framework found was the WHO's use of Grading of Recommendations Assessment, Development and Evaluation (GRADE) in vaccine assessment and decision-making (Duclos et al., 2012). For the GRADE framework, four academic articles reviewing the framework were located in PubMed and Web of Science. Two articles were by authors affiliated with the WHO and two in publications from the Centers for Disease Control which were mentions of the GRADE publications potential for use as an evidence-based framework (Ahmed, 2012).

PAHO's ProVac initiative has been praised in the literature as an effective framework for countries to use to make decisions about immunization programming (Andrus, Jauregui, De Oliveira, & Matus, 2011; Jauregui et al., 2011). For the purposes of finding a comparative framework for the VIS, the PAHO framework did not offer a comparison because its criteria were too similar to the VIS. PAHO's ProVac is heavy on quantitative indicators, which were similar to GAVI's. As the PAHO framework did not have any criteria beyond what GAVI used,

there were not any relevant examples to recommend policy improvements. Comparing the ProVac tool would not have provided substantive information or recommendations for the VIS. The GRADE framework is larger in scope than any of the other frameworks in that it considers more programmatic factors in decision-making, like monitoring and evaluation. However, GRADE was also very quantitative in its approach to indicators and did not offer any new criteria or indicators that might enhance the VIS (Duclos et al., 2012). GRADE's monitoring and evaluation portion of its framework was not relevant for GAVI, since that function is performed by a separate department within GAVI's policy department. Both the ProVac tool and the GRADE framework were too similar to the VIS to provide interesting criteria for the basis of recommendations.

Only the IOM SMART framework was chosen to compare and contrast with the VIS scorecards for two reasons. Firstly, the IOM SMART was chosen because it was the most similar in approach to the VIS, using mixed-methods to structure an evidence-based framework. Secondly, the IOM SMART framework has unique criteria in its framework to recommend for improving the VIS. The notes from GAVI committees and groups that worked on the creation of the VIS methodology (GAVI, 2013a, 2013b, 2013c, 2013d) and the forward to the IOM SMART framework have similar purposes regarding their respective methodology designs (IOM, 2013). The forward of Ranking Vaccines describes the challenges that the framework is meant to address, noting, "We live in an era of rapid change and frequent disruptions caused by globalization, changing markets, demographics, economies, and innovations in new technology development. These considerations make efforts to prioritize the development and delivery of new vaccines and other health technologies extremely challenging and progressively more complex" (IOM, 2013, p. vii).

7) COMPARATIVE ANALYSIS

7.1. The "Eightfold Path" to Guide Broad and Focused Analysis

Bardach's "Eightfold Path" was used as an organizing framework for this policy analysis. The Eightfold Path provided both a process overview and a narrowing point for comparative analysis. The Eightfold Path is described by Bardach as a public policy analysis that advocates for a systematic and logical approach to examining facts and making decisions. Bardach's Eightfold Path is not specifically focused on health, but it is often used to guide health policy analysis. An example of Bardach's Eightfold Path applied to health policy is the Johns Hopkins Policy Analysis Checklist used in the *Health Policy Analysis Checklist for the Development, Selection, and Assessment of Program Policies within Health Care Organizations* (Weiner 2005).

The Johns Hopkins Policy Analysis Checklist well contextualizes Bardach's book for health policy use. Most notably in the Johns Hopkins approach was the adapted eighth step of Bardach's path, where the Hopkins author expanded "decision memo" to "implement and improve." "Implement and improve" works for analyzing an existing health program, and it also relates to how GAVI piloted the VIS, fine-tuning the process as it was first used. To take advantage of both Bardach's pragmatic approach and the refinements of the Johns Hopkins health policy specific adaptations, the frameworks were fused for this thesis' conceptual model. This customization was done to make the best fit for this specific policy analysis, which looks at a large global body doing specific vaccine work in LMICs.

