

CONTEXTUALIZING GUIDANCE FOR
HEALTH SYSTEMS STRENGTHENING

DEVELOPING AND EVALUATING THE USE OF A WORKBOOK FOR
CONTEXTUALIZING HEALTH SYSTEMS GUIDANCE

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Lay abstract

Strong health systems are needed in order for the right mix of clinical care and public health interventions to get to those who need them. The World Health Organization writes guidance at the global level to help countries strengthen their health systems. This guidance can be used to develop health guidance or policy for the national or subnational (e.g., provincial, state) level, but it first needs to be contextualized or adapted to that particular jurisdiction. It is important to consider what the problem is and what causes it, policy options to help deal with the problem, implementation considerations, as well as factors related to both the health system and the political system that can affect whether or not the intervention will be implemented. A workbook was developed to help contextualize guidance. This dissertation explores the process of developing and evaluating its use to help in the planning of future tools, to provide insights for practice and research, and to improve the workbook.

Abstract

Strong health systems are needed to implement clinical and public health interventions. Global evidence-informed health systems guidance, such as that created by the World Health Organization (WHO), has been used to help strengthen health systems. However, global guidance needs to be contextualized or adapted to fit the realities of a particular setting. A workbook for contextualizing health systems guidance was developed to accompany WHO guidance on optimizing health worker roles to increase access to and use of key interventions for improving maternal and newborn health. This dissertation investigates the development and use of the workbook, using qualitative research methods, to help in the planning of future knowledge translation tools, to provide insights for practice and research, and to improve the workbook. First, a single case study explores the development of the workbook, which helped uncover the key features of the process, barriers that arose, and facilitators that helped overcome some of these barriers (chapter 2). Second, a single embedded case study examined the use of the workbook in two real-life settings, Peru and Uganda (chapter 3). Third, a critical interpretive synthesis of the literature was used to better define contextualization and to find what and how contextual factors could be used by policymakers to adapt guidance to their setting (chapter 4). Together, the three studies presented in this dissertation offer substantive, methodological and disciplinary contributions to the field of health systems and policy through a comprehensive examination of the workbook. It presents

recommendations for improving the workbook from the perspectives of global guidance developers, users at the national level, and the broader literature on guidance and guideline development, contextualization and implementation. It also supports the continued use of workbooks, or other tools, to contextualize guidance in an effort to strengthen health systems, especially in low- and middle-income countries.

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Glossary and abbreviations

CHWs – Community health workers (in Uganda; similar to lay health worker as defined in the OptimizeMNH guidance but without formal biomedical training)

ECV (external cephalic version) – procedure to turn a fetus in the uterus so it is head-down prior to delivery

ENDES (encuesta demográfica y de salud familiar) - Peru's demographic and family health survey

ENESA (encuesta nacional de establecimientos de salud) - Peru's maternal and newborn health centre survey

EVIPNet – Evidence-informed policy network (www.evipnet.org)

HIREB – Hamilton Integrated Research Ethics Board in Hamilton, Ontario, Canada

INS (Instituto Nacional de Salud) – National Institute of Health (supports the work of the Ministry of Health in Peru)

KT – Knowledge translation

LHW – Lay health worker (health cadre category in OptimizeMNH guidance)

LMICs – Low- and middle-income countries

MDG – Millennium Development Goals

MINSA – Ministerio de Salud – Peru's health ministry

MoH – Ministry of Health in Uganda

OptimizeMNH guidance – A WHO guidance document published in 2012 on optimizing health worker roles to improve access to key maternal and newborn health interventions

REACH - Region of East Africa Community Health Policy Initiative

SOM-REC – School of Medicine Research and Ethics Committee, Makerere University College of Health Sciences, Kampala, Uganda

SURE – Supporting the use of research evidence for policy in African health systems (a collaborative project involving researchers and policymakers in seven African countries, lasting 5 years, funded by the European Commission’s 7th Framework Programme, and supported by research teams in Canada and Europe)

UNAGESP (Unidad de Análisis y Generación de Evidencias en Salud Pública) – Unit for analysis and evidence production for public health (lies within INS)

WHO – World Health Organization

Declaration of academic achievement

This dissertation presents three original scientific contributions (chapters 2-4), along with introductory and concluding chapters (chapters 1 and 5). Each of the chapters in this dissertation is co-authored, and I am the lead author for each. Details of specific contributions are provided in the preface to each individual chapter. Overall, I conceived of each chapter with my supervisor, Dr. John Lavis, and with inputs from members of my supervisory committee, Dr. Melissa Brouwers and Dr. Lisa Schwarz. I completed all data collection and analysis for each chapter. Finally, I drafted all chapters, and each co-author provided feedback that was incorporated into subsequent revisions.

Introduction

“While half the world's deaths are potentially preventable with simple and cost-effective interventions using these public goods [life-saving technologies such as drugs, vaccines and diagnostics], the 2005 mid-decade assessment is expected to reveal that the MDGs are unlikely to be reached in several regions by 2015 due to shortfalls in the capacity of health systems.”

- WHO Report, Ministerial Summit on Health Research, 2004

The *Ministerial Summit on Health Research* held in 2004 in Mexico City provided a platform to address global cooperation for health research and emphasized the importance of translating research knowledge into action (overcoming the ‘know-do gap’) to narrow disparities in health system performance between high-income and low- and middle-income countries (LMICs) in order to improve population health. (1) It was emphasized that in order for effective clinical or public health interventions to save lives or improve the quality of lives, there needed to be strong health systems to deliver these interventions. (1,2) Health systems incorporate all the people, organizations, and actions involved in improving or maintaining health. (2,3) In the majority of countries, governments are fully or partially involved in the designing and functioning of health systems. Therefore, if a large-scale change in the preferred choice of intervention (e.g., a change in practice as guided by guidance or guidelines within a province or country) is needed within a publicly funded or government-run health system, then the government will be involved in funding, regulating and/or even delivering the intervention and supports for its widespread use. (4,5) Therefore, the government or Ministry of Health, depending on the

setting, will need to decide on approving such a change. (4) Unfortunately, many LMICs have significant resource limitations and numerous competing health and other priorities, and their health systems have sometimes been weakened by a focus on vertical or single disease programs (e.g., HIV, malaria) instead of integrated care. (2,4,5)

One of the approaches taken to strengthen health systems was for the World Health Organization (WHO) to develop evidence-based health systems guidance at the global level, which allowed for the pooling of resources and knowledge in order to help offset costs for researching possible solutions for countries facing the same or similar issues (e.g., maternal and newborn morbidity and mortality, HIV). (2,4,6) Global guidance can inform policies at the global level, such as the funding policy of an international organization. (4) One example of this is how global guidance on malaria affects funding for malaria prevention and treatment by international organizations, such as The Global Fund to fight AIDS, Tuberculosis and Malaria. (7) In addition, global guidance can be used in the development of national guidance by a guidance panel or by an Evidence-Informed Policy Network (EVIPNet team). An example of this is a 2010 policy brief developed in Ethiopia on human resources capacity with regards to malaria prevention and treatment, which incorporated recommendations from WHO's guidance document on increasing access to health workers in remote and rural areas through improved retention. (8,9) Lastly, guidance can inform the development of policy at the national or subnational level, such as a Ministry of

Health writing policy for the nation in unitary systems or for a province in decentralized systems. (4) An example of this can be found in Ontario's Skin Cancer Prevention Act for tanning beds in 2013, in which WHO recommendations provided a basis for creating the Act. (10) However, in order for guidance to have an impact, the issue first needs to compete for and be granted a place on the government's agenda, the guidance needs to inform policy development, and a policy needs to be approved and implemented. (4,11) As part of this process, the guidance recommendations need to be contextualized or adapted to a particular setting, whether national or subnational. (4)

Evidence briefs and policy dialogues have been advanced as methods to support the development of evidence-informed national guidance or policy. (4,12,13) An evidence brief is a document created at the national or subnational level which presents research evidence on a health or health system problem and its causes, possible policy options, and implementation considerations. (4,13) The evidence brief can then be used to inform a policy dialogue. A policy dialogue is organized to elicit the views, experiences and tacit knowledge of policymakers, stakeholders and researchers who are involved in or affected by decisions surrounding the topic and by the possible policy options at hand. A summary of the policy dialogue can help inform agenda setting, policy development and/or policy implementation. (4,13)

Between 2010 and 2012, WHO developed the 'OptimizeMNH' guidance for optimizing health worker roles in order to increase access to and use of key

interventions to improve maternal and newborn health in LMICs. (14) Because this document was addressing the roles of health workers, which could require changes in regulation, training or supervision, the group working on this guidance document recognized the need for a health systems approach (see chapter 2). McMaster University's WHO Collaborating Centre for Evidence-Informed Policy as well as select other institutions, were called upon to provide these insights (personal communication, 2012). Through this process, it was determined that a tool to support users at the national or subnational level contextualize the guidance recommendations with national (local) data and evidence to their settings should accompany the guidance document (personal communication, 2012). Local evidence includes evidence which is specific to the jurisdiction of focus, which could include national, provincial/state or municipal levels. However, there were no tools which addressed how to combine global recommendations with national / subnational assessments of local problems and their causes, as well as of existing health system arrangements that may need to be changed, and political system considerations that needed to be taken into account (4).

A workbook for contextualizing health systems guidance (henceforth, "workbook," see appendix A) (15) was developed de novo by myself and my supervisor (John Lavis). The workbook was based on the second article of the *PLoS Med* series on 'guidance for evidence-informed policies about health systems' (2,4,16), which outlined the contextualization or adaptation process from

global guidance to global or national policy or national guidance, and the contextual factors to take into account while developing an evidence brief. This article in turn drew from the content of the ‘SUPPORT tools for evidence-informed health policymaking’ articles, which include clarifying evidence needs in policymaking, (17–19) taking equity into consideration, (20) preparing policy briefs and policy dialogues, (21,22) engaging the public, (23) and planning monitoring and evaluation of policies (24). In addition, insights from the OptimizeMNH guidance panel discussions were incorporated into this work. (15) Briefly, the workbook included a narrative of how to use the workbook and provided questions for the users to consider in developing national or subnational guidance or policy informed by global guidance. The workbook also gave examples related to the topic of optimizing health worker roles for improving maternal and newborn health, which were drawn from the OptimizeMNH guidance and related systematic reviews, and it provided prompts for what type(s) of evidence (e.g., systematic reviews, local studies, administrative data, etc.) could be looked at to help answer the questions.

The workbook followed a newly developed framework called the ‘health systems guidance contextualization framework,’ which addressed: 1) clarifying the problem and its causes; 2) framing options for addressing the problem; 3) identifying implementation considerations; 4) considering the broader health system context; 5) considering the broader political system context; 6) refining the statement of the problem, options and implementation considerations in light

of health system and political system factors; 7) anticipating monitoring and evaluation needs; and lastly, 8) making national or subnational policy recommendations or decisions (15).

Since the workbook was a new tool, and the author of this dissertation was involved in developing the tool, it offered a unique opportunity to study the process of developing the workbook (chapter 2) and the process of evaluating the use of the workbook in real-life settings (chapter 3). In addition, a critical interpretive synthesis of the literature was used to better define what contextualization meant, especially as compared to other terms such as adaptation, and to find what contextual factors could be used by policymakers to adapt guidance to their setting, as an additional way to inform any future refinements of the tool (chapter 4). Together, the three studies presented in this dissertation offer a comprehensive examination of a new type of knowledge translation tool – the workbook -- and present recommendations for improving the workbook from the perspectives of developers of global guidance, from the perspectives of users at the national level, and from the perspectives of a broader literature on guidance and guideline development, contextualization and implementation. Even though it may be more common to conduct a literature review as a first study in a dissertation, the timeframe in which it was decided at the level of WHO that a workbook was needed to the time the workbook was to be submitted (a matter of a few months) did not allow for this literature review to occur first. Instead, the latest scholarly work in the field of health systems and policy research was used

to set up the structure and to operationalize the workbook. However, conducting a critical interpretive synthesis once the author was more familiar with the topic and had feedback from, and personal experience with, using the workbook in real-life settings also provided a unique opportunity to critically interpret the findings. This process added a rich level of understanding to the analysis and was also used to inform the recommendations made for improving the workbook.

Chapter 2 uses a single case study approach to explore the process of developing the workbook. A rich description of the process and the context in which it played out is provided, and the multiple steps in the process are described, along with barriers and facilitators. Exploring this process helped identify the common critical factors influencing each step, and reasons for why the work moved forward (or not) based on the presence (or absence) of these critical factors. A model is presented of the relationships between these critical factors. Recommendations were also provided to improve the workbook. These recommendations are elaborated further in chapter 5.

Chapter 3 examines the process of using the workbook to develop evidence briefs in two quite different settings, Peru and Uganda. An embedded case study approach is used to explore the process of using the workbook. The case study also highlights the importance of context in developing policy to fit the needs of a particular setting. Even though both countries started with the same guidance recommendations and the same method to develop an evidence brief (i.e., the workbook), and even the same facilitators (both myself and my

supervisor, John Lavis), each country team ended up focusing on very different topics, venues where decisions would be made, ways to define the problem and its causes, potential policy options, and considerations for implementation. Overall, the workbook was seen as helpful when compared with usual processes.

However, the process is still time and resource intensive and cannot replace the work of country experts (i.e., methods and content). Benefits and challenges of using the workbook are provided. Recommendations for improving the workbook based on what was learned are provided in chapter 5.

Chapter 4 uses a critical interpretive synthesis method of literature review combined with qualitative methods for data analysis (e.g., template-organizing style, and constant comparative method) to review a wide range of fields in order to better define contextualization and other related terms (e.g., adaptation) and to identify contextual factors which are used in adapting global guidance to the national or subnational level. Two models were created. The first model describes the processes by which guidance can be shaped to fit a particular setting and how context relates to this process and to the implementation of recommendations. The second model shows what factors influence the guidance contextualization process. In addition, the mechanisms by which contextual factors may affect the chances of policy being implemented are described. Lastly, recommendations for improving the workbook are gleaned from this work and are presented in chapter 5.

Chapter 5 provides reflection on how these studies individually and combined offer substantive, methodological and inter-disciplinary learnings. This includes suggestions for how to improve the workbook from what was learned through the three studies. These recommendations draw from the perspectives of global guidance developers (chapter 2), users of guidance at the national/subnational level (chapter 3), and a multi-disciplinary literature synthesis on guidance and guideline contextualization and adaptation (chapter 4).

Substantively, this dissertation overall provides a better understanding of the processes involved in developing and evaluating the use of the workbook and the contextual factors which affected various parts of these processes. Chapter 2 presents a model of the critical factors, and their relationships, that contribute to the success or non-success of each step, and sub-step, in the process of developing the workbook. These insights could help those looking to develop tools at the international level plan for possible barriers and facilitators in order to improve the chances that their work will be successful. Chapter 3 provides first-hand insights into what and how contextual factors played a role in developing an evidence brief and shaping policy recommendations in Peru and Uganda. Building on these findings and through a systematic literature review, two new theoretical models are presented in chapter 4. The first model is on the processes by which guidance can be shaped for implementation in a particular setting and how context relates to these processes and to the implementation of recommendations. The second model shows what factors influence the guidance

contextualization process. Mechanisms by which these contextual factors may affect the chances of policy being implemented are also described.

Methodologically, the three studies together offered a unique approach to evaluating the workbook using qualitative research methods. The case studies used in chapters 2 and 3 provided the opportunity to explore the processes of developing and evaluating the use of the workbook as well as the contexts surrounding these processes. Relating contextual factors to the processes were central to the creation of the models in this dissertation. In chapter 4, several related concepts were examined as part of a critical interpretive synthesis, which allowed for individual concepts to be examined (e.g., terms used to describe how guidance is shaped in order to be implemented, and how contextual factors are used in contextualizing guidance), but it also allowed for relationships to be built between the concepts (e.g., how do contextual factors affect the contextualization process). In addition, a template-style of data organization was used during data extraction in the critical interpretive synthesis in chapter 4, which facilitated the collection and analysis of data. Lastly in chapter 4, incorporating theories from various fields allowed for the development of models that could be applicable to a multitude of fields incorporating guidance or guidelines in the use of research evidence for informing policy decision making. Another unique methodological aspect of this dissertation overall was that these studies were conducted in a concurrent manner, and information gathered in one study was compared and contrasted to findings within the other studies to strengthen the concepts found in

each chapter and to strengthen the recommendations made to changing the workbook (e.g., the need to highlight advocacy strategies). These areas of overlap are further discussed in the prefaces of each chapter.

One important methodological note is that as soon as it was determined that a workbook needed to be developed and that this work would tie in to a dissertation project by the principal investigator (EA), a reflexive journal was started by EA. Qualitative research relies on the investigator being a research instrument. According to Janesick, (25) the researcher must know how to observe and perform face-to-face interviews, and qualitative design includes the researcher's biases and beliefs. Patton (26) adds that the "skill, competence and rigor of the person doing fieldwork" along with distractions in that person's life determine the credibility of the qualitative method. Lastly, Sword states, "Reflection on the influence of self not only creates personal awareness of how the research is shaped by one's own biography but also provides a context within which audiences can more fully understand the researcher's interpretation of text data." (27) So, researchers can influence the entire research process by bringing in their own pre-set values and beliefs and by influencing the process under study (e.g., as participant-observer), how data are collected (e.g., during interviews), and in data analysis (e.g., interpretation). The reflexive journal was used in a variety of ways by the principal investigator (see table 1). Examples include: keeping track of events in the development of the workbook and throughout the dissertation, planning and following up on work to be done as well as

understanding decision points, reflecting on the role of researcher, and developing themes and triangulating data. Some of the techniques used and examples of how these contributed to the dissertation are provided in table 1.

This dissertation contributes to the field of health systems and policy by suggesting ways in which to improve the workbook but also by suggesting considerations for the processes involved in developing and using similar future workbooks, such as incorporating a plan for dissemination and implementation during the preparation of a new knowledge translation tool. Chapter 2 highlights that understanding the critical factors involved in developing and implementing new tools can help identify potential points of tension and find ways to overcome them. For example, understanding the critical factors involved in the process of developing the workbook could help in the planning of the development of other tools (e.g., the need for a well-placed and credible champion) or in evaluating why a process may not be advancing as expected and potential solutions (e.g., trying to find the right language to build understanding and obtain buy-in). Chapter 3 highlights the potential role that WHO could play in the process of contextualizing guidance by institutionalizing the development of workbooks into its guidance development processes and by helping countries build capacity for local health- and political-system analysis. At the country level, chapter 3 highlights the need to have methods and content experts, including country experts who understand the health system and the priorities of the government or Ministry of Health. Chapter 4 contributes a framework of relevant contextual

factors to be considered in the process of contextualizing guidance. In addition, mechanisms are presented by which these contextual factors could improve the chances of implementing the global guidance recommendations.

The work presented in this dissertation is multi-disciplinary by its very nature and given the people involved in its creation, including the principal investigator, the supervisory committee, and the participants in the studies. In addition, there was an attempt to incorporate a variety of fields to expand the knowledge base, especially for developing the conceptual models in chapter 4. However, it is important to highlight that this dissertation is mainly grounded within health systems and policy approaches. As is seen in figure 1 (28), health systems and policy research overlaps with many other fields, and while these fields have enhanced the concepts presented, they were not the focus of the dissertation. Future work could look to incorporate further knowledge from some of these fields, such as quality management, priority-setting, and implementation science, among others.

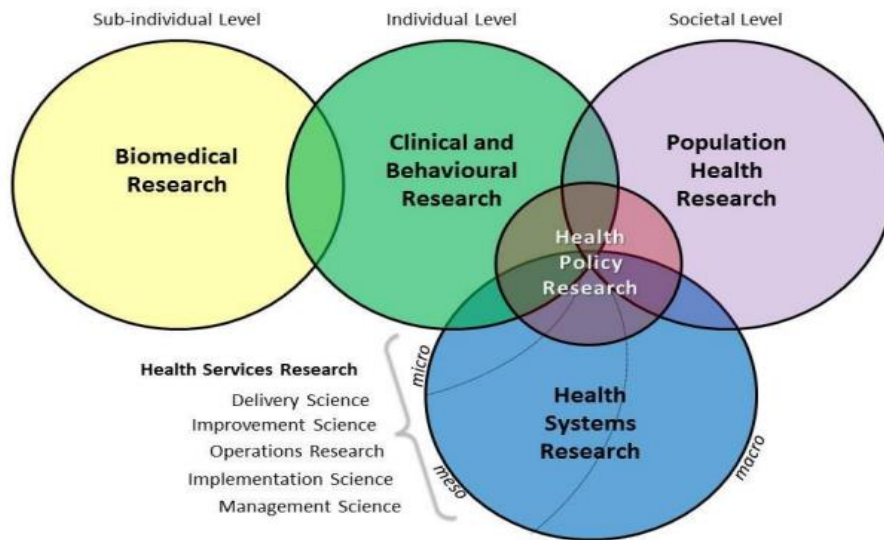


Figure 1. Health systems research as a multidisciplinary field of health research (28)

It has been noted throughout the dissertation that there is an interplay between global-level guidance development and national/subnational-level contextualization of the guidance. There have been concerns around the role of international health organizations and donors in the context of global policies being funded and implemented at the country level. (29–31) It is important to note that the contextualization process is meant to support national/subnational users in determining how global recommendations may best apply to their specific settings. Chapter 3 specifically highlights the need to have country experts involved in the contextualization process in order to tailor global recommendations to the needs of the populations affected by the proposed changes. This interplay of having WHO pool resources to address the same or

similar issues affecting multiple countries, and having the countries tailor the recommendations to their contexts is what has been proposed as a way to capitalize on the strengths and needs of the various organizations involved in using evidence to inform decision-making. (4)

Overall, this dissertation provides insights into the processes involved in developing and evaluating a workbook for contextualizing health systems guidance and contextual factors influencing these processes. The workbook itself was evaluated in two, diverse, real-life settings and was found to be useful in the process of developing evidence briefs. Recommendations drawn from the three studies are provided which could help advance the development of evidence briefs and inform other fields in which guidance/guidelines are used. Having a user-friendly, systematic and transparent process for combining global guidance recommendations with local data and studies and with local analyses of the health system and political system offers the potential to improve the chances of translating research evidence into implementable knowledge for strengthening health systems.

Table 1. Examples of how the reflexive journal was used in, and how it contributed to, the dissertation

Uses	Techniques used	How this contributed to the dissertation
Keeping track of events in the development of the workbook and throughout the dissertation	Emails were placed into the journal in chronological sequence and thoughts were added regarding the content or context of the email. Information from the email included who it was from, who it was sent to, the date, and the content.	Having strings of emails makes it difficult to follow events chronologically as one has to sort through the string to know when certain events occurred. However, placing each email separately by date helped keep track of when events occurred and the sequence of events prior to and following events or decisions. One example of when this was used was in creating the timelines in chapters 2 and 3, which was especially helpful when comparing events in two separate countries, as in chapter 3.
Planning and following up on work to be done as well as understanding decision points	As mentioned above, thoughts regarding the emails or meetings or other events were added into the journal. This allowed for a reflection on what the main points were and next steps. A “to-do” list was often created following certain emails or after meetings.	Organizing information in this way allowed for follow up on the steps to see if they had been completed. In addition, this practice also helped demonstrate where decisions had been made by highlighting changes in plans. For example, there were multiple drafts made while developing the workbook. Having these insights recorded in the journal allowed for reflection on why the workbook took the shape it did based on different people’s perspectives and needs.
Reflecting on the role of researcher	As part of the reflexive exercise, it was noted what roles the principal investigator played and how this might have shaped the processes and outcomes of the studies or the work done in Peru and Uganda.	Using these reflections helped note how the principal investigator played a role in shaping events. For example, in chapter 3, it was noted that there were three aspects of the process that were different in this study compared to prior processes used in Peru and Uganda. One of these aspects was that, “Each relevant recommendation from the OptimizeMNH guidance was worked through systematically for developing policy options for the evidence briefs, which according to country experts, is not how guidelines are typically used, and are instead used more generally as a reference.” This may have been in part due to the countries looking to the principal investigator to help direct the process of using the workbook and the principal investigator’s way of approaching this work. Addressing this explicitly allowed for other participants to reflect on the process and provide their insights into how the process moved forward, and whether this was beneficial or not (see chapter 3).
Developing themes and triangulating data	The journal entries were all coded and included as data in chapters 2 and 3. The journal was also used throughout data analysis in all three studies to reflect on emerging concepts and themes.	Writing about events and their contexts and reflecting on these in an ongoing way, especially during data collection and data analysis, helped create themes and triangulate data. For example, the principal investigator was frustrated when someone who had helped develop the workbook later stated during a conference that the language of the workbook was difficult to understand. It was noted in chapter 2 that global guidance developers were concerned about the academic language required for WHO guidance approval processes and how this may pose a problem for non-academic users at the national or subnational level. Putting this information together helped develop the theme around language as a barrier or facilitator in chapter 2. The issue of language was then explicitly addressed in chapter 3 with users of guidance at the national level by asking them if the language of the workbook was a potential barrier. Lastly, all of these findings helped provide recommendations for improving the workbook.

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Chapter 2 - Preface

This chapter uses a single case study approach to explore the process of developing the workbook. A rich description of the process and the context is provided, and the key features of the development process, along with barriers and facilitators are described. Understanding these critical factors can help in the planning of future tools. In addition, this chapter highlights the need to focus on the implementation of tools during the development process, the need to support countries in contextualizing guidance, and the benefits of using a case study approach to understand tool-development processes and factors influencing them. Recommendations for improving the workbook are provided from the perspective of global guidance developers. These recommendations are elaborated further in chapter 5.

As discussed in chapter 1, the three studies in this dissertation occurred concurrently, and information gathered from each study helped inform the others. While this chapter provides theoretical and applied barriers and facilitators to using the workbook at the national/subnational level from the perspectives of global guidance developers, chapter 3 provides an applied look at these barriers and facilitators from the perspective of users of guidance at the national/subnational level. The findings from this chapter helped direct some of the information that was looked at in chapter 3 around barriers and facilitators in the process of using the workbook in Peru and Uganda (e.g., advocacy strategies). Findings from chapter 3, in turn, helped strengthen the concepts in this chapter

around the role of these barriers and facilitators, especially how the barriers were overcome in Peru and Uganda, which allowed for the work to move forward there (e.g., providing human resources to support the work). Furthermore, the concepts from chapters 2 and 3 were considered in chapter 4 to see if, and how, these concepts were defined and how they played a role in the contextualization of guidance.

I was responsible for conceiving of the design of the study with my supervisor, Dr. John Lavis, and for completing all data collection and analysis. Dr. Lavis also contributed to the analysis during ongoing iterative cycles of analysis. I drafted the chapter, and Dr. Lavis, Dr. Brouwers and Dr. Schwarz provided comments and suggestions that were incorporated into subsequent revisions. In addition, Dr. Lavis and I were involved in the process of developing the workbook which is studied in this chapter and presented as appendix A. These roles are described further in the chapter.

Contextualizing global health systems guidance: Exploring the development of a workbook to support the process

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Abstract

Introduction: Countries can use global guidance to help strengthen their health systems in order to deliver effective interventions to their populations. However, in order for guidance to have an impact, it needs to be contextualized or adapted to a specific setting, get on the government’s agenda, inform policy development, and be implemented. Influencing these stages of the policy process is complex and needs to take into account contextual factors, such as health systems arrangements and political system factors. For example, not having a referral system in place could limit the implementability of certain recommendations around where care is delivered. A workbook was developed to help contextualize the World Health Organization’s OptimizeMNH guidance (Optimizing the delivery of key interventions to attain Millennium Development Goals 4 and 5’) at the national or subnational level. The objective of this study was to explore the process of developing the workbook in order to uncover the key features of the development process, barriers that arose, and facilitators that helped overcome some of these barriers.

Methods: A single case study design was used. Interviews, documents and a reflexive journal were used as data. Constant comparison and an edit-style of data organization were used during data analysis to develop concepts, themes, subthemes and relationships.

Results: Thirteen interviews were conducted and 52 documents were reviewed. Three main steps, and various sub-steps, were identified in the process of developing the workbook for health systems guidance contextualization: 1) determining the need for and gaining approval to develop the workbook, 2) developing the workbook (taking on the task, creating the structure of the workbook, operationalizing its components, undergoing approval processes, and editing it), and 3) implementing the workbook both at the WHO level and at the national / subnational level. Five barriers and/or facilitators emerged relevant to each step: 1) having well-placed and credible champions, 2) creating and capitalizing on opportunities, 3) finding the right language to engage various actors and obtain buy-in, 4) obtaining and maintaining meaningful buy-in, and 5) ensuring access to human, financial and other resources.

Discussion: Understanding the key steps and the critical factors involved in the process of developing the workbook could help in the planning of the development of other workbooks and in evaluating why a process may not be advancing as expected and potential solutions to address these barriers. Also, a plan for dissemination and implementation needs to be addressed in the preparation of workbooks. Not having a plan for implementation can severely

limit the use and therefore the usefulness of these time- and resource-intensive products.

Currently, there are many health and public health interventions available that are simple and effective (e.g., immunizations, kangaroo mother care for low birth weight infants); however, because of fragmented and overburdened health systems, these interventions are not reaching those who need them most, especially in low- and middle-income countries (LMICs) (1–4). One way to strengthen health systems is to develop evidence-based health systems guidance at a global level to help countries facing the same or similar issues (e.g., lack of trained health workers for the delivery of effective interventions) (1). This is being done by international organizations, such as the World Health Organization (WHO). Global guidance can be used to develop policies at the global level and guidance or policies at the national or subnational levels. (5) First, at the global level, international organizations can develop policies to be used within their sphere of activity (e.g., funding vertical or single-disease programs vs. integrative care). Second, a national guidance panel or an Evidence-Informed Policy Network (EVIPNet team) can use global guidance, along with national or local data, to develop a country-specific evidence brief. Local evidence includes evidence which is specific to the jurisdiction of focus, which could include national, provincial/state or municipal levels. An evidence brief is a written document presenting evidence on a health system topic, possible policy solutions, and implementation considerations, which can then inform a discussion among policymakers, stakeholders and researchers (i.e., policy dialogue). (6) The evidence brief and policy dialogue summary can be used to inform a

government's decision about a health system problem. (5,6) Third, global guidance can be used to develop policy at the national or subnational level (e.g., national level in a unitary system, such as in Sweden or Cuba, or subnational level in a decentralized system, such as in the United States or India), by using global guidance and a national evidence brief and/or policy dialogue summary (5).

In order for global health systems guidance to have an impact, it needs to get on the government's agenda, inform policy development, and be implemented (5). These steps are determined by whether a national or subnational government agrees to prioritize a particular framing of a problem and its causes, whether it agrees that the recommendations make sense for its health system, and whether it has the commitment and resources to implement it (1,5,7). Therefore, global guidance also needs to be contextualized or adapted to a particular national or subnational setting or jurisdiction. (5) However, even after policy has been developed and adopted, the implementation of global guidance recommendations faces numerous challenges, and countries have been asking WHO for support in implementing guidance for many years (3). Oxman, Lavis & Fretheim (8) found that a lack of resources for the development of recommendations and inattention to dissemination and implementation strategies by WHO contributed to recommendations not being implemented after they were published.

Until recently, there has been a lack of support for users of health systems guidance (i.e. policymakers, stakeholders and researchers) at the national or subnational level for combining global recommendations with national /

subnational assessments of local problems and their causes, as well as of existing health system arrangements that may need to be changed, and political system considerations that need to be taken into account (5). If these factors can be addressed during the guidance contextualization process, then the resulting policy decisions should be designed to inform and support the specific needs of policymakers and stakeholders who are grappling with these issues within their countries and to have the desired impacts on the health of the population.

Between 2010 and 2012, WHO developed a guidance document with recommendations for optimizing health workers' roles (through regulation, training and support) to improve access to and utilization of key interventions for improving maternal and newborn health in LMICs ('Optimizing the delivery of key interventions to attain Millennium Development Goals 4 and 5' or OptimizeMNH guidance) (9). In addition to the recommendations, WHO wanted to include a tool to help users at the national or subnational level to contextualize the recommendations, along with local (national) evidence and assessments of the health and political systems, into their own settings or jurisdictions. A workbook for contextualizing health systems guidance (henceforth "workbook") was developed de novo, by two of the authors of this paper (EA and JL), as it was determined by those involved in the development of the OptimizeMNH guidance and other international health systems and policy experts that no tools were already available for this purpose. (5,10,11) The OptimizeMNH guidance document was published online in December 2012 along with a two-page

summary and the annexed workbook addressing the contextualization and implementation of the guidance. (12)

The workbook was based on current scholarly work in the field of health systems and policy and addressed: 1) clarifying the problem and its causes; 2) framing options for addressing the problem; 3) identifying implementation considerations; 4) considering the broader health system context; 5) considering the broader political system context; 6) refining the statement of the problem, options and implementation considerations in light of health system and political system factors; 7) anticipating monitoring and evaluation needs; and lastly, 8) making national or subnational policy recommendations or decisions (12). These steps made up the ‘health systems guidance contextualization framework,’ which was created with the workbook.

Because EA and JL were involved in the development of the workbook, it presented a unique, first-hand, opportunity to study the process leading up to and during its creation and the context surrounding this process (e.g., who was involved, where did the work take place, etc.). It is noteworthy to point out that these processes do not occur in isolation, and instead rely on a mix of people and organizations to support these processes, especially at an international level. Exploring the process of developing the workbook helped uncover the key features of the development process, challenges that arose, and mitigating strategies that (at least partially) helped overcome these barriers. In addition, this

study collected preliminary information from the perspectives of international guidance developers on how to improve the workbook.

Methods

This study followed an exploratory holistic single case study design as described by Yin (13). Yin (13) states, “the distinctive need for case studies arises out of the desire to understand complex social phenomena,” and, “it allows investigators to retain the holistic and meaningful characteristics of real-life events.” Because of the nature of working with an international health organization such as WHO and developing health systems guidance, many people are involved in the decisions leading up to, during, and after the creation of any guidance document. The people working on or using this workbook came from different backgrounds and had diverse goals, interests, beliefs, ways of measuring success, and perceptions about barriers to policy development and implementation. This diversity lent itself to an in-depth case study approach where the components of the case (i.e. the process of developing a workbook for contextualizing health systems guidance) and the context could be studied (13). It was an exploratory case study since no prior similar work had been identified, and, as it was unique, a single case was chosen (13). Because multiple people were involved in the development of this workbook, a constructivist paradigm, where multiple realities are expected based on each person’s view, was fitting for this study (13,14).

The case in this investigation was the process of developing a workbook for the contextualization of global health systems guidance at the national or subnational level. It was important to set bounds for the case so the study remained focused (13). This case was bounded by the context, as only information relating to the creation of the workbook was used. This was especially important since the workbook was part of a broader guidance document, but this study focused only on the workbook and not on the development of the full OptimizeMNH guidance document. Indeed, there are many steps and groups of people involved in the development of guidance at the WHO level, but these processes have been more standardized, especially since the development of the Guideline Review Committee (GRC), and these processes are noted within the guidance document itself (9). However, because the workbook was a new tool, the process for its development had not been previously delineated. This case was also bounded by the participants involved in the case (i.e. in the process of developing the workbook), which included the policymakers, task-force members, researchers, and other stakeholders contributing to the creation of the workbook. Lastly, the case was bounded by time, starting with when the workbook was conceptualized, through the creation of the workbook and the approval process, and ending when the workbook was posted online along with the OptimizeMNH guidance document. (See figure 1) WHO guidance documents incorporate a continuous review process, which would include the workbook, so it was

important to set a time limit for this study as changes could be ongoing for many years.

Sampling and recruitment

Intensity sampling (15) was used to find participants who could provide in-depth information about the case, that is, if they were involved in the idea for developing the workbook (which the principal investigator, EA, was not) or in the development of the workbook (in which both EA and JL were involved).