Conceptual Model

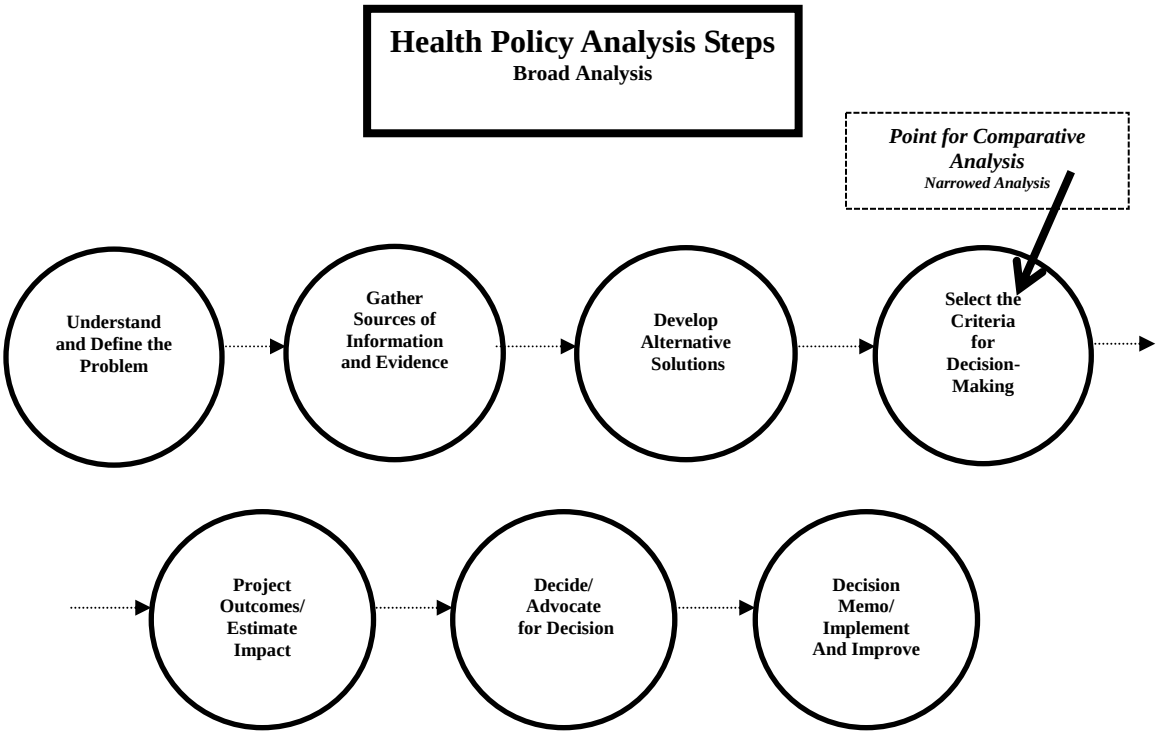


Figure (4): The conceptual model of the study adapted for this research
(Bardach 2005 p. xiv; Weiner 2005)

The Eightfold Path's policy analysis steps were used to understand the role the VIS framework played in GAVI's decision-making towards achieving the organization's goals. GAVI's policy department did not use the Bardach book to guide their process, but there are enough similarities in the approach to decision-making that make the Eightfold Path an appropriate methodology as a basis for analysis. Bardach's book discusses how the steps in both policy-analysis and policy-making are not necessarily chronological and fixed, but that the process is general and the steps can happen in all kinds of sequences; this description fits with the GAVI process (GAVI, 2013a). With a larger understanding of policy and its relation to the VIS process, this information was used to gain insight into the VIS criteria. The fourth point in

Bardach's framework, 'select the criteria for decision-making' (see Figure 4 above) was a logical reference point for examining the criteria that GAVI used in creating the VIS methodology.

To narrow the focus on criteria, a literature search was done for a source of comparable vaccination frameworks, described in detail in the literature review above. The three vaccine decision-making frameworks found to be comparable with GAVI's VIS process were the IOM SMART, PAHO's ProVac Initiative and WHO GRADE. These three models were all initially examined because they had similar evidence-based frameworks for vaccine decision-making. However, on closer examination ProVac and GRADE did not have distinct criteria from the VIS. Since both these frameworks lacked substantial sources of comparison with the VIS they were not selected. Of the three frameworks, the IOM SMART tool was chosen as the most suitable for comparing and contrasting with the VIS to find recommendations for improving GAVI's process.

7.2. Highlighted Frameworks Used for Focused Analysis

Figure (5): Vaccine-specific frameworks considered and the two selected in box frames

Once the IOM SMART framework was selected for comparison with the VIS scorecards, the criteria in both frameworks were analyzed. (See full IOM criteria in Appendix C.) Focusing

on both frameworks facilitated a microanalysis, which examined the function of criteria in the two decision-making frameworks, providing interesting contrasts. Narrowing the process to look at criteria helped ask and answer how the criteria guide the decision-making process. This focused analysis provided insight to answer part two of the study aims: can the criteria in the process be improved and what might be smart practices in vaccine decision-making frameworks?

Concentrating on the criteria of the two frameworks provided clearer information as to which vaccine investment criteria stood out as smart practice towards achieving GAVI's mission. Both the VIS and the IOM SMART decision-support frameworks look specifically at selecting vaccines with evidence-based criteria. Both frameworks use mixed-methods, asking both quantitative and qualitative questions to make smart decisions in vaccine policy. Quantitative criteria are used similarly in both of the frameworks, measuring disease and mortality, financial costs and other economic measures. The metrics vary, but what they measure is similar. Analyzing the IOM SMART vaccination prioritization framework helped gauge if changing or expanding the criteria used by GAVI would better achieve GAVI's mission. For the purpose of comparison, different criteria in the two frameworks were selected for focus. Similar criteria were not selected for comparisons, as similar criteria did not provide possibilities for substantive policy recommendations. Both frameworks' criteria were set in a grid to highlight distinct criteria side-by-side (see Figure 6); this visual comparison provided a way to better understand how evidence-based policy decision-making works and can potentially be improved.

7.3. A Problem of Choice

The VIS criteria aim to select the strongest combination of evidence to prioritize vaccines, but does the VIS utilize smart practices that lead to good investment decisions? The

Eightfold Path is based on the assumption that policy problems are problems of choice. A problem of choice succinctly describes what GAVI's VIS tries to confront. The VIS looks at a very wide field of vaccines to choose vaccines that will effectively reach GAVI's goals. Solving problems of choice are also what the IOM SMART framework tries to solve. The IOM SMART differs in that it is designed for use by public entities, from federal to county governments, and private entities like pharmaceutical companies and vaccine manufacturers. As a PPP, GAVI is in a way a hybrid of public and private interests. The different applications but similar designs of these methodologies are part of what made these two frameworks interesting for a policy analysis and for a source of recommendations. Both frameworks are trying to address both public and private concerns, and both frameworks use evidence to guide good policy decisions.