However, as stated previously, these events do not occur in isolation, and there are other people involved in these processes, especially at the international level. Therefore, other viewpoints were gathered through these interviews in order to understand the process and its context, and the barriers and facilitators in the process. Respondent-driven sampling was also used to find other policymakers, stakeholders or researchers who were considered to be information-rich sources about the case (i.e., process of developing the workbook). Recruitment was conducted through personalized emails. The initial email provided an introduction to both the principal investigator and to the study, explained the purpose of the interview, which related to gathering their insights around the process of developing the workbook and their roles in this process, listed several potential dates and times for an interview (leaving it open for other suggestions as preferred by the interviewee), and explained and included an informed consent form for participating in the study. (See appendix 1) One follow-up email was sent one to two weeks following the first email, if no response had been received (see results

section). Once a participant agreed to the interview, a second email was sent verifying the date and time, and included the interview guide (see appendix 2) and a link to the workbook, which was published online prior to the interviews. The workbook was included in case the interviewees had the time and interest in reviewing it, but it was not specified that they needed to do so for the interview. This was because many of the interviewees were involved in the part of the process where the idea for developing the workbook came to light, but they had not been involved directly in its creation. In addition, the purpose of the study was to understand the process of developing the workbook, not on evaluating the workbook itself. Where the interviewees had reviewed the workbook, specific questions regarding their thoughts on it were elicited. This was otherwise captured through questions about their hopes (as experts in global guidance) for a tool to help countries contextualize global guidance and the challenges they foresaw with such a tool (see appendix 2).

Criterion sampling (15) was used to find documents that related specifically to the process of developing the workbook, for example, meeting minutes. This was especially relevant because the development of the workbook was occurring in parallel with the development of the OptimizeMNH guidance, and some people were involved in both. However, the focus of the study was on the development of the workbook. These documents were found through literature searches, personal emails, or the interviews.

Data collection

Informed consent was obtained prior to conducting the interviews. (See appendix 1) Semi-structured interviews were conducted with interviewees by a single interviewer (EA) over Skype, and these were recorded with a digital recorder and transcribed. The interviewer asked participants about their role in, and the process with, regards to the development of the workbook for health systems guidance contextualization, challenges that arose during the process and how these challenges were overcome, other contributors to this work, and other documents for review. In addition, the participants were asked to describe what their hopes were for a tool to help countries contextualize global guidance and the challenges they foresaw with such a tool. (See appendix 2)

Documents came from the interviews, from personal emails, or through online searches by the principal investigator, and most were publicly available (see appendix 3). Lastly, a reflexive journal was kept by the principal investigator (EA) throughout the course of the study to keep track of events and their contexts (e.g., who was involved, what and why decisions were made, etc.), to provide insights into the role of the principal investigator as participant-observer, and to allow for personal reflection of the events and role (e.g., feeling uncomfortable calling myself a champion in this work) (16). Entries in this journal were also used as data.

Data analysis

The coding of data was mainly conducted by the principal investigator (EA), with input from JL on the codes, themes and subthemes, and presentation of the data. Data analysis occurred concurrently with data collection to help direct further data collection. A code structure was developed using an integrated approach, where both deductive and inductive methods were used (17). A deductive organizing framework or “start list” (17) was used, which included steps in the process of developing the workbook, challenges, and mitigating strategies. Additional steps and sub-steps, challenges and mitigating strategies were added to the start list in a temporal sequence following an edit-style organizing process (13,17,18). As this code structure was being developed, concepts, themes and subthemes emerged inductively. Also, relationships amongst the themes were elucidated. Constant comparison was used to compare new information to previous information to help build the concepts, themes and subthemes. These were then verified across each main step in the process. The code structure and interview transcripts were reviewed after these themes were developed to ensure no new themes or disconfirming evidence were found. Member checking was conducted with two of the interviewees. A summary of their respective interview transcripts was prepared and related to the themes. This summary and the table of themes were sent to the interviewees and they were asked for their impressions of the interpretations from their interviews. This step helped refine the concepts. Peer debriefing was also conducted whereby peers

(MB, LS) were asked to review the tables, diagrams and manuscript, which helped refine the presentation of the concepts, themes and relationships.

Ethical considerations

Ethics approval was obtained from the Hamilton Integrated Research Ethics Board (HIREB), Hamilton, Ontario, Canada, prior to data collection. In addition, each participant signed an informed consent form prior to being interviewed. (See appendix 1)

Results

A total of 17 individuals were approached for participation, and 13 of them agreed to participate and were interviewed. Three participants did not respond to two email requests and one declined participation due to uncertainty about being able to contribute to the study. A follow-up email was sent giving more explanation about the study and encouraging participation, but no reply was received. For reasons of confidentiality, specifics of the individuals participating are not provided in this paper. However, there was diversity in age, gender, and level of seniority for the participants' respective positions. Most wore many hats including those of healthcare professionals, directors of programs in various organizations, academics, and health system and policy analysts. The participants had collective experience at the district, national and international levels as well as represented every WHO region except South-East Asia. Broadly, for the purposes of this study, participants are described as belonging to one of three categories: member of the Secretariat of the guidance panel on task shifting (those

involved in developing the WHO OptimizeMNH guidance who either worked at WHO or at an outside institution – 3 participants), staff of WHO not part of the Secretariat of the guidance panel on task shifting (3 participants), or health system and policy analyst (7 participants). One interview was conducted with each participant. These interviews ranged from 19-65 minutes in length, with an average duration of 38 minutes. In addition, 52 documents were reviewed: 27 journal articles, 7 presentations, and 18 other documents (e.g. meeting agendas, reports, etc.). Multiple personal emails and a reflexive journal (Volume I – 195 pages, volume II – 127 pages, and volume III – 93 pages) were also used as data. (See appendix 3)

Three main steps, and various sub-steps, were identified in the process of developing the workbook for health systems guidance contextualization (described in more detail below): 1) determining the need for and gaining approval to develop the workbook, 2) developing the workbook (taking on the task, creating the structure of the workbook, operationalizing its components, undergoing approval processes, and editing it), and 3) implementing the workbook both at the WHO level and at the national / subnational level. At each of these steps, five critical factors surfaced from the data as barriers and/or facilitators (See table 1): 1) having well-placed and credible champions, 2) creating and capitalizing on opportunities, 3) finding the right language to engage various actors and obtain buy-in, 4) obtaining and maintaining meaningful buy-in, and 5) ensuring access to human, financial and other resources. General

descriptions of each of these factors, along with their relationships are provided first. (See table 1 and figure 2), Then, more detailed examples are given for how these factors influenced each step of the process. (See table 2)

Critical factors affecting the development of the workbook

Having well-placed and credible champions

Through the interviews and reflexive journal, several people emerged as being more prominent in moving ideas forward and/or devoting their time and other resources to completing tasks in the process. Without their commitment and persistence, the workbook may not have come to fruition. Champions can have different levels of involvement, and someone who is a champion at one stage of the process may not be a champion at another step of the process.

“...so I think my role was more kind of being the person pushing for this to be brought about, identifying the opportunity for [the person taking on this work as participant-observer], and then after that I moved into much more of a supporting role” (001, health systems and policy analyst)

“It took [the head of the Secretariat of the WHO guidance panel on task shifting] a lot of work in the background in the WHO to try and bring everyone on board [to using innovations in the guidance development process]” (002, member of Secretariat of WHO guidance panel on task shifting)

Creating and capitalizing on opportunities

The champion(s) either sought out or created opportunities to move the work forward, or other actors presented opportunities to the champion(s) who then capitalized on these opportunities.

“We knew that the recommendations from the guidance were going to be directed to policymakers and that is why we involved [the health systems

policy expert] in the panel.” (003, member of Secretariat of WHO guidance panel on task shifting)

There were times when the work could have moved forward, but it did not, resulting in missed opportunities. One example noted from several journal entries is that even though the workbook was presented at a WHO- African Regional Office (AFRO) meeting in Addis Ababa, Ethiopia in 2012, and there was excitement for this work, there were several missed opportunities to promote the evaluation of the workbook at the country level. Lastly, there was a potential opportunity identified by a participant that could be capitalized upon in the future. This involves the contextualization process identifying gaps in the evidence, which could then be fed back into and inform research processes.

“But it would be nice if it could go both ways. The actual process of contextualization also highlights weaknesses with the research in the first place, you know, that could be fed back to the research, so... can start doing more research that has more relevance to the contexts that we’re trying to reach” (011, member of Secretariat of WHO guidance panel on task shifting)

Finding the right language to engage various actors and obtain buy-in

Compiling information from the interviews and journal, the concept surfaced that the champion(s) used persuasive language to gain buy-in from those who were involved in the process and could have created barriers in the process. A more subtle way to help obtain buy-in was to first build a shared understanding of the concepts or issues by using common terminology that resonated with the target audience. This level of shared understanding was seen as especially useful for trying to communicate the relevance of the work or how to apply the work.

“..he [the head of the Secretariat of the WHO guidance panel on task shifting] gave me the opportunity to pitch the idea to the committee members, which I did in the form of a brief presentation and they seemed to be quite excited about the idea. And I also, because in sharing the meeting...after two days, I was able to insert a bunch of examples that had come back, come directly from them, that were the type of things that a good workbook would flag for people.” (001, health systems and policy analyst)

Several participants stated that following standard academic or scientific language could be a facilitator when working with specific audiences, such as WHO’s Guideline Review Committee (GRC), but this could be a barrier for other audiences, such as policymakers, who may not be familiar with this language.

Poor communication within WHO was also noted as a barrier.

“I think one of the criticisms we have had of the Optimize guidelines is that it feels, some people have said it feels very academic. You have done quite a good job of pulling together all those current literatures all methodologically sound and all that, but you know it is quite difficult to digest as a user in the field. I can see where they are coming from because we’re – we are researchers and we’re also trying to adhere to these WHO standards which require sort of – kind of requirements of certain kinds of language and so on. I think that is probably true of all the evidence coming out of this project, that how we kind of make those things more accessible” (002, member of Secretariat of WHO guidance panel on task shifting)

Obtaining and maintaining meaningful buy-in

The need for obtaining and maintaining buy-in was mentioned by one participant, but the concept resonated with what many of the other participants stated.

“it is not the member state, it’s not WHO, it’s not the NGOs, it takes many to tango. It’s more like carnival, it’s not like a tango. But it’s different at the same time because if you want to overcome those obstacles that exist, this petty politics and things like this, you really have to... persevere, it requires lots of perseverance. You have to talk all the time, you have to go

to the right people all the time, you have to convince a higher up, a senior person, and then this person gets distracted and you have to go back and press, and you have to ask your friends to call this person. It's relentless.” (007, staff of WHO not part of Secretariat of guidance panel on task shifting)

As noted in the journal, reflecting on these concepts during the analysis led to thinking about institutionalization as a type of “permanent buy-in” by an institution. Unless a process is institutionalized, a change in leadership could result in previous buy-in being lost. Therefore, either continuous communication with new leadership is required to secure meaningful buy-in from new leadership, or institutionalizing a process by one group or leader could bypass the future need to obtain buy-in. One participant remarked that the difficult part can be knowing if there is meaningful buy-in or if the buy-in is for a secondary purpose (e.g., advancing other work). This could manifest itself as appearing to have meaningful buy-in at one stage of the process but not having buy-in at another stage.

“My sense is that the panel which had more health systems and policy people on it, was very very supportive... but from the WHO staff people we continued to have this problem that if they come from clinical epidemiology backgrounds, their sense is their usual way of doing by and large can be aloofness, but they recognize that they sometimes still need to have people like me in the room to make it look like they are doing things differently, but I am not convinced at the end of the day that they are committed to doing things differently.” (001, health systems and policy analyst)

However, ascertaining this level of information could require immense transparency on the part of the actors involved as it seems it would be unlikely for people to be open about secondary motives. As was noted in the journal, the problem of buy-in could also be difficult to distinguish from a separate problem

of lacking resources (e.g. buy-in from one group of people may not secure resources from other groups of people).

Ensuring access to human, financial and other resources

Resources included human resources, finances, time, motivation, knowledge and technology. Most participants noted the need for resources, especially human resources, finances, and time for different steps in the process.

“So right now, you know, everyone puts all the effort into the front end and then the guidance is there and there is no energy or money to see it implemented....we really need to re-think how we develop critical paths for developing guidance and the guidance development process ends relatively early in that timeline and then we have lots of time and resources left to do all this other stuff. Otherwise the whole exercise is for naught.” (001, health systems and policy analyst)

In addition, several participants mentioned that having people from different organizations involved in the work with WHO also meant there were different agendas, timelines, and priorities involved. Human resources include the people involved in doing the work. Further attributes of these individuals, which arose from the data, include motivation and knowledge. Motivation to work on a particular topic is necessary when there are competing demands on an individual or on an agency. This can be seen as prioritizing specific work. Knowledge can come from existing knowledge of the individuals involved in the work or can be found through searches for information. So, this attribute can be intrinsic (e.g., expertise) or extrinsic (e.g., library resources). Finances include salaries or payments for those carrying out the work, funding for traveling, and funding to secure supplies. Time is required for individuals to do the work, and individuals

and agencies have timelines for getting the work done. Technology can also support or be a barrier in advancing the work. The lack of technology for users at the national / subnational level to look up evidence was discussed with one of the participants. During the same interview, the participant tried to find the link to the workbook and found that unless the page was scrolled down, the link was cut off on the screen, which had also been encountered as a problem before by the principal investigator.

Steps in the process of developing the workbook

It is important to re-iterate that the focus of this study was explicitly on the development of the workbook and not on the development of the full OptimizeMNH guidance for reasons already described in the methods section. As stated above, there were three discrete steps, and several substeps, in the process of developing the workbook. (See table 2) The first step included determining the need for and gaining approval to develop the workbook. In essence, this step helped explain the purpose of the workbook and gave a concrete reason for the workbook to be developed, which was to contextualize the OptimizeMNH guidance. The second phase was the development of the workbook. This phase ranged from the time approval was gained to move ahead with this work in April 2012 to the time the workbook was published online by WHO in December 2012. The third phase continues and encompasses the dissemination, implementation and institutionalization of the use of the workbook both at the level of WHO and at the national / subnational level. This last phase is critical for improving the

workbook itself through user testing but also for helping improve the uptake of health systems guidance recommendations, which is the purpose of the workbook. While the first two steps were anticipated at the beginning of the study and questions were directly asked during the interviews to elicit information about these steps, the third step came from questions addressing the hopes for and anticipated challenges of the workbook. In addition, the substeps in the development of the workbook were not clearly delineated at the outset of the study. Of note, is that each step involved different people (with some overlap) and different actions, yet the five critical factors listed above were found at each step in the process. The implications of the presence or absence of these critical factors at each step are discussed next.

Step 1 – Determining the need for the workbook

As the principal investigator was not involved in this step of the process, the information presented reflects a summary of the interviews, unless noted. Documents obtained through personal emails showed that in 2010, the Department of Reproductive Health and Research at WHO led a guidance scoping meeting in an effort to support countries with health worker shortages increase access to effective practices. (19–23) The scoping meeting and subsequent work by the WHO-led guidance panel on task shifting (henceforth ‘the guidance panel’) eventually led to the development of the OptimizeMNH guidance. (9,24–27) This case study begins in early 2012 when participants who were part of the Secretariat of the guidance panel (i.e., those responsible for writing the guidance; henceforth

‘the Secretariat’) stated they realized that the recommendations from the guidance were going to be aimed at policymakers, and that the implementation considerations they were incorporating into their guidance document aligned with the contextualization work that was being discussed as part of a different WHO-led taskforce on developing health systems guidance (henceforth ‘the taskforce’). They decided at that point to involve a health systems policy expert, who was also involved in the taskforce, to help address these issues.

Compiling information from several participants showed that credible champions were well-placed during this first step. The head of the Secretariat acted as champion by inviting the health systems policy expert to help in directing the work around contextualization of the OptimizeMNH guidance, by allowing the workbook to be incorporated into the guidance development process, and by working in the background at WHO to obtain buy-in for using the workbook and other innovations arising from the development of the OptimizeMNH guidance document. The health systems policy expert acted as champion by agreeing to partake in the work of the guidance panel, by moving the ideas of the taskforce forward, and by finding the appropriate language to build buy-in from others involved in this process.

Opportunities were created and capitalized upon to move this work forward during this step of the process. For the reasons listed above, the Secretariat invited a health systems policy expert to become involved in and co-lead a guidance panel meeting, creating an opportunity for the work on

contextualizing health systems guidance to be furthered. The health systems policy expert capitalized on this opportunity by agreeing to participate if given the chance to try to move forward the ideas of the taskforce, which he did by “pitching” the idea to the members of the guidance panel through a brief presentation during their meeting. In addition, another member of the Secretariat of the guidance panel was also involved in the work of the taskforce, which created a greater opportunity to move the ideas from the taskforce forward.

There were three levels at which buy-in needed to be obtained during this step, and both champions found the right language to engage various actors to obtain this buy-in. First, the members of the Secretariat bought in to the need for developing a workbook for contextualizing health systems guidance. This was known because they were the ones seeking someone to help in this area of the development of the guidance. Second, the members of the full guidance panel needed to buy-in, as they had the ability to block this work from moving forward. One challenge was that many of the guidance panel members understood concepts about health systems contextualization in relation to the WHO building blocks for health systems strengthening and some wondered how this work related to what they were already familiar with. (3) However, the health systems policy expert was able to overcome this challenge by using common terminology and examples from the guidance panel members themselves to build understanding and persuade the guidance panel members of the need for this workbook. Third, WHO, more broadly, also needed to buy-in to incorporating the various

innovations, including the workbook, in the development of the OptimizeMNH guidance. Because there are standards that are set for guideline/guidance development, these innovations needed to gain approval from the GRC. This level of buy-in was achieved through the work done by the head of the Secretariat by building understanding and using persuasive language for the various actors within WHO.

Resources for the guidance panel were already secured prior to determining the need for the workbook. While some of the Secretariat and guidance panel members were from WHO headquarters, others were from outside agencies, so time and funding were required for traveling to the guidance panel meeting and for developing the OptimizeMNH guidance. Human resources, time and finances were all secured for this step in the process.

Overall, there were few barriers in this step of the process, and each was overcome by having the champion(s) build understanding and use persuasive language to obtain buy-in. This step was successful, as approval was obtained to develop the workbook and incorporate it into the OptimizeMNH guidance document.

Step 2 – Developing the workbook

Both EA and JL were involved in this step of the process, so much of this information is a compilation from the reflexive journal and personal emails, but the events were also verified through the interviews from those involved in this process, which included the members of the Secretariat. Several sub-steps were

noted in the development of the workbook. These included taking on the task, creating the structure of the workbook, operationalizing its components, undergoing approval processes, and editing it. Some of the critical factors were more pronounced in specific sub-steps. As a whole, the five critical factors mentioned above were seen to play a role in this general step, but this section will emphasize the main factors that influenced each sub-step in chronological order.

After approval was obtained from the guidance panel, someone needed to take on this task. This sub-step relied on champions, language and obtaining buy-in. Acting as a champion, JL created an opportunity by bringing the idea up to someone who could take on this task (EA), and then acted in a supportive role throughout the development of the workbook. JL presented the idea as a win-win situation to EA who then bought into and agreed to take on this work. In a way, EA also became a champion by developing, iteratively revising, and promoting the use of the workbook.

Creating the structure of the workbook relied greatly on maintaining buy-in from the champions and on resources, especially human resources, time, motivation, knowledge and technology. Dedicated time to do this work was imperative. A participant noted that one challenge was that there was no previous example of a workbook to contextualize health systems guidance, which is why there had been a call to develop one, so it was difficult to know where to start. However, work from the health systems and policy fields and from the OptimizeMNH guidance were drawn upon to create the structure and to

operationalize the workbook. Specifically, the workbook was based on the second article of the *PLoS Med* series on ‘guidance for evidence-informed policies about health systems’ (1,5,28), which outlined the contextualization or adaptation process from global guidance to global or national policy or national guidance, and the contextual factors to take into account while developing an evidence brief. This article in turn drew from the content of the ‘SUPPORT tools for evidence-informed health policymaking’ articles [clarifying evidence needs in policymaking, (29–31) taking equity into consideration, (32) preparing policy briefs and policy dialogues, (33,34) engaging the public, (35) and planning monitoring and evaluation of policies (36)]. In addition, insights from the OptimizeMNH guidance panel discussions were incorporated into this work. (12) Researching and sharing information was done with the use of technology.

Operationalizing the components of the workbook also relied on maintaining buy-in from the champions and resources, but the use of language became more significant in this step. It was perceived as important to operationalize the workbook so that it would make sense to those using it, especially for those without training in health policy. And, even though the workbook was developed so that it would be generic enough to use with any health system issue, examples from the OptimizeMNH guidance were included to help users contextualize recommendations from this particular guidance document. These steps were taken to help build understanding about the relevance of this work and about how to use the workbook.

The GRC had to provide preliminary and final approval for the OptimizeMNH guidance, which included the workbook, as part of the formal process for any WHO guidance or guideline. (37) This stub-step greatly relied on obtaining buy-in and the use of standardized language. There needed to be buy-in from the GRC in order to approve the OptimizeMNH guidance, including the workbook. From personal emails, it was noted that one challenge during the approval process was that the workbook was too lengthy to be incorporated into the OptimizeMNH guidance document itself. Therefore, a 2-page summary was developed to be incorporated into the OptimizeMNH guidance document, and the workbook was moved as an annex. This step was needed in order to conform to the standards of the GRC.

Once the OptimizeMNH guidance and the workbook received GRC approval, an editing process required the continued buy-in from the champions and from the Secretariat of the guidance panel. This work was also supported by resources such as human resources, finances, time, motivation and technology. Personal emails show that even though the workbook was published online with the OptimizeMNH guidance, the final execution of the proposed edits for the workbook did not occur. Participants stated this may have been a combination of not having true buy-in by the Secretariat or from a lack of time and other resources, such as administrative access to the website to make changes. In addition, personal emails reveal that there were no resources to translate the workbook into other languages (it was published online only in English).

Overall, several participants pointed out that one challenge throughout the entire step was the involvement of multiple agencies (i.e., the Secretariat developing the OptimizeMNH guidance, and a separate, but parallel, group developing the workbook) each with its own timelines and agendas. The majority of the time and resources of the guidance development process were spent on the OptimizeMNH guidance document itself and not as much emphasis was given to developing or pilot testing the workbook. However, these participants also stated a benefit of this separation of work was that there were people dedicated to producing the workbook. Otherwise, this part of the process may have not received as much attention, as there was already so much to be done within tight timelines for developing the OptimizeMNH guidance.

In this second step, there were a few barriers in needing to standardize the language to meet the GRC standards and in having the necessary resources, including human resources, time, knowledge and funding to carry out the work. These barriers were overcome by changing the format of the workbook to follow the GRC standards and by obtaining the necessary resources, such as using prior work in the field to create the structure of the workbook. Overall, this step was successful in that the workbook was developed and published online in December 2012. However, as noted above, even though further editing was done, the workbook was never replaced with the final copy edited version, likely due to a lack of buy-in and/or resources.

Step 3a – WHO level implementation of the workbook

The information for the next two steps came either directly from the interviews or from reflection on what was learned through the interviews. For example, some participants focused on the role of WHO and others focused on the role of the Member States in these next steps. Therefore, it was determined that two levels of implementation of the workbook needed to be examined, as there are two separate but related processes for work developed by WHO. First, in order for this work to have traction, it needs to be institutionalized by WHO so that each health system guidance document produced by WHO has an accompanying workbook (or other tool) to help in its contextualization. In addition, WHO plays a role in disseminating the materials and supporting countries in using such workbooks. This level of implementation has been fraught with barriers as described next. Second, this work can gain traction by having countries use, evaluate and institutionalize the use of the workbook in contextualizing global health systems guidance (See Step 3b below).

At the WHO level, two participants identified two separate champions (internal and external actors) who have been trying to push for the idea that workbooks for helping countries contextualize health systems guidance should be incorporated into the process of developing health systems guidance documents. However, thus far, buy-in from those with decision-making power has not been obtained by these champions. In addition, a Secretariat member who had acted as champion at earlier stages of the development of the workbook did not act as

champion for the full institutionalization of the workbook idea or the dissemination of this workbook, most likely due to a focus on the dissemination of the OptimizeMNH guidance itself.

Several participants, multiple personal emails and journal entries concur that there have been missed opportunities for the institutionalization of the workbook at the level of WHO and dissemination and support of its use at the national / subnational level. As already described, even though there is a need for support at the national / subnational level to contextualize health systems guidance, the development of workbooks (or other tools) to do this has not become part of the routine process of developing health systems guidance documents. Also, there was agreement with WHO that the workbook would be evaluated in 2-3 countries. However, it seemed the focus remained with disseminating the guidance and not as much emphasis was placed on disseminating the workbook, so there was a missed opportunity for WHO to be part of the evaluation process. In addition, earlier work done by the taskforce around developing health systems guidance was not published or endorsed by WHO, which led to another missed opportunity to institutionalize the work of the taskforce. This has led to duplication of work in that WHO is dealing with similar issues around differentiating between clinical guidelines and health systems guidance, which the taskforce had already grappled with.

“During this last year with the work that we were doing around [a] policy compendium, many of these questions surfaced [about the difference between clinical guidelines and health systems guidance]. One thing which is a bit funny, it is that nobody among all the partners who are

working with us on this piece of work which is about policies and their implementation, none of them have come up with reference to look at what [the taskforce on developing health systems guidance] are mentioning. I don't know, either they have low uptake or understanding or people are assuming they are not using it. The people we are working with...thinking that maybe we should go back and see what exactly was the difference made between clinical guideline policies and health systems properties.” (008, staff of WHO not part of Secretariat of guidance panel on task shifting)

Language could also be a barrier in implementing the workbook by WHO.

First, the workbook may be too detailed and difficult for people not trained in health systems and policy to understand, or the language may not resonate with people trained in clinical epidemiology. More generally, however, it was felt by several interviewees that there was a need within WHO to be conscious of the language used in developing guidance, since the end-users (i.e. policymakers and stakeholders) may not be familiar with the academic language of researchers, who are the ones typically developing the guidance documents. In addition, one participant noted that international guidelines or guidance documents tend to be written in English, and there may be concepts that are not understood by users in all contexts.

Buy-in for implementing this work at the WHO level has not occurred.

There are three lines of thought as to why this may be. First, two participants noted that there seems to be a conflict between those who think about issues from a purely clinical-epidemiological perspective and those who think about issues from a health systems / health policy perspective. This difference in viewpoints seems to have been dispelled during the step in determining the need for the

workbook, but it seems to be a barrier in institutionalizing or disseminating the workbook (or a different process for contextualizing health systems guidance) as those with decision-making power at WHO tend to follow the more traditional clinical-epidemiological viewpoint and may not see the importance of this work. In addition, this clinical-epidemiological mindset may lead to the focus of the guideline development process to be spent on the methodological aspects of the process instead of the equally complex contextual work.

“If we were to instead start to see much more openness on the part of staff and consultants who have clin-epi training and who are currently controlling these processes, then you know yes, the challenges would start to become much more about ensuring that there is adequate resources and time to pull this off. So completely reconceptualising the timeline for guidance developments” (001, health systems and policy analyst)

A second rival theory brought forth by two other participants is that people within WHO with decision-making power do understand and agree with the importance of contextualizing guidance recommendations, but the barrier to institutionalizing this work comes from political or personal issues, such as not having involved certain people in the taskforce on developing health systems guidance. Therefore, the barriers are punitive and could manifest themselves as not gaining buy-in.

“I definitely feel it is much more the politics. Because they do think it is important to contextualize. Very much. Very, very much.” (007, staff of WHO not part of secretariat of guidance panel on task shifting)

Lastly, one participant stated it could be that there was not true buy-in and that adding the workbook into the OptimizeMNH guidance could have been done to make it seem that WHO was placing importance on thinking about supporting the contextualization of health systems guidance.

As described earlier, resources at the WHO level were put into developing and disseminating the OptimizeMNH guidance but almost nothing by comparison was put into disseminating or supporting the use of the workbook at the national or subnational level.

Overall, there are champions dedicating their time and energy into implementing the workbook at the WHO level, and there is an expressed need for support at the national / subnational level in contextualizing health systems guidance recommendations. However, the champions have not yet been able to obtain the necessary buy-in from those with decision-making power at WHO to do this. Therefore, this step has not been successful, and the institutionalization of the development of workbooks for guidance documents at WHO, and the full dissemination and support for the use of this workbook by WHO at the national level has not occurred.

Step 3b – National / subnational level implementation of the workbook

Most participants stated that national or subnational use and evaluation of the workbook is essential to help refine the workbook and make it more user-friendly. Institutionalization of contextualization processes for health systems guidance at the national or subnational level will help ensure that value for money is achieved by addressing the needs of specific contexts.

Two participants stated that it can be challenging to find champions within countries to move this work forward. In some regions or countries, the use of evidence-informed policymaking is not valued. In addition, there can be limited

capacity for locally relevant research or for local guidance development at the national / subnational level. Support from champions outside of the country can help relieve some of the need for human resources capacity. This outside support, along with champions within two countries, Peru and Uganda, did allow for the workbook to be used and evaluated (which is the focus of chapter 3).

Creating and capitalizing on opportunities for countries to use and evaluate the use of the workbook is critical to improving the workbook and institutionalizing the use of workbooks to support the contextualization of health systems guidance. Personal emails and journal entries note that in the fall of 2012, WHO-AFRO held a Regional Consultation on Optimizing Health Workers' Roles to Improve Access to Key MNH Interventions through Task Shifting. This consultation was held to discuss the OptimizeMNH guidance, but also provided an opportunity to present on the work around the contextualization of the guidance. However, there were several missed opportunities during the consultation to encourage countries to receive support in using and evaluating the use of the workbook. Even though WHO was not involved in recruiting countries to help in the evaluation of the workbook, as originally planned, an opportunity was created to evaluate the use of the workbook by recruiting two countries through the professional networks of JL and EA. A separate potential opportunity for the future, identified by an interviewee, is that gaps in knowledge could be identified through the use of the workbook at the national or subnational level and used to inform the research process itself.

Many participants explained that language is very important for implementing the workbook at the national / subnational level. Using common terminology that resonates with the users is vital to building understanding, which is especially helpful for communicating the relevance of and how to use the workbook. Several potential barriers were identified. First, people may lack training in health systems and policy, which could make understanding the complexities of the components of the workbook more difficult. Second, preliminary feedback on the workbook is that while it does provide a systematic approach to contextualizing health systems guidance, it is too long and detailed overall. However, one interviewee stated that step 8 of the workbook, around developing evidence briefs, convening policy dialogues and engaging the public, could use more details. Third, it was felt that using a wider range of examples could make the workbook more helpful. Overall, though, the participants expressed that field testing the workbook would be the best way to obtain substantive feedback in order to revise the workbook and ensure it is useful to those who could benefit from this tool.

Participants pointed out that obtaining buy-in can be difficult at the national level. As discussed previously, there is a need and expressed demand for this work, which is why countries have been asking for support in contextualizing health systems guidance, yet some regions or countries do not place much importance on evidence. In addition, there needs to be not just buy-in from policymakers but also from those who are responsible for implementing the

policies. According to the interviewees, the workbook could be helpful in terms of building ownership by including processes for stakeholder and public engagement. However, one interviewee also felt that more on strategies for advocacy could be included. Journal entries and personal emails (chapter 3) show that in Peru and Uganda, buy-in by champions at the country level for evaluating the workbook was secured as they already had an understanding of the importance of contextualizing health systems guidance to their settings.

Many participants highlighted the lack of resources, including human resources, finances, knowledge, motivation, time, and technology, as a barrier for implementing the workbook at the national / subnational level. First, many countries have multiple funding agencies and priority-setting processes, which can make carrying out this work difficult. Second, many countries have little capacity for local research and for embedding the use of workbooks into their policymaking processes. Third, there is often a lack of resources for the implementation of the policies. Fourth, there is a need to build on the existing health systems evidence base over time to know what works within which contexts. Fifth, there is also a need to build a greater understanding of how aspects of the political system affect the local analysis of the problem and its causes, and the implementation of policy options. Lastly, technology can allow more people to have access to information, however, in many settings, people lack access to technology. Journal entries show that technology can also, at times, act as a barrier if it is not user-friendly. Human resources and some financial

resources helped support the work of using and evaluating the use of the workbook in Peru and Uganda.

Overall, there are many barriers to using, evaluating and institutionalizing the use of the workbook to develop health systems policy at the national or subnational level. Creating opportunities by reaching out to countries, having champions at the country level who buy into the need for this work, having support from champions outside of the country who can help build understanding for the need for and use of the workbook, and ensuring sufficient resources are secured have helped move this work forward in Peru and Uganda.

Discussion

Principal findings

Three main steps and various sub-steps were identified in the process of developing the workbook for health systems guidance contextualization: 1) determining the need for and gaining approval to develop the workbook, 2) developing the workbook (taking on the task, creating the structure of the workbook, operationalizing its components, undergoing approval processes, and editing it), and 3) implementing the workbook both at the WHO level and at the national / subnational level. Within these steps, five critical factors affecting the development of the workbook surfaced as barriers and/or facilitators: 1) having well-placed and credible champions, 2) creating and capitalizing on opportunities, 3) finding the right language to engage various actors and obtain buy-in, 4)

obtaining and maintaining meaningful buy-in, and 5) ensuring access to human, financial and other resources.

Each of these factors was needed in order to proceed to the next step of the process. However, some factors played larger roles at different sub-steps. For example, in developing the workbook, the sub-step of taking on the task relied heavily on champions, language and buy-in, while the sub-step of creating the structure of the workbook relied more on resources. Steps 1 and 2, determining the need for and gaining approval to develop the workbook and developing it, were both successful in that the workbook, along with the OptimizeMNH guidance, was published online in December 2012. Barriers encountered during these two steps were overcome. However, the implementation of the workbook at the WHO level and at the national / subnational level have encountered many barriers and have yet to occur. The exceptions are Peru and Uganda where the use of the workbook is being evaluated (which is the focus of chapter 3).

Several points are noteworthy. While it is not known what percentage of WHO-led work is approved and taken up systematically at WHO, through this investigation, two instances were found where this did not happen. The development of the *Handbook for developing health systems guidance* (38), while not central to this study, came up sufficiently during the interviews to enable observations to be made about its process of development. First, the need for developing health systems guidance was evidenced by the formation of a WHO-led taskforce, which was funded by a Rockefeller Foundation grant. The taskforce

included experts in the fields of health systems and policy and experts in various methodologies, including qualitative methods, participatory methods and systematic reviews. Second, this taskforce produced the *Handbook for developing health systems guidance* and published three articles in PLoS Medicine on health systems guidance development (1,5,28). However, the *handbook for developing health systems guidance* was published, but not by WHO, as was the original plan. The reasons for this were unclear from the interviews. Third, because of the decision by WHO to not endorse this *Handbook* it has not had systematic uptake within WHO. The extent of its use by departments in WHO is therefore unknown. This represents another lost opportunity for advancing the work in health systems strengthening. Instead, as evidenced through the interviews, groups within WHO are trying to distinguish between health systems guidance and clinical guidelines without referring to the work of the taskforce.

Strengths and limitations of the study and in relation to other studies

There are five main strengths of this study. First, following a qualitative case study method, including the use of multiple sources of data such as interviews, documents, and a reflexive journal, allowed for an in-depth look at the process of developing the workbook. Certainly, many of these steps would not be captured in other formats. Second, the role of participant-observer added to the richness of the findings in that EA and JL had first-hand accounts of the process. Third, member checking helped in strengthening the analysis but also in confirming that the views of the participants were reflected appropriately through

the analysis. Fourth, using peer debriefing not only helped organize the case study analysis and the concepts, themes and relationships, but it also gave a way to ensure that the findings followed leading scholarship in health systems and policy research.