COMPARATIVE ANALYSIS TREE

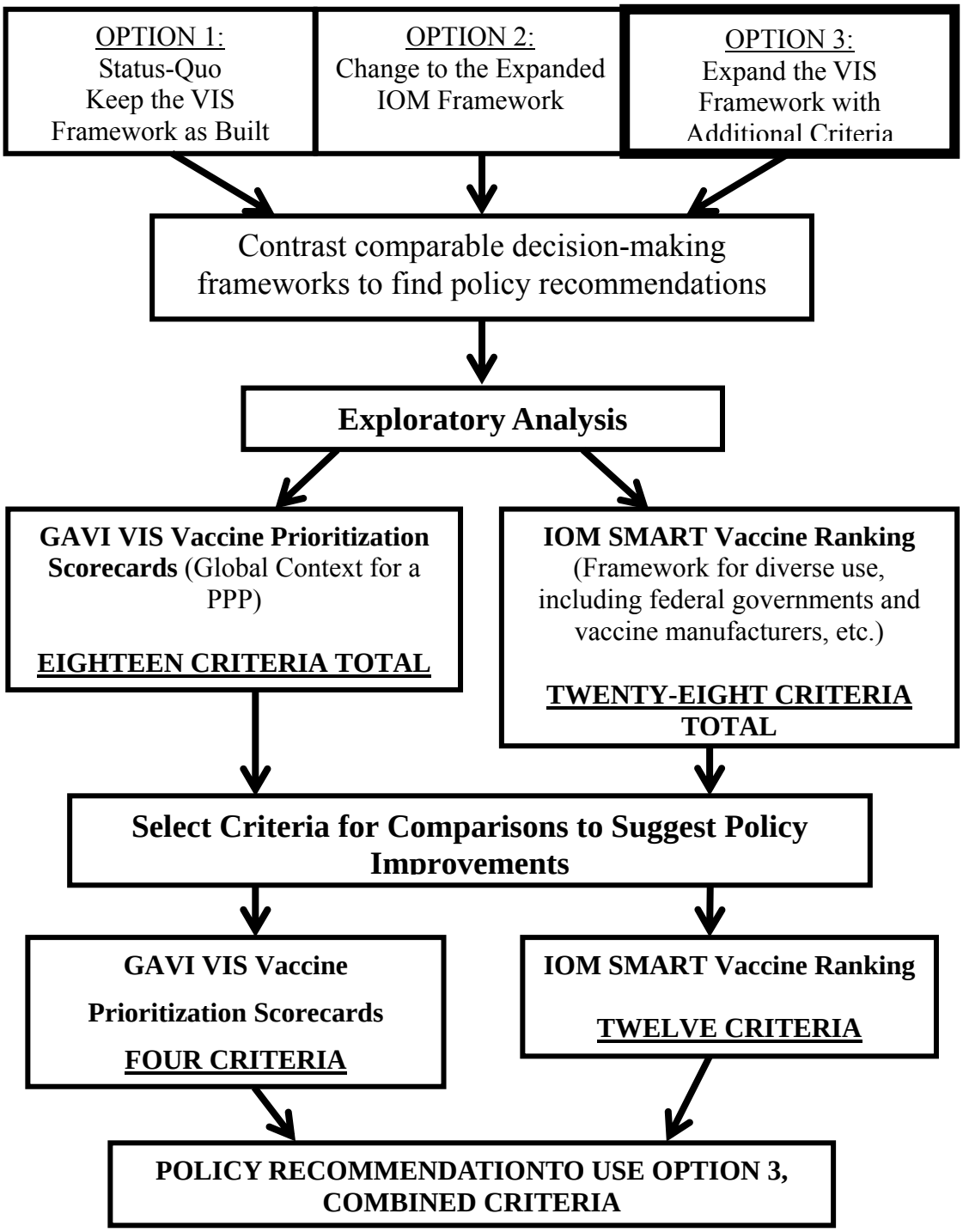


Figure (6): Comparative analysis tree, a visualization of comparative steps in the thesis

7.4. Combining Criteria to Make Policy Recommendations

Both GAVI and the IOM are using evaluative frameworks to make evidence-based decisions. GAVI's existing VIS framework is robust and working well to achieve GAVI's mission. Using option three (see top of Figure 6 above) *expand the VIS framework with additional criteria,* as a policy recommendation proposes a way to achieve stronger outcomes towards GAVI's goals. In option three, all of GAVI's criteria are kept, and three criteria from the IOM SMART decision-framework are recommended for addition into the GAVI VIS framework.

Option one, *Status-Quo Keep the VIS Framework as Built,* was dismissed, as it is recommended that the existing VIS framework be improved. Comparisons of the IOM and VIS frameworks revealed ways to combine criteria and build smarter practice, leading to option three being selected. Option two, *Change to the Expanded IOM Framework*, was initially intriguing as the IOM framework is larger, with twenty-eight criteria, and can be used by a wide range of actors in a variety of settings. However, the specificity of the GAVI framework made more sense; the organization needs a specific framework that is custom-built for its needs. The existing GAVI framework provides a solid base that can be expanded on. For example, the unique criteria in the VIS scorecards that address LMIC settings like herd immunity and diseases of regional importance are important pieces of the VIS decision-making framework. The value of GAVI's unique criteria is elaborated on in the discussion section.

The comparative analysis tree (Figure 6) shows the flow of the analysis used in comparing frameworks side-by-side. Again broadly similar criteria were not considered for comparisons as they held less relevance for policy recommendations. Different criteria were compared and criteria that would substantively add to GAVI's larger goals were selected for recommendations. The main measure found in the results, to recommend smart practice and

improved outcomes, was adding criteria around vaccine affordability to the VIS. Details of these results follow in the discussion and recommendation sections.

To compare and analyze both the VIS and SMART decision frameworks to make policy recommendations, the steps in the comparative analysis tree above were followed. This process led to identifying the following recommendation:

OUTCOME: CRITERIA THAT HELP ACHIEVE GAVI'S GOALS AND MISSION
RECOMMENDATION: ADD IOM CRITERIA AROUND VACCINE **AFFORDABILITY**

Figure (7): Recommended enhancements in the context of GAVI's goals

Below are details of how the two frameworks' different criteria were analyzed (see Figure 8 below). The IOM results in green indicate criteria recommended for addition to the VIS. Results in orange were not selected for this comparison.