Lastly, the reflexive journal helped ensure that the investigator's biases could be reflected on in terms of how this influenced data collection, analysis and interpretation. These biases included that JL was involved in the work that led up to determining there was a need for a workbook, or other tool, to help contextualize health systems guidance, and both EA and JL hold the beliefs that health systems guidance and the contextualization of guidance recommendations hold promise in helping to strengthen health systems. Furthermore, the use of research evidence to inform policymaking is another value held by both investigators. These beliefs and values could have led to interpreting the data to support the positive aspects of the findings. However, these biases were recognized, and several methods were used to try to mitigate their influence, including asking for feedback on both positive and negative aspects of the workbook during the semi-structured interviews, including these aspects in the member-checking process, and using peer review with people who had not been involved in the process of developing the workbook. Due to the sampling strategy, which included people who were involved in the development of the workbook, these biases cannot be fully removed as all the participants may hold

similar beliefs. At a broader level, it is also important to note these biases and how they may influence initiatives globally.

There is one main weakness of this study, which is the potential for recall bias with retrospective interviews, and two noted challenges in the use of the case study methodology. The interviews recounted events that were as distant as 4 years and as recent as 6 months, so there were some areas that may have been subjected to recall bias. However, having multiple interviewees and triangulating information with documents helped decrease the impact of this recall bias. One of the challenges with the case study methodology is that findings cannot be generalized from a single case to other cases, as the context of the work done within and alongside an international organization such as WHO may be unique. Therefore, readers would need to consider their own contexts before applying these findings to their settings. However, as pointed out, a second case involving the *handbook for developing health systems guidance* may show similar findings. A full evaluation would need to be carried out on this case in order to confirm these findings. The second challenge in any qualitative study, is that even though the role of participant-observer has its strengths, it can also be difficult to situate oneself in the analysis. For example, even though the EA was heavily involved in the development of the workbook, it was awkward to label this role as that of a champion, even though time and resources were put into the development process and this person helped push the ideas forward. It was much easier to label others

as champions. This point was discussed with the rest of the research team to ensure that the description of this role accounted for any potential biases.

Many frameworks and tools for clinical practice guideline implementation have been developed, and the processes of developing these tools have been described. (39–45). This study reinforces the use of qualitative methods to examine the process of developing a tool in order to help understand the process itself but also the context. One study by Gagliardi et al (46) highlights the importance of context in the implementation of integrated knowledge translation (IKT), or collaboration between researchers and policymakers. IKT may be seen as a tool in the use of research evidence for decision-making, and each organization needs to develop its own approach to IKT. Challenges and enablers affecting the success of IKT were similar to those found in this study and included champions, opportunities, organizational endorsement, resistance to change, resources, motivation, and time. Further, findings in this study align with some of the concepts from Greenhalgh et al's review of diffusion of innovations frameworks (47), including champions, leadership and vision, enablement of knowledge sharing via internal and external networks, values and goals, power balance, innovation-system fit, dedicated time/resources, and motivation.

Implications for policy and practice

There are three implications for policy and practice that were found through this study. First, understanding the key steps and the challenges involved in developing and implementing new tools can help in the planning of these and

in the identification of potential points of tension to find ways to overcome them.

For example, understanding the critical factors involved in the process of developing the workbook could help in the planning of the development of other tools (e.g., the need for a well-placed and credible champion) or in evaluating why a process may not be advancing as expected and potential solutions (e.g., trying to find the right language to build understanding and obtain buy-in).

Second, as was seen in this study, and in the case of the *Handbook*, a plan for dissemination and implementation needs to be addressed in the preparation of these tools. Whether it is in planning the development of a clinical guideline, health systems guidance, country-level policy, or a new tool, not having a plan for implementation can severely limit the use and therefore the usefulness of these labour- and resource-intensive products. Third, many considerations were listed as barriers to the implementation of workbooks at the WHO and national / subnational levels. These are all areas that could be addressed in practice so that guidance recommendations have a better chance of being implemented and can have a positive impact on the health of populations.

Implications for research

There are two implications for research that were found through this study. First, as mentioned above, using qualitative, or mixed methods, to study processes of tool development can help not only describe the process but also understand the context to tease out facilitators and barriers in these processes. Second, the use of the workbook is being evaluated in two countries (chapter 3). However, in

order to improve guidance contextualization processes at the national / subnational levels, further evaluations of the workbook will be needed to help refine the language and structure to make the workbook more user-friendly and therefore more useful.

Acknowledgements

We would like to thank Fadi El-Jardali, Kaelan Moat and Mita Giacomini for their input into the interpretation and representation of the data.

Figure 1. Timeline of events in the development of the workbook for contextualizing health systems guidance

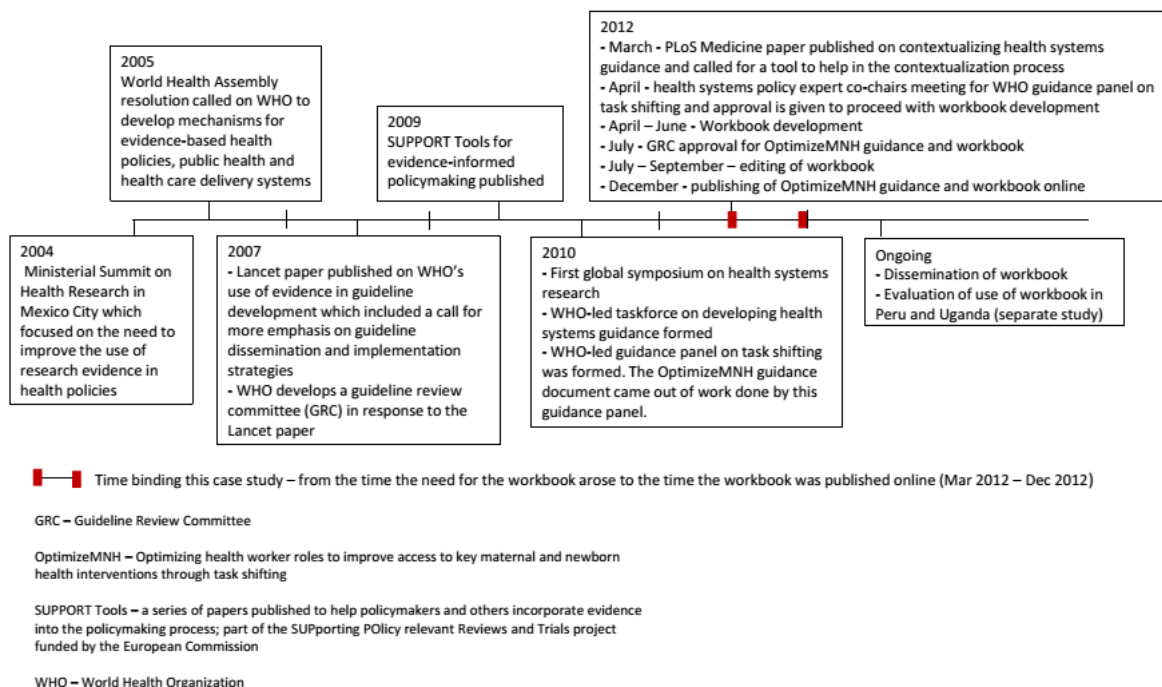


Figure 2. Relationships among critical factors influencing the development of the workbook for contextualizing health systems guidance recommendations

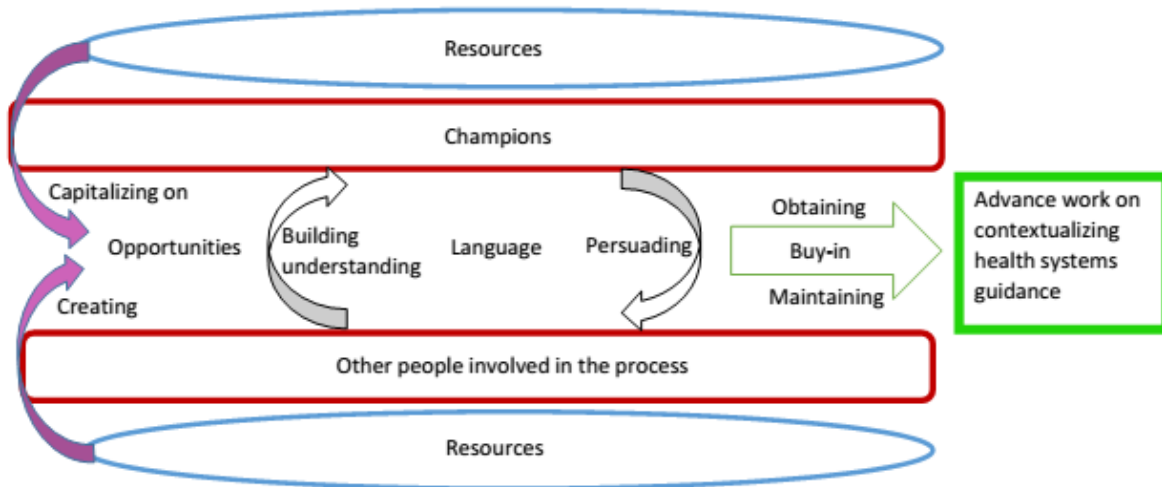


Table 1. Critical factors influencing the process of developing the workbook on contextualizing health systems guidance - Table of themes, subthemes, and their descriptions

Themes	Subthemes	Descriptions of themes and subthemes
Having well-placed and credible champions	<ul style="list-style-type: none"> - People promoting ideas (Ideas) - People devoting their time/resources to completing the work (Work) 	Champions were people who helped move ideas forward and/or who devoted their time and other resources to complete the work. Without their commitment and persistence, the work may not have occurred. Champions could have different levels of involvement, and someone who is a champion at one stage of the process may not be a champion at another step of the process.
Creating and capitalizing on opportunities	<ul style="list-style-type: none"> - Creating opportunities (Creating) - Capitalizing on opportunities (Capitalizing) - Missed opportunities (Missed) - Potential opportunities (Potential) 	The champion(s) either sought out or created opportunities to move the work forward, or other actors presented opportunities to the champion(s) who then capitalized on these opportunities. There were times when the work could have moved forward, but it did not, resulting in missed opportunities. Lastly, there are potential opportunities that could be capitalized upon to move the work even further in the future.
Finding the right language to engage various actors and obtain buy-in	<ul style="list-style-type: none"> - Building understanding by using common terminology (Building understanding) - Using persuasive language to “sell” an idea (Persuading) - Following standards (e.g. use of scientific language, page length for publishing) (Standardizing) 	The champion(s) used persuasive language to gain buy-in from those who were involved in and could have created barriers in the process. However, a more subtle way to help obtain buy-in was to first build a shared understanding of the concepts or issues by using common terminology that resonated with the target audience. This level of shared understanding was seen as especially useful for trying to communicate the relevance of or how to apply the work. Following standards for language could be a facilitator when working with specific audiences, such as WHO’s Guideline Review Committee, which requires specific formatting and the use of academic language, but this can be a barrier to other audiences, such as policymakers who may not be familiar with scientific or academic language. Poor communication could act as a barrier.
Obtaining and maintaining meaningful buy-in	<ul style="list-style-type: none"> - Obtaining buy-in (Obtaining) - Maintaining buy-in for the current work (Maintaining) - Institutionalizing the process or work (Institutionalizing) 	First, one needed to obtain buy-in and then buy-in needed to be maintained. Institutionalization can be seen as a type of “permanent buy-in” by an institution. Unless a process is institutionalized, a change in leadership could result in previous buy-in being lost. Therefore, either continuous communication with new leadership is required to secure meaningful buy-in from new leadership, or institutionalizing a process by one group or leader could bypass the future need to obtain buy-in. The difficult part can be knowing if there is meaningful buy-in or if the buy-in is for a secondary purpose (e.g., advancing other work). This could manifest itself as appearing to have meaningful buy-in at one stage of the process but not having buy-in at another stage. However, ascertaining this level of information could require immense transparency on the part of the actors involved as it seems it would be unlikely for people to be open about secondary motives. Also, this problem could be difficult to distinguish from a separate problem of lacking resources (e.g. buy-in from one group of people may not secure resources from other groups of people).
Ensuring access to human, financial and other resources	<ul style="list-style-type: none"> - Human resources (HR) - (Motivation) - (Knowledge) - (Finances) - (Time) - (Technology) 	Resources were used in carrying out the work and included human resources (HR), finances, time, motivation, knowledge and technology. Without these resources, the work was likely to be abandoned. Human resources include the people involved in doing the work. Further attributes of these individuals, which arose from the data, include motivation and knowledge. Motivation to work on a particular topic is necessary when there are competing demands on an individual or on an agency. This can be seen as prioritizing specific work. Knowledge can come from existing knowledge of the individuals involved in the work or can be found through searches for information. So, this attribute can be intrinsic (e.g., expertise) or extrinsic (e.g., library resources). Finances include salaries or payments for those carrying out the work, funding for traveling, and funding to secure supplies. Time is required for individuals to do the work, and individuals and agencies have timelines for getting the work done. Technology can also support or be a barrier in advancing the work.

Table 2. Critical factors influencing the development of a workbook for health systems guidance contextualization at each step of the process

Themes	Barrier(s)	Facilitator(s)	Example(s)
Step 1 – Determining the need for and gaining approval to develop the workbook – WHO guidance panel on task shifting			
Champions			The head of the Secretariat of the WHO guidance panel on task shifting and an expert on health systems policy acted as champions by creating and capitalizing on opportunities, by helping move forward the idea for a workbook on contextualizing guidance recommendations, and by building buy-in.
Opportunities			An opportunity was created by the head of the Secretariat of the WHO guidance panel on task shifting by asking an expert on health systems policy to join and co-chair a panel meeting. The expert capitalized on several opportunities to advance the work and build buy-in. A further opportunity was created in that another member of the Secretariat of the guidance panel was also involved in work that was concurrently being carried out by WHO on developing health systems guidance.
Language			Because this work was new, people were unfamiliar with it, which created a challenge. Using common terminology helped build understanding and persuade those involved in the process about the need for this work.
Buy-in			The Secretariat of the WHO guidance panel on task shifting, the panel members of the WHO guidance panel on task shifting, and others at WHO bought-in to the need for this work. Even though some panel members did not have a background in health systems, which created a challenge, the champions found the right language to engage the panel members and obtain buy-in.
Resources			Human resources, time and funding for carrying out the work of the WHO guidance panel on task shifting were all secured.
Step 2- Developing the workbook – sub-steps included: taking on the task, creating the structure of the workbook, operationalizing its components, undergoing approval processes and editing it			
Champions			The health systems policy expert acted as champion by bringing the idea up to someone who could take on this work, by acting in a supporting role throughout the development of the workbook, and by promoting the use of the workbook. A participant-observer acted as champion by developing the workbook and iteratively revising it throughout the development process, and by promoting the use of the workbook.
Opportunities			The health systems policy expert presented the opportunity to develop the workbook to the participant-observer taking on this work
Language			The health systems policy expert presented the idea of developing the workbook as a win-win situation to the participant-observer who took on the work. Operationalizing the workbook was important to explain how to use the workbook, especially for those without training in health policy. One challenge during the approval process was that the language of the workbook had to conform to the standards of the WHO

			Guideline Review Committee (GRC), therefore changes to the workbook were made (e.g. a 2-page summary was developed).
Buy-in			Buy-in was obtained from the participant-observer to take on the development of the workbook and by the WHO GRC to approve the inclusion of the workbook. Buy-in was maintained through the development and approval processes from the Secretariat of the WHO guidance panel on task shifting, which also helped shape the design of the workbook.
Resources			Human resources, dedicated time, motivation, knowledge and technology were used in developing the workbook. Having no previous example of a workbook to contextualize health systems guidance created a challenge, but this was overcome by using knowledge from prior work done in the field. Researching and sharing information was done with the use of technology. Having multiple agencies involved in this work created some challenges with competing timelines and agendas but it also helped focus attention on the development of the workbook. The workbook was published online, but the final execution of the proposed edits did not occur, which could have been due to a combination of not having true buy-in by the Secretariat of the WHO guidance panel on task shifting or due to a lack of time and other resources.
Step 3a – WHO level implementation of the workbook: Institutionalizing the development of workbooks for guidance documents at WHO and disseminating and supporting the use of such workbooks at the national level			
Champions			Champions exist for this work and have been trying to gain traction to incorporate workbooks for contextualizing health systems guidance into guidance development processes at WHO, but, thus far, the necessary buy-in from those with decision-making power has not been gained. In addition, a Secretariat member who had acted as champion at earlier stages of the development of the workbook did not act as champion for the full institutionalization of the workbook idea or the dissemination of this workbook.
Opportunities			There is a need for support in contextualizing health systems guidance recommendations at the national/subnational level, and this workbook is meant to address this need. However, there have been several missed opportunities including that this process has not been institutionalized at the WHO level, WHO has not been involved in evaluating the use of the workbook at the national/subnational level, and prior work on developing health systems guidance was also not institutionalized at WHO.
Language			Language could act as a barrier to institutionalizing the work within WHO or at the national or subnational levels if the language is not easy for end-users to understand (e.g., too detailed, jargon, English-specific concepts).
Buy-in			There are rival theories as to whether differing viewpoints (clinical epidemiology vs. health systems and policy) have acted as barriers in institutionalizing workbooks to accompany health systems guidance or whether there is understanding and agreement with the importance of this work by those who have decision-making power at WHO and instead there are political or personal issues that stand in the way.
Resources			Resources at the WHO level were put into developing and disseminating the OptimizeMNH guidance, but these resources were not used in parallel to disseminate or support the use of the workbook at the national or subnational level.

Step 3b – National/subnational level implementation of the workbook: using, evaluating and institutionalizing the use of the workbook to develop health systems policy			
Champions		Peru and Uganda	It can be challenging to finding champions within countries to move this work forward. However, Peru and Uganda have found champions who, along with support from those who developed the workbook, have agreed to use the workbook to develop health systems policy and to allow for the evaluation of using the workbook.
Opportunities		Peru and Uganda	Dissemination of the OptimizeMNH guideline and the workbook occurred at the WHO African Regional office (WHO-AFRO) Regional Consultation on Optimizing Health Workers' Roles to Improve Access to Key MNH Interventions Through Task-shifting in Addis Ababa in 2012. However, there were some missed opportunities at this event to offer support to countries to evaluate the use of the workbook in their countries. Opportunities were created for two countries through different channels. A potential opportunity exists for this process to identify gaps in knowledge, which can, in turn, inform the research process itself.
Language			Preliminary feedback suggests that the workbook may be helpful, as it does provide a systematic approach to contextualizing health systems guidance, but it is too long and detailed overall, and people using the workbook may need some training in health policy, or support, in order to understand the complexities of the components of the workbook. Field testing will be the best way to evaluate the workbook and ensure it is understandable and relevant to the users.
Buy-in		Peru and Uganda	While some countries have asked WHO for support in contextualizing guidelines, some regions or countries do not place much importance on evidence and guidelines. Several participants noted that there may be a need for a culture shift towards developing health systems policy and evidence-informed policymaking in these regions or countries. In addition, it was noted that buy-in is required from policymakers but also from those who are responsible for implementing policies at the national or subnational level. In Peru and Uganda, buy-in by those champions at the country level was secured as they already had an understanding of the importance of contextualizing health systems guidance for their settings. The workbook may be helpful in building ownership to improve buy-in by including processes for stakeholder and public engagement.
Resources		Peru and Uganda	Resources for evidence-informed policymaking are often lacking at the national or subnational level. Multiple funding agencies and priority-setting processes within most countries can make carrying out this work difficult. Many countries have little capacity for research or for embedding this work into guidance development or policymaking processes and they do not have adequate resources to see implementation through. There is a need to build a health system evidence base over time to know what works within which contexts, and even though technology can be an asset by allowing more people to have access to more information, in many settings, people lack access to technology. Human resources and some financial resources are helping support the work of evaluating the use of the workbook in Peru and Uganda.

Appendix 1. Informed consent form for interviews



Interview letter of information/consent

Title of study: The development of a health systems guidance workbook to support the contextualization of the World Health Organization's 'Optimizing the delivery of key interventions to attain Millennium Development Goals 4 & 5' (OptimizeMNH) guidance at the national or subnational level

Principal investigator: Elizabeth Alvarez, MD, MPH, PhD (Candidate)

Co-investigator(s): John N. Lavis, MD, PhD

Funding sources: International Development Research Centre (IDRC)
International Research Chair in Evidence-Informed Health Policies and Systems

Government of Canada: Vanier Canada Graduate Scholarship

You are being invited to participate in a research study. The purpose of the study is to understand the process of identifying the need for and then developing a workbook for the contextualization of the WHO's 'Optimizing the delivery of key interventions to attain Millennium Development Goals 4 & 5' (OptimizeMNH) guidance to help with policy development and implementation at the national or subnational level. Specifically, you are being invited to participate in an interview about the process around the development of this workbook and your role in this process. Your involvement would mean participating in a 45-minute (approximately) semi-structured telephone/in-person/skype interview to be scheduled at your convenience. During the interview, I will ask you questions about your role in the process of developing the workbook, the process itself, and others who were also involved in the process. In addition, I will ask your thoughts about the workbook itself (i.e. hopes, challenges, recommendations). This is a student research project conducted under the supervision of Dr. Lavis. The study will help the student learn more about the topic area and develop skill in research design, collection and analysis of data, and writing a research paper.

Your participation in this research study is voluntary. You may refuse to participate in the research study and you may choose to withdraw from the study at any time. We cannot promise any personal benefits to you from your participation in this study. However, a possible benefit includes helping improve global efforts to support the use of global guidance recommendations to strengthen health systems.

Your interview and any information provided in the form of documents that are not in the public domain will be treated as confidential. With your permission, the interview(s) will be audio-recorded and transcribed and personal identifiers will be assigned to each digital file and transcript by us. We will ensure that the transcript and any confidential documents are kept in a locked

cabinet, the digital files containing the audio-recordings and transcripts are stored on a security protected computer, and the digital files, transcript and confidential documents are destroyed 10 years after the last publication of our findings. We will make the summary of our findings publicly available for use by others interested in improving their efforts to support policy development using global guidance in health systems policymaking.

Your anonymity as a research study participant will be safeguarded. We will ensure that the list of study participants and their participant numbers will be stored in a different locked cabinet or security protected computer from those where the digital files, transcripts and confidential documents are stored. Every effort will be made to report information in a way which will not identify individual respondents or departments; however, there is a slight chance that someone may be recognizable by his/her role or comments.

Please check yes or no to the questions below to indicate whether you consent to participate in our study and, if so, whether you are willing to have your name and position appear in the study acknowledgements and whether you would like to review and comment on the draft project report. We would be pleased to provide you with additional information about our study and your potential participation. For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Integrated Research Ethics Board may consult your research data. However, no records which identify you – be it name or initials will be allowed to leave the university. By signing this consent form, you authorize such access.

Request for consent	Yes	No
1. I am willing to participate in a 45-minute (approximately) in-person/telephone/skype interview to be scheduled at my convenience.		
2. I am willing to have the interview audio-recorded		
3. I am willing to have my name and position appear on the study acknowledgement list as one of the respondents.		
4. I would like to review and comment upon the draft project report.		
5. Please contact me. I would like additional information about the study and/or my participation.		

I will receive a signed copy of this form.

Participant

Print name: _____ Signature: _____

Date: _____

Person obtaining consent

Print name: _____ Signature: _____

Date: _____

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the

research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call The Office of the Chair, HIREB at 1-905-521-2100 x 42013.

Sincerely

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Appendix 2. Semi-structured interview guide

Study 1 - Semi-structured interview guide (15-45 minutes) – February 19, 2014

Participant ID _____ Date _____
Location _____ Researcher _____
Start time _____ End time _____ Date of informed consent _____
OK to record: Y / N

-Thank you for agreeing to be part of this study. Have you had a chance to look over the interview questions that I sent you beforehand? I will first ask you some broad questions, and at the end, I will ask you some specific questions to help understand the context of this work-

Semi-structured interview questions

1) What is/was your role with regards to the development of the workbook for health systems guidance?

Probes – Were you involved in discussions about the need for this type of workbook?

Were you involved in the development of the workbook?

Were you involved in the use / providing feedback on the use of this workbook?

2) Can you describe the process of developing the workbook?

Probes – Who was involved? Where did the work take place? How was it arranged? What information was used?

Need for the workbook – discussions, rationale

Development and approval process of the workbook – structure, rationales, events/steps

Providing feedback on the workbook – changes recommended, why

3) Who else do you think was a contributor to the development of the workbook, and how? Can you provide contact information for this/these individual(s)? Or, are there documents which may be relevant to the development of the workbook which I could access?

Probes – Policymakers, researchers, task-force members and/or other stakeholders

- If time, continue to question 4, otherwise go to end of interview (see next page) –

Participant _____ Date _____

4) What are your hopes for a workbook for health systems guidance? (i.e. why was it developed, in your words)

Probes – health system strengthening

5) What challenges do you foresee with a workbook for health systems guidance?

Probes – time and resources; allowing for cross-country considerations

6) Are there any changes you would recommend making to the workbook as it is now?

7) Is there any other information you feel I have left out which you would like to tell me about regarding the workbook for health systems guidance?

- Before ending this interview, I need to gather some personal data for contextual factors -

Demographic information

Age _____ Gender: F / M Country _____

Current professional designation _____ Length of time at current position _____

Other professional designation(s) _____

Other professional designation(s) _____

Thank you for your time. Is it ok to contact you again if I need any clarifications or have other questions? Thanks again!

OK to contact for further interview: Y / N

Appendix 3. Documents reviewed for the study

Date	Document Title	Author	Document Type	Source
2003 March	Guidelines for WHO guidelines	Global Programme on Evidence for Health Policy	Document	Internet search
2004; 2011 (Updated)	Ministerial Summit on Health Research, Mexico City, Mexico - November 16-20, 2004	WHO	Documents	Interviewee
2004	Informed choices for attaining the millennium development goals: towards an international cooperative agenda for health-systems research	Task Force on Health Systems Research	Journal article	Interviewee
2004	Overcoming health-systems constraints to achieve the millennium development goals	Travis et al	Journal article	Interviewee
2007	Use of evidence in WHO recommendations	Oxman et al	Journal article	Personal email
2007	WHO signals strong commitment to evidence	No author listed	Journal article	Personal email
2007	Everybody's Business. Strengthening health systems to improve health outcomes. WHO's framework for action.	WHO	Document	Proposal to Rockefeller Foundation. 2009. (48)
2008	Task shifting: rational redistribution of tasks among health workforce teams. Global recommendations and guidelines	WHO	Document	Personal email
2009	Systems thinking for health systems strengthening	Alliance for Health Policy and Systems Research (AHPSR), WHO	Document	Bosch-Capblanch X. Development of a protocol to elaborate health system guidelines: Pre-proposal. Swiss Centre for International Health; 2010.(49)
2009	Proposal to Rockefeller Foundation	No author listed	Document	Multiple interviewees
2009	The use of research evidence in two international organizations' recommendations about health systems	Hoffman et al	Journal article	Personal email
2009	SUPPORT Tools for evidence-informed health policymaking (STP) 1: What is evidence-informed policymaking?	Oxman et al	Journal article	Personal email
2009	SUPPORT Tools for evidence-informed health Policymaking (STP) 4: Using research evidence to clarify a problem	Lavis et al	Journal article	Personal email
2009	SUPPORT Tools for evidence-informed health Policymaking (STP) 5: Using research evidence to frame options to address a problem	Lavis et al	Journal article	Personal email
2009	SUPPORT Tools for Evidence-informed Policymaking in health 6: Using research evidence to address how an option will be implemented	Fretheim et al	Journal article	Personal email
2009	SUPPORT Tools for evidence-informed health Policymaking (STP) 9: Assessing the	Lavis et al	Journal article	Personal email

	applicability of the findings of a systematic review			
2009	SUPPORT Tools for evidence-informed health Policymaking (STP) 10: Taking equity into consideration when assessing the findings of a systematic review	Oxman et al	Journal article	Personal email
2009	SUPPORT tools for evidence-informed policymaking in health 11: Finding and using evidence about local conditions	Lewin et al	Journal article	Personal email
2009	SUPPORT Tools for evidence-informed health Policymaking (STP) 12: Finding and using research evidence about resource use and costs	Oxman et al	Journal article	Personal email
2009	SUPPORT Tools for evidence-informed health Policymaking (STP) 13: Preparing and using policy briefs to support evidence-informed policymaking	Lavis et al	Journal article	Personal email
2009	SUPPORT Tools for evidence-informed health Policymaking (STP) 14: Organising and using policy dialogues to support evidence-informed policymaking	Lavis et al	Journal article	Personal email
2009	SUPPORT Tools for evidence-informed health Policymaking (STP) 15: Engaging the public in evidence-informed policymaking	Oxman et al	Journal article	Personal email
2009	SUPPORT Tools for evidence-informed health Policymaking (STP) 16: Using research evidence in balancing the pros and cons of policies	Oxman et al	Journal article	Personal email
2009	SUPPORT Tools for evidence-informed health Policymaking (STP) 17: Dealing with insufficient research evidence	Oxman et al	Journal article	Personal email
2009	SUPPORT Tools for Evidence-informed Policymaking in health 18: Planning monitoring and evaluation of policies	Fretheim et al	Journal article	Personal email
2010	The global health system: actors, norms, and expectations in transition	Szlezak et al	Journal article	Interviewee
2010	The global health system: strengthening national health systems as the next step for global progress	Frenk	Journal article	Interviewee
2010	The global health system: linking knowledge with action-learning from malaria	Keusch et al	Journal article	Interviewee
2010	The global health system: lessons for a stronger institutional framework	Moon et al	Journal article	Interviewee
2010 Feb	Development of a protocol to elaborate health system guidelines: Pre-proposal	Bosch-Capblanch	Document	Interviewee
2010 March	WHO handbook for guideline development	WHO	Document	Personal email
2010 April 15-16	Task force on guidelines for health systems strengthening - draft agenda for meeting	No author listed	Document	Interviewee
2010 November	Optimizing the delivery of key interventions to attain MDGs 4 and 5: Background document for the First Expert ‘Scoping’ Meeting to Develop WHO Recommendations to Optimize Health Workers’ Roles to Improve Maternal and Newborn Health in Geneva, 6-8 December 2010	WHO: Department of Reproductive Health and Research	Document	Personal email

2010 December	Optimizing the delivery of key interventions to attain MDGs 4 & 5: Draft agenda - December 2010 scoping meeting - Centre International de Conférence Genève (CICG), Geneva, Switzerland 6-8 December 2010	WHO	Document	Personal email
2010 December	Optimizing the delivery of key interventions to attain MDGs 4 & 5: background and approach	Oladapo	Presentation	Personal email
2010 December	Optimizing the delivery of key interventions to attain MDGs 4 & 5: meeting objectives.	Gülmezoglu	Presentation	Personal email
2010 December 16	Notes from the Technical Consultation on Optimizing the Delivery of Key Healthcare Interventions to attain MDGs 4 & 5: 6-8 December 2010, Geneva, Switzerland	No author listed	Document	Personal email
2011 May 31-June 1	The guideline development process: WHO recommendations for optimizing the delivery of key interventions to attain MDG 4 and 5 through task shifting	No author listed	Presentation	Personal email
2011 May 31-June 1	Optimizing the delivery of key interventions to attain MDGs 4 & 5 through task-shifting: Background and objectives	Gülmezoglu	Presentation	Personal email
2011	Handbook for supporting the development of health system guidance	Bosch-Capblanch	Document	Multiple interviewees
2011 (Updated)	SURE guides for preparing and using evidence-based policy briefs	WHO / SURE	Documents	Interviewee
2012	Safe abortion: technical and policy guidance for health systems	WHO, Department of Reproductive Health and Research	Document	Personal email
2012	Guidance for evidence-informed policies about health systems: rationale for and challenges of guidance development.	Bosch-Capblanch et al	Journal article	Personal email
2012	Guidance for evidence informed policies about health systems: linking guidance development to policy development	Lavis et al	Journal article	Personal email
2012	Guidance for evidence informed policies about health systems: assessing how much confidence to place in the research evidence	Lewin et al	Journal article	Personal email
2012	Better guidance is welcome, but without blinders	Peters & Bennet	Journal article	Interviewee
2012 April 16-19	Optimizing the delivery of key interventions to attain MDGs 4 & 5: Draft agenda - Geneva, Switzerland 16-19 April 2012	WHO	Document	Personal email
2012 April 16-19	Optimizing the delivery of key interventions to attain MDGs 4 & 5 through task-shifting	Gülmezoglu	Presentation	Personal email
2012 April 19	Supporting the contextualization of the guideline	Lavis	Presentation	Personal email
2012 June 7	Supporting the contextualization of the Optimize4MNH Guidance at the national level	Lavis	Presentation	Meeting
2012	OptimizeMNH: Optimizing health worker roles to improve access to key maternal and newborn health interventions through task shifting	WHO	Document	Interviewee
2012	Annex 8. Contextualizing the guidelines - workbook	WHO	Document	Principal investigator, online search

2012, Mar 3 – 2013, Nov 19	Reflexive Journal I (Workbook)	Principal investigator	Reflexive Journal – 195 pgs,	Principal investigator
2013, Nov 20 – 2014, Jun	Reflexive Journal II (Workbook)	Principal investigator	Reflexive Journal – 127 pgs	Principal investigator
2014, June 5 – 2015, Jan 23 (ongoing)	Reflexive Journal III (Workbook)	Principal investigator	Reflexive Journal – 93 pgs	Principal investigator
2011-2014		Emails, 2011-2014	Personal correspondence	Personal emails, some forwarded through interviewees

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Chapter 3 - Preface

Moving from developing the workbook to using it, this chapter employs a single embedded case study approach to examine the process of using the workbook for contextualizing the OptimizeMNH guidance in two countries, Peru and Uganda. A case study approach, along with prospective data collection techniques, allowed for an in-depth look at the process for using the workbook and its context. The detailed description of these techniques could help inform the study of other cases of similar tools being used in the field. The case study highlights the importance of context in developing policy to fit the needs of a particular setting. Overall, the workbook was seen as helpful when compared with usual processes. However, the process is still time and resource intensive and cannot replace the work of country experts (i.e., methods and content). Benefits and challenges of using the workbook are provided. Recommendations for improving the workbook based on the perspectives of users at the national level are provided in chapter 5.

While chapter 2 provides theoretical and applied barriers and facilitators to using the workbook at the national/subnational level from the perspectives of global guidance developers, chapter 3 provides an applied look at these barriers and facilitators from the perspective of users of guidance at the national/subnational level. Because these chapters were developed concurrently, each study informed the other and allowed for a cross-examination of these barriers and facilitators which helped further develop the concepts found in both

chapters. For example, in chapter 2, issues around capacity for local health and political analysis as well as the need for advocacy were brought up as potential barriers or facilitators in the use of the workbook and in the implementation of global guidance recommendations. These concepts were considered during the use of the workbook in Peru and Uganda, which helped verify that indeed, these were potential barriers or facilitators at the national/subnational level. In addition, looking at how these issues were overcome in Peru and Uganda, which allowed the work to move forward in these settings, helped strengthen the concepts found in chapter 2. Furthermore, the concepts from chapters 2 and 3 were considered in chapter 4 to see if and how these concepts were defined and how they played a role in the contextualization of guidance.

I was responsible for conceiving of the design of the study with my supervisor, Dr. John Lavis, and for completing all data collection and analysis. Dr. Lavis also contributed to the analysis during ongoing iterative cycles of analysis. I drafted the chapter, and Dr. Lavis, Dr. Brouwers, Ms. Carmona Clavijo, Professor Sewankambo, Dr. Solari, and Dr. Schwarz provided comments and suggestions that were incorporated into subsequent revisions.

Contextualizing global health systems guidance: Examining the process of using a guidance-contextualization workbook to support the development of evidence briefs in Peru and Uganda

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Abstract

Introduction: Countries can use global evidence-based guidance to help strengthen their health systems in order to deliver effective interventions to their populations. However, in order for guidance to have an impact, it needs to get on the government's agenda, inform policy development, and be implemented.