Different Criteria in GAVI and IOM decision tools

GAVI Alliance Evaluation Criteria and Indicators

Category	VIS Criteria	Phase I Indicator
Additional impact considerations	Herd Immunity	▫Herd immunity threshold
	Disease of regional importance	▫Burden concentrated in a subset of GAVI countries within the same region
Implementation feasibility	Capacity and supplier base	▫Capacity to meet GAVI demand and # of manufacturers by 2020
	GAVI market shaping potential	▫GAVI demand (by volume) as % of global demand

(Kallenberg, 2014)

IOM at the National Academies of Health

Choices of Attributes in SMART Vaccines 1.0	
Demographic Considerations	▫Benefits military personnel
	▫Benefits other priority population
Intangible Values	▫Vaccine raises public health awareness
	▫Workforce productivity gained per year
Scientific and Business Considerations	▫Potential litigation measure beyond usual
	▫Demonstrates new production platforms
	▫Existing or adaptable manufacturing techniques
	▫Likelihood of financial profitability for the manufacturer
	▫Interests from NGO's and philanthropic organizations
Programmatic Considerations	▫Disease raises fear and stigma in the public
	▫Interest for national security preparedness and response
	▫Advances nations foreign policy goals

(IOM, 2012, p. 24)

Figure (8): Comparison of different criteria in the GAVI and IOM frameworks

To make the process described in the above comparison less abstract and more concrete, an example follows to show specifically how criteria were examined and recommendations were developed:

7.5. COMPARISION FOR RECOMMENDATIONS: AN ILLUSTRATED EXAMPLE

COMPARATIVE ANALYSIS USING PCV (PNEUMOCOCCAL CONJUGATE VACCINE) DECISION-MAKING WITHIN THE CONTEXT OF GAVI'S GOALS

Critique is that an excessive amount of GAVI's budget goes to PCV and market-shaping mechanisms have been slower than GAVI projected at reducing costs (Usher, 2014) and (Gilchrist & Nanni, 2013)

GAVI VIS Vaccine Prioritization Scorecards (Global Context for a PPP)
Capacity and supplier base: Capacity to meet GAVI demand and # of manufacturers by 2020
GAVI market shaping potential: GAVI demand (by volume) as % of global demand

(Kallenberg, 2014)

IOM SMART Vaccine Ranking (Framework for diverse use, including federal governments and vaccine manufacturers, etc.)
Demonstrates new production platforms
Existing or adaptable manufacturing techniques
Likelihood of financial profitability for the manufacturer

(IOM, 2012, p. 24)

Figure (9): Comparison analysis, PCV decision-making within the context of GAVI's goals

Making efficient investments in immunizations that prevent a broad spectrum of childhood diseases is GAVI's aim, but spending too much money on PCV misses the mark. Writing in *The Lancet*, Ann Usher critiqued the fact that so much of GAVI's budget goes

towards paying for one vaccine, PCV (Pneumococcal Conjugate Vaccine) which protects children from bacterial respiratory infections. Usher points out that using the bulk of GAVI's budget to pay for one vaccine monopolizes GAVI funds, and in fact these funds should be used to pay for a wide range of vaccines. She advocates for finding ways to negotiate a lower price for PCV vaccine (Usher, 2014). Along a similar track, writing in *Health Policy and Planning*, Shawn Gilchrist and Angeline Nanni write that GAVI market-shaping mechanisms have been slower than GAVI modeled, most notably with PCV (Gilchrist & Nanni, 2013). GAVI had estimated that its pooled vaccine purchasing mechanism would lower the costs of PCV vaccine faster than what occurred. Spending a high percentage of GAVI's money to pay one PCV vaccine manufacturer is misaligned with GAVI's goals of "of creating equal access to vaccines for children, wherever they live" ("The partnership model - GAVI," 2014).

Figure 9 shows how both frameworks have distinct criteria relating to vaccine manufacturer concerns. The first item in GAVI's criteria (Figure 9) is about the vaccine supply base and the ability of manufacturers to realistically meet pooled purchasing demand generated by GAVI countries. The second item pertains to GAVI's ability to shape the market by pooling country needs to guarantee a market for the vaccine product. The IOM SMART provides criteria with more direct manufacturer concerns: "demonstrating new production platforms," "existence of manufacturing techniques" and "likelihood of manufacturer profit" (IOM, 2012, p. 24). As the IOM framework is designed to also be used by vaccine manufacturers, it makes sense that measures of cost, production and profit are a part of their framework. GAVI can profit from using more manufacturing criteria as well. By adding more direct criteria that specifically address vaccine manufacturer concerns, GAVI could facilitate ways to improve negotiation within its PPP structure.

GAVI's internal prioritization process for vaccines involves representatives with ties to vaccine manufacturing. GAVI uses its ties with manufacturers and markets specifically to answer and provide evidence for the criteria, capacity and supplier base: "capacity to meet GAVI demand and # of manufacturers by 2020" and "GAVI market shaping potential: GAVI demand (by volume) as % of global demand" (Kallenberg, 2014). GAVI's PPP is equipped to answer these market-based concerns regarding GAVI's ability to achieve their mission; this is both a function of and advantage of GAVI's public-private structure. This same PPP structure should be used to discuss vaccine affordability issues and how more affordable vaccines can impact GAVI's broad goals. If GAVI's process discusses market supply capacity, discussing vaccine pricing and lowering prices is a reasonable next step. Adding criteria to the VIS framework that address vaccine affordability would formally bring the topic into GAVI's vaccine investment decision-making process.

Presently the criteria GAVI uses regarding vaccine manufacturers is one-sided, more focused on what manufacturers can provide for GAVI. It is important to also look at what the GAVI partnership does for the vaccine industry. GAVI has considerable purchasing power with an annual budget of $1.9 billion. How the money is spent is crucial to GAVI's PPP and its mission. Adding the IOM criterion, likelihood of financial profitability for the manufacturer, clearly brings profit into the VIS decision-making process. Understanding what GAVI investments mean for profit margins gives all partners at GAVI, public and private, a way to evaluate what reasonable prices are for vaccines. Looking at how much vaccine manufacturers profit from GAVI's vaccine purchases is relevant to find the best use of donor funds and find the highest positive impact for beneficiaries. How GAVI's operating budget is spent directly impacts achieving GAVI's goals. By formally adding affordability criteria into the VIS

framework, consideration of profit becomes an official part of the process. Clearly understanding what manufacturers have to gain by selling vaccines for GAVI countries is essential. This information would also put public interests inside of GAVI, like LMIC country representatives and civil society organizations, on stronger negotiating footing in internal GAVI discussions around costs and goals.