Influencing these stages of the policy process is complex and needs to take into account contextual factors, such as characteristics of the problem and features of the health system and political system. A workbook was developed to help contextualize the World Health Organization's OptimizeMNH guidance (Optimizing the delivery of key interventions to attain Millennium Development Goals 4 and 5'). The process of using the workbook to contextualize the global guidance to enable development of evidence briefs at the national level in each of Peru and Uganda was examined.

Methods: A qualitative embedded case study design was used. Participant-observations, emails, field notes, interviews, documents and a reflexive journal

were used as data sources. Data analysis was conducted through a template-organizing style of data organization and constant comparison to develop concepts and themes.

Results: Nineteen participant-observation sessions and 8 interviews were conducted, and 50 documents were reviewed. Overall, the workbook was viewed positively, and participants in both countries are using or would use it again for other topics. Many benefits (e.g., examples in the workbook were helpful) and several challenges (e.g., the workbook had areas of redundancy) were found in the process of using the workbook. Contextual factors, including the cadres of health workers available in each country, and the way the problem and its causes were framed, potential policy options to address the problem and its causes, and implementation considerations for these policy options varied substantially between Peru and Uganda. However, similarities were found in the process of using the workbook.

Discussion: Organizations that produce global guidance, such as WHO, need to consider institutionalizing the development of workbooks into their guidance development processes to help users at the national / subnational level create actionable and context-relevant policies. Contextualizing health systems guidance is a time- and resource-intensive process. There are multiple steps in the process and many elements need to be considered. While the workbook may simplify this process by providing a systematic tool, it cannot replace the work required by a team of methods and content experts. In addition, feedback mechanisms need to

be established so that findings coming out of the process of guideline contextualization can be taken into consideration during future guidance development and research priority-setting. An inventory of evidence briefs and health policies arising from global guidance is encouraged.

Weak health systems hinder the delivery of and access to effective interventions to those most in need, especially in low- and middle-income countries (LMICs) (1–3). Developing evidence-based health systems guidance at a global level is one way to help countries that are facing the same or similar issues strengthen their health systems (e.g., lack of trained health workers) (1). Health systems guidance has been defined as “systematically developed statements produced at global or national levels to assist decisions about appropriate options for addressing a health systems challenge in a range of settings and to assist with the implementation of these options and their monitoring and evaluation.” (1) Global guidance can, in turn, be used to: 1) develop policies at the global level (e.g., funding vertical or single-disease programs vs. integrated care); 2) develop guidance at the national level, (e.g., national guidance panel or Evidence-Informed Policy Network (EVIPNet) developing an evidence brief); and 3) develop policy at the national or subnational level (e.g., Ministry of Health making policy at the national level in centralized or unitary systems or at a subnational or provincial/state level in federal or decentralized systems). (4) In order for guidance to have an impact, the issue first needs to get on a government’s agenda, guidance needs to be contextualized or adapted to the particular setting and inform policy development, and a policy needs to be approved and implemented. (4,5) Two methods that have been used to support evidence-informed policymaking at the national or subnational level in high-income as well as in LMICs include evidence briefs (at times referred to as

policy briefs) and policy dialogues (6–8). An evidence brief is a document which presents research evidence on the problem and its causes, possible policy options, and implementation considerations for a specific setting (4,8). The evidence brief can then be used to inform a policy dialogue. A policy dialogue is organized to elicit the views, experiences and tacit knowledge of policymakers, stakeholders and researchers who are involved in or affected by decisions surrounding the topic and possible policy options at hand. A summary of the policy dialogue can help inform agenda setting, policy development and/or policy implementation (4,8). While there are no systematic reviews evaluating the impact of the use of evidence briefs or policy dialogues, there has been research to show evidence briefs can impact on the use of evidence in specific cases. (7) Evidence briefs help overcome some of the barriers that have been noted to affect the use of research evidence by policymakers, including greater interaction between researchers and policymakers, timeliness for gathering evidence to inform a policy decision, and alignment with the beliefs and values of policymakers and the public. (7)

Several tools are available to help users at the national or subnational level develop evidence briefs. First, a series of 19 articles published in *Health Research Policy and Systems* in 2009, the ‘SUPPORT tools for evidence-informed health policymaking’ articles, guides policymakers, and those supporting the work of policymakers, in finding and using research evidence and in writing evidence briefs and convening policy dialogues. (9) Each article presents a set of questions to guide users in the development of an evidence brief, but it also provides types

of research evidence that can be used to help answer each question (e.g., use of systematic reviews to find evidence on potential benefits or harms from a proposed policy option). (10) Based on the SUPPORT tools, the ‘SURE guides for preparing and using evidence-based policy briefs’ were published in 2011, with a focus on producing evidence briefs within the contexts of African health systems. (11)

However, until recently, there were no tools available that supported users of health systems guidance at the national or subnational level in combining global recommendations with national / subnational assessments of the local problems and their causes, along with reflection on the existing health system arrangements (i.e., delivery, financial and governance arrangements) that may need to be changed and political system considerations that need to be taken into account (i.e., institutions, interests, ideas and external factors) (4). Taking these factors into consideration during policy development can help ensure that the policy options are designed to meet the needs and realities of a given setting, which can then help with implementation. (4)

In 2012, a workbook for contextualizing health systems guidance (henceforth, “workbook”) was developed de novo by two authors of this paper (EA and JL). (6) (See appendix A) This workbook was created to help contextualize a World Health Organization (WHO) guidance document on optimizing health worker roles for increasing access to and use of key

interventions for improving maternal and newborn health in LMICs

(OptimizeMNH guidance). (12)

The workbook was based on the second article of the *PLoS Med* series on ‘guidance for evidence-informed policies about health systems’ (1,4,13), which outlined the contextualization or adaptation process and the contextual factors to take into account while developing an evidence brief. This article and the workbook also drew from the content of the ‘SUPPORT tools for evidence-informed health policymaking’ articles clarifying evidence needs in policymaking, (10,14,15) taking equity into consideration, (16) preparing policy briefs and policy dialogues, (17,18) engaging the public, (19) and planning monitoring and evaluation of policies (20). In addition, insights from the OptimizeMNH guidance panel discussions were incorporated into the workbook.

(6)

The workbook follows a framework called the ‘health systems guidance contextualization framework,’ which addresses: 1) clarifying the problem and its causes; 2) framing options for addressing the problem; 3) identifying implementation considerations; 4) considering the broader health system context; 5) considering the broader political system context; 6) refining the statement of the problem, options and implementation considerations in light of health system and political system factors; 7) anticipating monitoring and evaluation needs; and lastly, 8) making national or subnational policy recommendations or decisions (6). Briefly, the workbook includes a narrative of how to use it and provides questions

to guide the users through each of the eight steps in the health systems guidance contextualization framework. The workbook also gives examples related to the topic of optimizing health worker roles for improving maternal and newborn health, which were drawn from the OptimizeMNH guidance and related systematic reviews. In addition, the workbook provides prompts for type(s) of evidence that could be looked at to help answer each question (e.g., systematic reviews, local studies, administrative data, etc.).

As this was a new tool, it was important to examine the use of the workbook to see whether and how it could be beneficial in the process of contextualizing health systems guidance to develop evidence briefs.

Methods

Study design

This study followed an embedded single case study design as described by Yin (21). A case study is the “preferred method when (a) “how” or “why” questions are being posed, (b) the investigator has little control over events, and (c) the focus is on a contemporary phenomenon within a real-life context” (Yin, 2009, p.2). The purpose of this study was to examine how a workbook was used in the process of contextualizing global guidance at the national or subnational level in LMICs, which constituted a “how” question. It looked at a current-day phenomenon (i.e. process of using the workbook) in its natural setting – a country. And, while the investigators were involved as participant-observers in this process, they worked with country teams to develop the evidence briefs, which

meant that the investigators did not have sole control over the events. A reflexive journal, which is often used in qualitative research designs, was kept throughout the study to keep track of events and their contexts (e.g., who was involved, how and why were certain decisions made, etc.), to provide insights into the roles of the investigators and potential ways they influenced the case (e.g., helping set up meetings and conducting research to inform the development of the evidence briefs), and to record decisions about procedures used and interpretations of the data during data analysis. (22)

The single case design was chosen, as the case was expected to be unique, since this type of workbook had not been used in the past, but the case was also expected to be representative of similar cases where a workbook might be used in the contextualization of global guidance at the national or subnational level (21). An embedded design, which incorporates two or more units of analysis (in this case, two different countries), was chosen over a multiple case design as there were many shared attributes between the embedded units (i.e. countries) in that the global guidance was the overall context of the work. This shared context includes a shortage of health human resources that contributes to weak health systems. This problem has been partly blamed for the inability of many countries to achieve the health-related Millennium Development Goals (MDGs), especially MDGs 4 and 5 regarding maternal and child health (12). The MDGs are eight goals that United Nations Member States agreed to try to achieve by 2015 to address issues of poverty, hunger, disease, illiteracy, environmental concerns and

discrimination against women. (23) Recognizing that it takes many years to train health workers, the World Health Organization (WHO) developed a guidance document about improving access to and use of key maternal and newborn health interventions through the optimization of health worker roles (OptimizeMNH guidance) (12). For example, recommendations from the OptimizeMNH guidance include that auxiliary nurse midwives should be able to deliver neonatal resuscitation and midwives should be able to insert and remove contraceptive implants, given the proper training and supervision and within the proper regulatory framework. The workbook, which is the main object of analysis for this study, was created to support the contextualization of this global guidance. In addition, this research design also allowed for country-level factors to be explored within each embedded unit.

The complexity of having multiple people (e.g. policymakers, stakeholders, researchers) with varying perspectives involved in the process of contextualizing guidance through the development of evidence briefs lent itself to an in-depth case study approach where the components of the case and the context could be studied (21). And, because multiple people were involved in the process of using the workbook, a constructivist paradigm, where multiple realities are expected based on each person's view, was fitting for this study (21,24).

The case in this study was the process of using a workbook to support the contextualization of global health systems guidance, with national or local evidence, to develop evidence briefs at the national / subnational level. Local

evidence includes evidence which is specific to the jurisdiction of focus, which could include national, provincial/state or municipal levels. It was important to set bounds for the case so the study remained focused (21). The case was bounded by the setting, which included the countries where the workbook was used in developing the evidence briefs. Because the workbook was meant to help contextualize global guidance, the setting was important, as this determined how the contextualization process unfolded. This case was also bounded by the participants involved in the case (i.e. process of using the workbook) which included policymakers, stakeholders and researchers. Lastly, the case was bounded by time, starting with the countries' decision to utilize the workbook in helping them contextualize the OptimizeMNH guidance through the development of draft evidence briefs or through the development of terms of reference for an evidence brief. (See figure 1) The difference in these descriptions is that in Peru, the evidence brief was developed directly and modified as needed, whereas in Uganda (as in Canada), terms of reference are typically developed first with input from a working group, and then the evidence brief is developed from the terms of reference. The reason for choosing this timeframe relates to the purpose of the workbook, which is to support the development of an evidence brief. It is not expected that the workbook itself will be used in the other steps of the policy decision-making process because it is not designed to do so at this time.

Theoretical frameworks

The role of evidence briefs in translating research knowledge into policy was discussed in the introduction to this paper. In addition, the frameworks for the suggested factors to be considered in the contextualization of guidance come from the field of health systems and policy. First, as already noted, every clinical, public health or health policy intervention is implemented within a health system. (1,4,25) The health system and policy research field provides a framework for breaking down the health system into delivery arrangements (e.g. who provides the care, where is the care provided), financial arrangements (e.g., financing mechanisms, remunerating providers) and governance arrangements (e.g., policy authority, commercial authority). (4,6) Second, health systems function within overarching political systems, and changes within a health system may need to be approved or supported by the political system. (1,4) Therefore, consideration needs to be given to these factors. The “3I” framework (institutions, interests, ideas and external factors) provides a structure for understanding the components of a political system. (4,7) Institutions include government structures (e.g., unitary or centralized vs. federal or decentralized systems), policy legacies (e.g., past policies shaping current structures), and policy networks (e.g., some interest groups have greater access to the policy process). (4,7,26,27) Interests include groups of people who may benefit or be harmed by a policy decision and may mobilize politically for or against this decision (e.g., patient groups, civil society). (7,28) Ideas include values and beliefs of policymakers and the public, and

research evidence. (4,7) Lastly, external factors, such as economic changes or media coverage, can either bring attention to or away from other topics.

Sampling and recruitment

Criterion sampling (29) was used to select two countries for this study. Criteria included: 1) there was commitment from policymakers, the WHO country office, regional office and/or headquarters, or from the Ministry of Health to support the development of an evidence brief by using the workbook to contextualize the OptimizeMNH guidance, and 2) the country had not conducted formal work on task shifting with regards to the OptimizeMNH guidance. Several countries were contacted through the professional networks of EA and JL and these were initially interested, but ongoing commitment was only shown by Peru and Uganda. Initial contact occurred via personalized emails (Peru) or through face-to-face meetings followed by personalized emails (Uganda) with country representatives. These country contacts provided access to other participants involved in the process and to initial meetings with the country teams.

Criterion sampling was also used to select participants for semi-structured interviews in each country. Inclusion criteria for interviews included: 1) the participant must have been involved in using the workbook for developing the evidence briefs, and 2) the participant needed to be at least 18 years of age, which was explicitly stated since different countries have different ages for majority. Recruitment was conducted through personalized emails.

In addition, criterion sampling was used to select documents which related to the use of the workbook (e.g., minutes from the meetings) or information about the contexts in which the workbook was used (e.g., Uganda health assessment). These documents were found through personalized emails, personal files, internet searchers, participant-observations or interviews.

Data collection

Several data collection techniques were used in an attempt to capture the events in the process of using the workbook. First, participant-observations were conducted by one researcher (EA) with the country teams in Peru and Uganda. (See appendix 1 for participant-observation guide) The term ‘participant-observation’ is used in qualitative research to signify that the researcher takes part in an event or in a phenomenon that is also the object of study. (30) That is, the researcher is observing an event to gather data but is also a participant in the event. In this study, the participant-observations (henceforth “meetings”) took the form of skype meetings (both Peru and Uganda), face-to face meetings (Uganda), or gmail chats (Peru) where EA interacted directly with the country teams (one or more people) in real-time. Second, other forms of communication were used with the country teams but did not involve an immediate interaction (e.g., emails). These emails were also used as data. Third, because of the interplay between the researcher and data collection in qualitative research, a reflexive journal is often kept, not only to keep track of events, but also to note the role of the researcher in the research process and how one influences this process. “Reflexivity refers to

the technique by which researchers turn the focus back on themselves to evaluate their influence on the findings and interpretations” (31) Journal entries were also used as data. Fourth, field notes can also add to the information gathered of an event or phenomenon, and these notes were recorded during and after the meetings. According to Eisenhardt (32), two keys to good field notes include: 1) writing down impressions whether deemed important or not at the time, and 2) pushing the thinking in the field notes by asking questions such as what is being learned or how this situation differs from the last. Fifth, relevant information from these meetings was also circulated to the corresponding country teams as meeting notes. This helped ensure the information was accurate as all attendees had a chance to verify the information and correct any misunderstandings. These meeting notes were regarded as documents in this study. Other documents were found through participants at the meetings, through personal emails, from personal files, or through online searches. (See appendix 5) Documents were used to help understand the context and process of using the workbook (e.g., health system assessments in both countries, WHO and United Nations International Children’s Emergency Fund (UNICEF) websites for health indicators, meeting notes) or they were documents which arose from the use of the workbook (e.g., multiple iterations of the draft evidence briefs or terms of reference for an evidence brief). Sixth and last, semi-structured interviews were conducted with interviewees by a single interviewer (EA) over Skype or email once the draft evidence briefs or terms of reference for an evidence brief were written. (See

appendix 2) This timing was chosen so that participants could reflect on the process of contextualizing guidance and on the workbook itself. The interviews were recorded with a digital recorder and transcribed (or translated and summarized into English for interviews conducted in Spanish). The interviewer asked participants about their role in, and the process with, regards to the use of the workbook for health systems guidance contextualization and their impressions of using the workbook (including useful components and areas to be improved).

Data analysis

Coding was conducted by EA, with input on the code structure, concepts, and themes from JL. An initial guiding code structure was created to look for information related to the steps in the process of using the workbook, evaluation of the process of using the workbook, and contextual factors for Peru and Uganda. Codes were added or modified throughout the analysis as guided by the data. Following a template-organizing style, guided by the initial code structure, data from the interviews, meetings, emails, documents and reflexive journal were coded and organized into a table using Microsoft Word. Notes were made throughout this part of the analysis to keep track of emerging concepts from and interpretations of the data (31). Constant comparison was used to compare new information to previous information, which helped in the development of the concepts. The concepts were then linked into themes. These were further developed through iterative reviews of the data to ensure completeness of the concepts and themes. Once all of the themes had been developed, the data were

once again reviewed to make sure no new concepts arose and no rival theories were found. Peer debriefing was also conducted whereby peers were asked to review the tables, diagram, and manuscript, which helped provide feedback on the interpretation of the findings (as many of the authors were also involved in the process of using the workbook to develop the evidence briefs) and helped refine the presentation of the concepts and themes.

Ethical considerations

Ethics approval was obtained from the Hamilton Integrated Research Ethics Board (HIREB), Hamilton, Ontario, Canada, prior to country recruitment and data collection. Meetings and interviews were conducted remotely for Peru, which were covered through the HIREB approval process. Ethics approval was obtained from the School of Medicine Research and Ethics Committee (SOM-REC) at Makerere University College of Health Sciences in Kampala, Uganda prior to conducting on-site observations in Uganda. Participants signed informed consent forms if they were present at events which were deemed to be participant-observations (i.e., the meetings), as described previously. (See appendix 3) In addition, participants were also asked to sign separate consent forms prior to being interviewed. (See appendix 4) Because of the small number of participants involved in these events, and for reasons of confidentiality, specifics of the individuals participating are not provided in this paper.