Vaccine costs and profits are sensitive issues, but in 2011, for the first time, UNICEF revealed more about the prices they pay for vaccines ("UNICEF promotes vaccine pricing transparency – UNICEF Press Center," 2011). If GAVI adds formal framework criteria around cost concerns, this would facilitate ways to bring individual vaccine costs down. Along with the IOM criterion, likelihood of financial profitability for the manufacturer, the criteria demonstrates new production platforms and existing or adaptable manufacturing techniques should be added to the VIS. These are also criteria that advantage the vaccine industry. As a partnership, GAVI partners should openly discuss ways that their work benefits all partners and can best benefit the recipients the GAVI PPP was formed to serve.

Another advantage of adding affordability criteria to the VIS process is that the information around vaccine pricing could be used to support MIC graduating from GAVI funding. MICs that leave the GAVI system can struggle to find ways to procure affordable vaccines without outside funding. Expensive new vaccines like PCV are a particular challenge for MICs. MICs need more information and support to negotiate directly with vaccine manufacturers for affordable prices. Adding the IOM SMART criteria concerning vaccine manufacturers could inform middle-income countries by providing transparency around pricing. Providing more information about pricing would prepare health ministries in middle-income

countries to negotiate with manufacturers. The benefits of this recommendation are further elaborated on below.

8) ELABORATION OF RESULTS

As this thesis research evolved, recommendations focused on what would be smart practices. The results and discussion are for policy recommendations, drawn from an analysis of narrowed criteria. Focused results were selected to make recommendations in the context of GAVI's larger goals. This followed the Eightfold Path for policy analysis, a "classic research model, in which ends determine means—that is, a constantly evolving set of knowledge objectives gives shape to the strategy of source selection and consultation. It is applicable to policy research as to any other sort of social inquiry" (Bardach, 2005, p. 71).

RECOMMENDATION: ADD IOM CRITERIA AROUND **VACCINE AFFORDABILITY** TO THE VIS SCORECARDS
RESULT: GAVI'S VIS IS ROBUST AND ADDING SELECTED IOM CRITIERA CAN MAKE IT A STRONGER EVIDENCE-BASED FRAMEWORK
OUTCOME: ACHIEVE GAVI'S GOAL AND MISSION

Figure (10): Flowchart: recommendations to result to outcomes

8.1. Examples of GAVI Criteria that Provide a Solid Base to Enhance

There are many strengths in GAVI's existing VIS framework that work well. The success GAVI and its partners have had in reaching so many children demonstrate the effectiveness of the organization. Using a mixed-methods framework helped GAVI, and

quantitative and qualitative indicators provided criteria that added depth to specific decisions in LMICs with weak health systems and other vulnerabilities (Balabanova et al., 2013). The mixed methods in the VIS scorecards facilitated a pragmatic use of criteria with designed flexibility to consider needs in diverse and complex settings. A more flexible mixed-methods framework is what GAVI has found to be compatible with their mission of vaccinating children worldwide. Decision-making on the basis of investment cases was done from 2000 to 2008. Models from the business world, looking at more classic risk and reward measures, lacked the comprehensiveness GAVI needed. Investments with a high amount of uncertainty, which is inherent in the settings where GAVI works, are not often selected in a highly quantitative framework.

A highly quantitative framework that has been used in evidence-based medicine and policies is the NICE framework (National Institute for Health and Care Excellence) from the United Kingdom government National Health Service. This framework utilizes cost-effectiveness analysis, drawing praise in many instances. However, the NICE framework has also been criticized in cases where it has not allowed for more qualitative input and favored outcomes with low risk and cost (Andronis, Barton, & Bryan, 2009; Littlejohns et al., 2009; Owen-Smith, Coast, & Donovan, 2010). A highly quantitative framework not adapted for uncertainty would not meet GAVI's needs to make decisions in diverse country settings. In discussions, GAVI determined that the appropriate way to manage uncertainty while simultaneously keeping the context of working in LMICs in mind (GAVI, 2013a, 2013c, 2014) was to use a mixed-methods methodology. Qualitative indicators balance the quantitative indicators in the VIS framework, to provide a full range of information needed to serve recipients in LMICs.

8.2. Examples of Unique GAVI Criteria Suited to the VIS Framework

Specific examples of qualitative and context-specific GAVI VIS criteria that work well within LMIC contexts and with infectious disease are herd immunity and disease of regional importance. Herd immunity has the indicator of herd immunity threshold. Disease of regional importance has the indicator burden concentrated in a subset of GAVI counties within the same region. These are criteria whose inclusions in the VIS framework were discussed in depth at GAVI meetings because they are not relevant in all LMIC settings (GAVI, 2013c, 2013e; Zuber et al., 2011).

The criterion of herd immunity is advantageous because it has been proven to have broader protective impacts beyond vaccinated individuals to entire communities. Herd immunity occurs when a certain percentage of the population has been immunized and the immunized population provides protection to unimmunized individuals. The immune population breaks the transmission path of an infectious disease. Fine et al. speak to the definition often used with vaccination that "…a particular threshold proportion of immune individuals that should lead to a decline in incidence of infection" (Fine, Eames, & Heymann, 2011, p. 911). Beyond the known herd immunity effects of vaccination coverage of over 90% for measles, ("Global control and regional elimination of measles, 2000-2011," 2013) recent studies have shown the ability of mass Oral Cholera Vaccine (OCV) at lower vaccination coverage levels to slow cholera outbreaks.

OCV has been shown useful at vaccine coverage rates of 50-86% to help slow cholera outbreaks in densely populated environments with weak water and sanitation infrastructure (Luquero et al., 2013; Riedmann, 2014). Luquero et al. showed that OCV at coverage levels as low as 50% make a difference in slowing cholera outbreaks in settings that lack alternative

interventions like a rapid large scale water and sanitation response. GAVI made a decision to invest in the global stockpile of OCV in case of need due to outbreak. GAVI decided that they were in a unique position to contribute and have an impact in "poor and fragile settings" (GAVI, 2013c, p. 7). Investing in the global stockpile of OCV is uncertain, because the OCV is kept in reserve in anticipation of an outbreak and the vaccine could expire before it is used. GAVI chose to invest in OCV in spite of this uncertainty.

GAVI's indicators for regional concerns allowed for the inclusion of yellow fever vaccine campaign support in Africa and expanding Japanese encephalitis in EPI schedules in Asia. Disease of regional importance was included as an indicator after internal discussion at GAVI decided the criteria worked well for diseases like Japanese Encephalitis and Yellow Fever which have disproportionate impacts in Asia and Africa respectively (GAVI, 2013a). It was decided these vaccines addressed accomplishing the mission of GAVI, since these diseases were a burden in a large number of GAVI countries (GAVI, 2013a; MacLennan & Saul, 2014). With variable criteria, like disease of regional importance, GAVI considered if the inclusion of this kind of specific but qualitative criteria in the VIS methodology concentrated or diluted the process. In the end, they decided to include these measures for some of the very same reasons that their exclusion was debated; these criteria added a measure of flexibility to the VIS and also allowed for setting specific considerations when needed. These deviations made sense to add more evidence to the framework and meet goals in the LMIC where GAVI's work is focused.

9) RECOMMENDATIONS

9.1. Adding IOM Smart Criteria to GAVI's VIS for Smart Practice

The IOM SMART indicators work to enrich the VIS tools because they add vaccine affordability as criteria to better reach GAVI's goals. Criteria from the IOM SMART Vaccine frameworks are more expansive and enhance the VIS scorecards for smart practice. The three SMART criteria identified: demonstrating new production platforms, existence of manufacturing techniques and likelihood of manufacturer profit, build a stronger VIS framework (IOM, 2012, p.24). These vaccine affordability concerns add information to the process that addresses important considerations for GAVI.

9.2. Vaccine Affordability, Criteria that Serve Middle Income Countries

Vaccine costs need to be transparent, and vaccines need to be affordable. Figure 9, above, uses the example of PCV to point out that vaccine affordability criteria needs to be added to the VIS scorecards to lower costs and better achieve GAVI's goals. Concerns around vaccine affordability are a critical issue facing MICs that graduate from GAVI funding. GAVI defines graduating countries as "Countries whose Gross National Income (GNI) per capita crosses the GAVI eligibility threshold (currently US$1,570) enter a graduation process and start phasing out of GAVI support. During this phase, GAVI will intensify its efforts to help graduating countries be in the best position to financially sustain their routine programmes and new vaccines" ("Graduation Policy - GAVI," 2014).

Expanding GAVI VIS criteria to include criteria that address vaccine affordability considerations from the IOM SMART framework (see Figure 9) would allow for more transparent evaluation of vaccine manufacturing roles and for better understanding of vaccine affordability. PCV is a vaccine many MIC cannot afford because PCV was recently developed

and remains expensive. PCV is also an example of where, GAVI can "…intensify its efforts…" to help graduating countires ("Graduation Policy - GAVI," 2014). Besides PCV, there are a number of vaccines that fall into this same category of too new and too expensive for MIC. Both Human Papilloma Virus (HPV) and rotavirus are new vaccines with hefty price tags. If more price transparency criteria are added to the VIS framework, the same information can be used by MIC to negotiate fair prices. Helping MIC negotiate vaccine access would also move towards GAVI's partnerships "shared goal of creating equal access to vaccines for children, wherever they live" ("The partnership model – GAVI," 2014).

Saxenian et al. have written about the need for new ideas with graduating MIC "As the graduation process advances, GAVI and graduating countries should continue to contribute to global collective thinking about how developing countries can successfully end their dependence on donor aid and achieve self-sufficiency" (Saxenian et al., 2014, p. 1). Giving MIC the know-how and knowledge to negotiate directly with multinational pharmaceutical companies helps these countries stand on their own and build their independence. Looking at challenges facing middle-income countries, Kaddar et al write: "Given the growth in the number of MICs and their considerable domestic income disparities, they are now home to the greatest proportion of the world's poor, having more inhabitants below the poverty line than low-income countries (LICs). However, they have little or no access to external funding for the implementation of new vaccines, nor are they benefiting from an enabling global environment… some additional tools developed for LICs could prove useful to MICs and thus should be adapted for use by them. In addition, new approaches need to be developed to support MIC-specific needs" (Kaddar, Schmitt, Makinen, & Milstien, 2013, p. B. 81). Providing MIC with more information for negotiating affordable vaccines is a way to offer them more support.

In the IOM introduction to the SMART framework, they address and justify the inclusion of manufacturing concerned criteria, particularly the indicator likelihood of financial profitability for the manufacturer (IOM, 2013). In justifying the inclusion of such criteria, the IOM SMART states that business is an essential part of private sector solutions. As a PPP, GAVI has many vaccine manufacturer representatives on their board. Donor-based solutions like GAVI have been developed to solve the problem of vaccine affordability for MICs, as discussed in *Global Health and the New Bottom Billion: What do Shifts in Global Poverty and Disease Burden Mean for Donor Agencies?* (Glassman, Duran, & Sumner, 2013) Instead of focusing on donor agencies to find funding solutions for the shifting disease burden, support should be given to MIC to negotiate solutions directly with the private sector. This option offers MIC an autonomous and sustainable solution for affordable vaccine procurement.

10) LIMITATIONS

One of the aims of this thesis is to share information about the decision-making process at GAVI specifically, but this specificity raises questions as to how much the information can be generalized. Since GAVI's PPP and mission are singular, extrapolating the process for other organizations may be difficult for different conditions and contexts. Nevertheless, it is hoped that the use of indicators and criteria, as used by GAVI to build an evidence-based framework, will be broadly illustrative in itself. While the VIS framework is unique to vaccines, there is the possibility to apply it to other health technologies. Other health technologies that would be suited to an evidence-based framework are water and sanitation interventions or mosquito reduction strategies in areas with malaria, dengue or other mosquito-borne disease. With more

scholarship and research into evidence-based frameworks in LMIC, including both analytical and descriptive studies, more solid conclusions about the importance and broader applicability of GAVI's VIS framework can be drawn.

There is only a small body of research available on evidence-based frameworks for health policy decision-making and vaccine decision-making frameworks. Limitations for this thesis were a lack of prior peer-reviewed research available to inform and guide the policy analysis methodology used here, allowing for more trial and error in evaluating the VIS process. A larger body of research also contributes a wider field of ideas and experiences to examine, which is particularly important in policy analysis. Bardach speaks of the importance of refining ideas and, if possible, collaborating, "Over the course of your analytical work, your empirical and conceptual understanding will evolve" (Bardach 2005, p. 8-9). Unfortunately, working without a great deal of background research and with a restricted time frame constrained the amount of development that could be done on ideas and concepts. The Johns Hopkins Health Policy Analysis Checklist (Weiner, 2005) emphasizes the importance of group work and collaboration in policy work, which is not adapted to an individual's thesis format. Evidence-based framework could benefit from more resources and research, as could further study of the VIS and GAVI's use of the framework.

Another limitation was access to primary data and possible bias in internal data provided by GAVI. GAVI agreed to provide data on their process, but this data was self-selected, so it is possible not all the data on certain indicators or topics was given. GAVI expressed a desire to be very transparent about their VIS process, which they already accomplish through published VIS materials on their website. To the best of the researcher's knowledge, GAVI was forthcoming with all data requested, with no omissions. However, this is not equivalent to having free and

unhindered access to all internal correspondence on the VIS framework and could have possibly limited this research and its conclusions.

11) CONCLUSIONS

Smart practice is a flexible methodology that analyzes diverse groups of vaccines for a wide range of country contexts and needs. GAVI has a well-built framework that draws on an evidence-based structure with both sound quantitative data and rich qualitative information. The VIS process will be strengthened by adding additional criteria. Expanding criteria around vaccine affordability accomplishes a number of goals. Firstly, it brings relevant information to the forefront within GAVI's PPP to structure internal negotiations for better pricing. With an annual budget of $1.9 billion and an upcoming replenishment request of $7.5 billion to donors, GAVI wields substantial purchasing power. This financing better serves beneficiaries and donors if it is wisely spent. Secondly, more transparency around vaccine pricing and profit will provide relevant information to MICs graduating from GAVI funding, assisting them in obtaining sustainable pricing from vaccine manufacturers.

GAVI's idealism, seen in its mission to fully vaccinate children worldwide, is highlighted by the consultative multi-year process they used to create the VIS framework. GAVI has invested considerable time and energy creating a decision-making process that led to smart practices. As PPPs continue to grow to solve problems in the arena of global health, finding more ways for these collaborations to be more supportive and inclusive can help ensure continued success towards meeting the goals of vaccinating the world's children (Keith, Agostini Bigger, Arthur, Maes, & Daems, 2013). GAVI's partner, UNICEF, reported that "The year 2014

has been one of the worst on record for the world's children… in a report that chronicled a litany of war, violence, atrocities and disease…" (Gladstone, 2014). This same year has included new outbreaks of polio in South Sudan and Madagascar and a record year for measles with the largest number of cases reported in over twenty years ("Poliovirus in South Sudan and Madagascar, 2014; "Measles, Immunization, Vaccines and Biologicals", 2014). GAVI's work is vital and needs to be swiftly and efficiently accomplished. By expanding their VIS framework GAVI will be better placed to find smarter ways to serve beneficiaries in need worldwide.

Sharing more information about the VIS tools and process by adding to the literature around complex decision-making in LMIC settings contributes to the field of policy analysis literature. GAVI is a forerunner in public private partnerships that "embrace self-critique and self-improvement" (Buse & Tanaka, 2011, p. 8). Sharing GAVI's experience with the VIS process provides valuable information for other organizations seeking to build or strengthen evidence-based frameworks. GAVI's VIS framework has helped them achieve results and sharing information will provide other organizations with examples to structure their own evidence-based frameworks and build their own smart practices and policies.

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Judith Kallenberg, Head of Policy and Performance

Dr. Robert Newman, Managing Director of Policy and Performance and Clinical Associate Professor, University of Washington

APPENDIXES

A. New and underused vaccine support at GAVI since November 2013 ("New and underused vaccines support", 2014)

Human papillomavirus support

Inactivated polio vaccine support

Japanese encephalitis vaccine support

Measles vaccine support

Measles-Rubella vaccine support

Meningitis A vaccine support

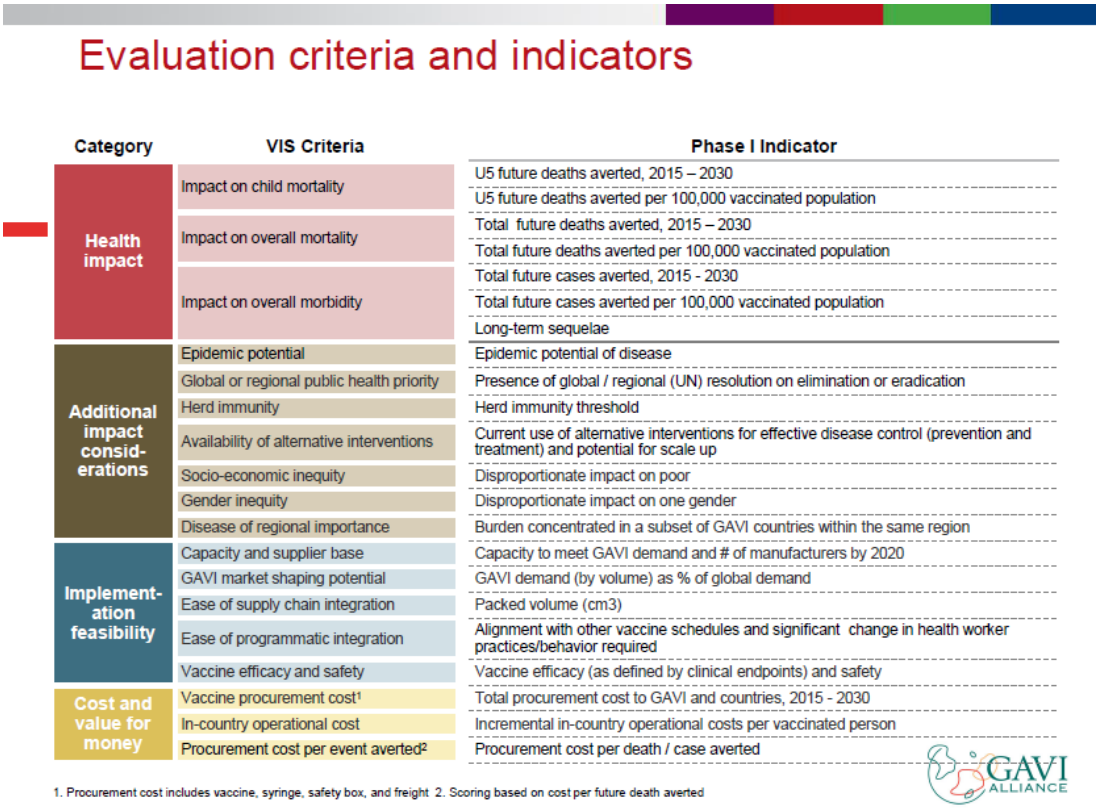
Pentavalent vaccine support

Pneumococcal vaccine support

Rotavirus vaccine support

Yellow fever vaccine support

B. GAVI VIS Scorecard Format (Kallenberg, 2014)



Evaluation criteria and indicators

Category	VIS Criteria	Phase I Indicator
Health impact	Impact on child mortality	U5 future deaths averted, 2015 – 2030
		U5 future deaths averted per 100,000 vaccinated population
	Impact on overall mortality	Total future deaths averted, 2015 – 2030
		Total future deaths averted per 100,000 vaccinated population
	Impact on overall morbidity	Total future cases averted, 2015 - 2030
		Total future cases averted per 100,000 vaccinated population
		Long-term sequelae
Additional impact consid-erations	Epidemic potential	Epidemic potential of disease
	Global or regional public health priority	Presence of global / regional (UN) resolution on elimination or eradication
	Herd immunity	Herd immunity threshold
	Availability of alternative interventions	Current use of alternative interventions for effective disease control (prevention and treatment) and potential for scale up
	Socio-economic inequity	Disproportionate impact on poor
	Gender inequity	Disproportionate impact on one gender
	Disease of regional importance	Burden concentrated in a subset of GAVI countries within the same region
Implement-ation feasibility	Capacity and supplier base	Capacity to meet GAVI demand and # of manufacturers by 2020
	GAVI market shaping potential	GAVI demand (by volume) as % of global demand
	Ease of supply chain integration	Packed volume (cm3)
	Ease of programmatic integration	Alignment with other vaccine schedules and significant change in health worker practices/behavior required
	Vaccine efficacy and safety	Vaccine efficacy (as defined by clinical endpoints) and safety
Cost and value for money	Vaccine procurement cost[1]	Total procurement cost to GAVI and countries, 2015 - 2030
	In-country operational cost	Incremental in-country operational costs per vaccinated person
	Procurement cost per event averted[2]	Procurement cost per death / case averted

1. Procurement cost includes vaccine, syringe, safety box, and freight 2. Scoring based on cost per future death averted

GAVI ALLIANCE

C. IOM SMART Criteria description (IOM, 2013)

TABLE S-1

Choices of Attributes in SMART Vaccines 1.0

Health Considerations	• Premature Deaths Averted per Year • Incident Cases Prevented per Year • QALYs Gained or DALYs Averted
Economic Considerations	• Net Direct Costs (Savings) of Vaccine Use per Year • Workforce Productivity Gained per Year • One-Time Costs • Cost-Effectiveness ($/QALY or $/DALY)
Demographic Considerations	• Benefits Infants and Children • Benefits Women • Benefits Socioeconomically Disadvantaged • Benefits Military Personnel • Benefits Other Priority Population
Public Concerns	• Availability of Alternative Public Health Measures • Potential Complications Due to Vaccines • Disease Raises Fear and Stigma in the Public • Serious Pandemic Potential
Scientific and Business Considerations	• Likelihood of Financial Profitability for the Manufacturer • Demonstrates New Production Platforms • Existing or Adaptable Manufacturing Techniques • Potential Litigation Barriers Beyond Usual • Interests from NGOs and Philanthropic Organizations
Programmatic Considerations	• Potential to Improve Delivery Methods • Fits into Existing Immunization Schedules • Reduces Challenges Relating to Cold-Chain Requirements
Intangible Values	• Eradication or Elimination of the Disease • Vaccine Raises Public Health Awareness
Policy Considerations	• Interest for National Security, Preparedness, and Response • Advances Nation's Foreign Policy Goals
User-Defined Attributes	• Up to Seven Attributes

NOTE: DALYs = disability-adjusted life years; NGOs = nongovernmental organizations; QALYs = quality-adjusted life years.

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