Results

Peru and Uganda were selected as the embedded units for this study. Both countries had established EVIPNet teams and met the country selection criteria. Having EVIPNet teams already established made the process of contextualizing guidance to develop evidence briefs easier since participants were familiar with evidence-informed policymaking, had developed evidence briefs in the past, and had connections with policymakers. Participants were also selected in each country. While specifics of the participants are not provided for confidentiality reasons, it is worthy to note that the participants were diverse in age, gender, and level of seniority in their respective positions. All people interviewed had backgrounds as researchers. All but one interviewee also had backgrounds as health professionals or policymakers. For the purposes of this study, participants involved in the interviews and/or in the meetings are described broadly as belonging to the Secretariat in Peru, the Secretariat in Uganda, or the working group in Uganda. The Secretariat in Peru represents those involved in using the workbook directly to develop the evidence brief. They will also convene policy dialogues and revise the evidence brief based on these dialogues in Peru. The Secretariat in Uganda also includes those involved in using the workbook directly to develop the evidence brief. These participants will revise the evidence brief based on feedback from the working group and then convene a policy dialogue. The working group in Uganda includes policymakers, stakeholders and researchers who are not directly using the workbook but provide feedback to the

Secretariat throughout the development of the evidence brief. To note, Peru does not typically use working groups to provide feedback during the development of evidence briefs. Instead, they conduct several policy dialogues with policymakers, stakeholders and researchers once the draft evidence brief is completed. A total of 5 people were involved in the meetings with Peru (all were part of the Secretariat and included EA and JL). Nine people were involved in the meetings with Uganda (7 as part of the Secretariat, including EA and JL, and 2 as part of the working group). Nineteen meetings were conducted (4 with participants in Peru, and 15 with participants in Uganda). Interviews were conducted with 8 participants (3 in Peru and 5 in Uganda). Working group members in Uganda were not approached for interviews, as they did not work directly with the workbook. EA and JL were part of the Secretariats in both countries and were also not interviewed. One interview was conducted with each participant over Skype, except for one interview, which was conducted via email after multiple failed attempts to connect via Skype and phone. These interviews ranged from 31-85 minutes in length, with an average duration of 59 minutes. In addition, fifty documents were reviewed (not including the documents reviewed for developing the evidence briefs in either country): 40 documents (e.g. Uganda health system assessment, meeting notes) and 10 websites (e.g., UNICEF statistics for both countries). Multiple personal emails and a reflexive journal, which included the field notes (Volume I – 195 pages, volume II – 127 pages, and volume III – 93 pages) were also used as data (see appendix 5).

A comparative approach is used throughout the results section in order to highlight major points of difference in the process of using the workbook between Peru and Uganda, major issues arising from the application of the workbook, and insights for future work.

Select contextual features in Peru and Uganda

Every step of the workbook prompts users to consider data from their own contexts in the development of the evidence brief. This was seen by participants as useful since it served as a checklist for the types of information that were needed. Documents and information from the meetings were used to gather information about the contexts in Peru and Uganda. These countries varied significantly in their geographic, social and demographic factors, in their health systems arrangements and in their health indicators (see appendix 6). First, while Peru is about 5 times larger than Uganda, Uganda has 4 times more administrative units than Peru, which may increase the local capacity to self-govern and to adapt policy and services to the communities' needs, but it also requires more human and financial resources. (33–36) Also, while more than three-fourths of Peruvians live in urban areas, less than one-fifth of Ugandans live in urban centres, which can have a significant impact on the delivery of services. (37,38) Both Peru and Uganda have a mix of public, private and donor funding and delivery of health services, but the contribution of each of these is quite different in both countries. One example is that donor financing in Peru accounts for 2% of total health expenditure, while in Uganda donor financing ranges from 32% to over 50%.

(39,40) One common problem in both health systems is that there is little cooperation between the public and private systems, which can lead to poor planning and coordination. (39,40)

Notably, Peruvians have a life expectancy of 75 years for males and 79 years for females while Ugandans have a life expectancy of 56 years for males and 58 years for females. (35,36) However, large variations exist within these countries as well, especially as noted in Peru between its urban (72-77 years) and rural (57-63 years) populations (40). In addition, lifetime risk of maternal death, neonatal mortality rates, infant mortality rates and under-5 mortality rates are markedly higher in Uganda than in Peru. (37,38) One contributor to these higher rates is that a skilled birth attendant is present in 87% of births in Peru but only in 57% of births in Uganda. (37,38) Yet, the issues surrounding maternal and child mortality are complex, and multiple factors need to be considered in order to ensure appropriate policy options are implemented. As noted by the participants and in journal entries, the workbook helped users identify some of these considerations.

Peru and Uganda varied in their available health cadres. Under step 1 (clarifying the problem), the workbook prompts users to consider: ‘1) Is there a significant problem with a lack of provision of key interventions needed to attain MDGs 4 & 5 in particular communities/ regions which affect the access to / utilization of these interventions? (the key interventions are listed in the workbook); 2) Is the availability of skilled health workers a significant contributor

to the problem, and if so, which cadres of health workers are in short supply and in which communities (rural/urban; poor/wealthy neighbourhoods)?; 3) What cadres covered by the OptimizeMNH guidance recommendations might be candidates for expanded training, regulation and support to enhance access to / utilization of key interventions needed to attain MDGs 4 & 5, and for which interventions might they take responsibility?; and 4) Are health system supports (e.g. training and supervision) for existing and needed cadres lacking?’ Based on these prompts, it was decided by each Secretariat that the applicable recommendations (depending on the topic selected in each country) would be looked at to see 1) how did existing cadres in the country compare with the definitions of the cadres based on the OptimizeMNH guidance, 2) what interventions were each cadre performing in reality, and did current practice line up with WHO’s recommendations, and if not, 3) what would be needed in order for that cadre to be able to perform the recommended intervention in that setting’s context and what supports would be needed. This information was elicited in the meetings where country experts (i.e., having health backgrounds) were involved as part of the Secretariat in both countries. Table 1 illustrates the complexity of contextualizing global guidance to a specific setting, as health cadres go by different names and have varying levels of training in different settings. Neither Peru nor Uganda had equivalent cadres to advanced level associate clinicians or to auxiliary nurse midwives. On the other hand, both countries had equivalents to midwives, nurses, and non-specialist doctors (in Peru, there were several cadres

that fell under this category in regards to the OptimizeMNH guidance, and in Uganda, they were called medical officers). However, Uganda had a more nuanced description of these prior two cadres in that there were two main levels of training for midwives and nurses (enrolled and registered). In addition, there was a “double-trained” cadre which had training in both nursing and midwifery. Both countries had a similar cadre to lay health workers (LHW). In Peru, this cadre was called *promotores de salud* or health promoters. In Uganda, there were community health workers (CHWs), but this cadre, in contrast to WHO’s definition of LHWs, tended to be made up of volunteers in the community, some were illiterate, and few had any biomedical training. These differences were important in developing the options and determining implementation considerations (e.g., many interventions listed for LHWs required some level of biomedical training, which CHWs in Uganda generally lacked). Lastly, while Peru had *técnicos the enfermería* (nursing technicians), which aligned with WHO’s auxiliary nurse cadre, Uganda no longer trained this cadre or had formal roles for them in its system. In contrast, an equivalent cadre to WHO’s associate clinician did not exist in Peru, but it was equivalent to a clinical officer in Uganda. It was important to have health workers who were familiar with the health cadres, and the interventions performed by each health cadre, in order to elicit this level of information.

Peru and Uganda both had EVIPNet teams, and the Secretariats for each country were familiar with evidence-informed policymaking and the use of

evidence briefs. However, the structure of their EVIPNets were significantly different. Participants described their organizational structures during the meetings and interviews. Peru's EVIPNet team had a formal organizational structure with and accountability to the Ministry of Health through the National Institute of Health. The Ministry of Health was responsible for health policy structure and approval in Peru. Uganda's EVIPNet team had professional connections with Ministry of Health personnel but no formal organizational structure or direct accountability to the Ministry of Health. In Uganda, the Ministry of Health develops health policy in conjunction with other ministries and donor organizations, but policy is approved by Cabinet. Another difference is that Uganda's EVIPNet team is housed within Makerere University and has connections with outside academic centres, while Peru's EVIPNet team is not affiliated with an academic centre. One participant noted that it may be easier to access electronic databases through an academic centre, which could facilitate the process of finding and using research evidence.

The process for developing evidence briefs varied in each country. Most notably, Peru's process included fewer people to develop the draft evidence brief, and the outcome of the evidence brief and policy dialogue could lead to policy decisions by the Ministry of Health. In Uganda, as compared to Peru, more people were involved in the process of developing the draft terms of reference (i.e., a Secretariat in charge of gathering the evidence and writing the document and a working group to provide input on this work). However, it seems this

participatory process is needed, as the evidence brief and policy dialogue serve to inform the policy process, which is in itself more participatory in Uganda, involving the Ministry of Health along with other Ministries and donor organizations. Yet, many similar factors were found in how each section of the workbook was used in both countries (see table 2).

Timeline of events in the process of using the workbook in Peru and Uganda

As was noted previously in the dissertation, processes do not occur in isolation. There were people and actions which were needed to be in place in order for the workbook to be used. Events surrounding the processes of using the workbook to develop evidence briefs were quite different in both countries (see figure 1). This information was gathered through the journal, emails and interviews. Once ethics approval was obtained through the Hamilton Integrated Research Ethics Board in Hamilton, Ontario, and countries were selected, work on the evidence brief started immediately in Peru based on the topic of institutional delivery, which was determined by the respective director in the Ministry of Health. However, two events prolonged the work in Peru. First, the main person in charge of this work was off for maternity leave, and second, by the time she returned to work, there had been a turnover in several directors at the Ministry of Health, including the one involved in this work, which also caused the topic to change based on the new director's priorities. Once a formal document was received from the Ministry with their priority topics (so there would be less chance of topics changing with another unexpected change in directors), using the

workbook to develop the evidence brief took about four months with another two months for feedback from the rest of the Secretariat and revisions to the document. At the time of writing this report, the Secretariat is waiting for the Ministry to formalize connections with health officials in Loreto in order to meet and discuss the work since the focus of the evidence brief is on Loreto. Members of the Secretariat in Peru expect that representatives from other regions may take part in some of the policy dialogues in order to see what they can apply for their regions.

In Uganda, discussions were first held regarding the purpose of the work, the make-up and roles of the Secretariat (i.e., those involved in using the workbook to develop the terms of reference and the evidence brief and in planning the policy dialogue), timelines and the structure of the terms of reference. Because the Secretariat in Uganda was made up of volunteers adding this to their other priorities, it was important to get everyone on-board with these decisions. Once the team approved the work, discussions were then held around issues involving the workbook, such as choosing a topic, selecting and involving the working group members, applying for country ethics, preparing for fieldwork and conducting background research. In Uganda, the terms of reference were developed using the workbook in about two weeks of intense fieldwork by (EA) and the rest of the Secretariat in Uganda. In addition, a research assistant was hired to conduct interviews with health professionals to verify, across a couple of settings, the work the Secretariat had done around the interventions each cadre

provided in Uganda, which formed the basis for the policy options developed in the evidence brief. At the time of this writing, discussions around developing the evidence brief from the terms of reference and convening (including funding) for the policy dialogue are taking place. As mentioned earlier, the workbook is not expected to play a role in these other processes.

Main findings in the process of using the workbook to develop an evidence brief in Peru and terms of reference in Uganda

Key steps in the process of using the workbook in Peru and Uganda are noted in table 2. In both countries, the workbook was seen as a methodology for developing the evidence briefs. However, in Uganda, the workbook also helped define the overall process by refining the structure of the terms of reference for development of the evidence brief and the timeline.

Selecting the topic

The workbook does not currently address ‘selecting a topic’ as an explicit step. However, it was found that selecting the topic was a discrete step in the process, even with an available guidance document. The reason was that the issue had to align with the priorities of the government or Ministry of Health. In Peru, the topic was changed from delivering (birthing) at a health facility, to increasing access to and use of contraception in one specific region, Loreto, Peru, because of considerations of the Ministry’s priorities (which changed due to a change in leadership). In Uganda, the topic remained broad and all of the recommendations in the OptimizeMNH guidance were reviewed, but this was after much discussion

around other factors which could have influenced selecting a topic. Uganda's REACH Policy team usually worked through a rigorous process of selecting a topic that was relevant to policymakers in Uganda (including surveys and Delphi techniques to select topics). Having the workbook, and focusing on the guidance, however, made this process much shorter than it otherwise would have been because the OptimizeMNH guidance already described the problem of lack of access to key interventions to improve maternal and newborn health from a global perspective, and because it was determined that the process would include working through the relevant recommendations for Uganda.

In all, Peru chose the topic of 'increasing access to modern family planning methods in Loreto, Peru', while Uganda chose to keep the broader topic of 'optimizing health workers' roles to increase access to and use of key interventions to improve maternal and newborn health.' Factors used in both countries for selecting the topic included: 1) alignment with priorities of the government or Ministry of Health, 2) alignment with the OptimizeMNH guidance, 3) consideration of priority regions/populations, and 4) preliminary consideration of the relevant OptimizeMNH recommendations to ensure there was enough substance for developing an evidence brief on that topic. First, the topic needed to reflect the priorities of the Ministry of Health or the government. In Peru, this process was more formal with the Ministry requesting information on three specific priority areas through a written document. In Uganda, the government had moved away from the idea of task shifting, but the dire health

human resource shortage and the ever-present focus from within and outside of the country on maternal and newborn health issues kept this issue on the government's agenda.

“I have no doubt that Uganda...will be interested in collaborating. As you would expect maternal and newborn health are major priority issues in this country...” (email from Member of Secretariat in Uganda, March 23, 2013)

Second, in order for the OptimizeMNH guidance to be relevant, the topic had to align with the topic of the guidance (i.e., in this case, optimizing health worker roles to improve access to and use of key maternal and newborn health interventions). In Peru, one of the priority areas of the Ministry included access to modern family planning methods, which aligned with some of the interventions in the OptimizeMNH guidance. Uganda's topic was already aligned with the OptimizeMNH guidance. Third, consideration of priority regions or populations helped narrow down the topic in Peru to the region of Loreto. Comparing indicators related to maternal and newborn health and unmet need for family planning showed that this region, as compared to other regions in Peru, was a priority area. In contrast, lack of data at the district level in Uganda did not allow for the topic to be narrowed down to a particular group or district. Fourth, preliminary work reviewing the cadres and interventions in the OptimizeMNH guidance helped make sure there would be enough substance to develop an evidence brief on the selected topics in each country.

Identifying the venue for the evidence brief

The workbook currently mentions that a venue for decision-making should first be identified, which helps determine the audience, format, and language for presenting the information found through the process of developing an evidence brief. It was found that this step was discrete, yet iterative, in relation to selecting the topic and other aspects of developing the evidence brief. For example, deciding whether the target venue was at the national or a subnational level was discussed for both countries, following the suggestions of the workbook. The venue turned out to be different based on the contextual factors of each country. Determining the venue was important for deciding who to involve in the process (e.g., working group in Uganda) and the context used for clarifying the problem, framing the options and identifying implementation considerations, including consideration of health system and political system contextual factors.

The venue for Peru was chosen as the health authority at the regional level (Loreto) and for Uganda it was the Ministry of Health at the national level. Several factors were considered in selecting the venue for each country: 1) the level of government responsible for health policy and/or implementation, 2) the government's commitment to evidence-informed policymaking, 3) established professional connections, 4) types of research evidence available within the country (national vs. regional level data), and 5) other considerations such as prior laws or the level of authority for regulations and training of health workers.

Even though the government of Peru delegates its authority for policymaking on health matters to the Ministry of Health, the regions are responsible for health decisions (e.g., adapting policy to fit its needs, managing funds and services, etc.). There were also many changes in leadership within the Ministry during the development of the evidence brief, and it was unclear how much interest there would be at the national level for the use of evidence for informing policy. And, even though the Secretariat had to wait for the Ministry of Health to establish formal connections with health officials in Loreto, a member of the Secretariat had worked with health officials in Loreto on other topics and knew they were interested in the use of evidence. In addition, regional-level evidence showed Loreto to be an area of high need. Finally, previous national legislation established what roles health workers played in family planning in Peru (although this had not been fully implemented across the country), but regions were responsible for overseeing the delivery of services (41). For all of these reasons, the venue was selected as the health authority at the regional level of Loreto, Peru.

In Uganda, the Ministry of Health works with many stakeholders to develop health policy, but this still needs the approval of Cabinet. The national government had also shown a clear interest in evidence-informed policymaking through its support of their EVIPNet team, a rapid response system, and more recently, the Africa Centre for Systematic Reviews and Knowledge Translation. There were already established professional connections between the EVIPNet

team and the Ministry of Health through prior work. In addition, there was not enough evidence at the district level reported in national surveys to justify choosing one district over another in terms of determining specific districts of high need, and regulation and accreditation for training of health cadres was done at the national level. For all of these reasons, the venue for Uganda was chosen as the national Ministry of Health.

Using the workbook to develop the evidence brief

Clarifying the problem

The workbook follows a stepwise process to help guide development of evidence briefs. The first step in the process involves clarifying the problem. In this step, it was found that using the OptimizeMNH guidance and the workbook helped to do this in the following ways. First, WHO had already narrowed the topic, found the evidence, and made recommendations in the OptimizeMNH guidance. Second, the questions in the workbook helped the users define the problem and its causes by breaking down considerations for what could be contributing to the problem for a particular setting, by prompting the user to consider how the problem came to attention, what indicators could be used and what comparisons could be made in order to establish the magnitude of the problem, and how the problem could be framed to motivate various groups. Third, the workbook provided examples of how the OptimizeMNH guidance could be used to help answer these questions. It was also found that using the workbook helped identify gaps in policy and in the evidence. For example, even though

Uganda had many past policies on improving access to maternal and newborn health interventions, most had not been fully implemented. In addition, it was found that working with a team helped frame the problem. For example, in Peru, country experts knew that framing the topic in line with the MDGs was not as useful as framing it within country goals for Peru because of the importance of aligning the definition of the problem with the priorities of the Ministry of Health.

“The guidance is geared towards the MDGs but these are up next year, but the relevance is not in the MDGs, but the relevance of family planning falls within an objective of a national health strategy that extends until 2020, so within that framing it remains very important” (Member of Secretariat in Peru, Interview 2-01)

Framing the policy options

The second step in the workbook is to frame the policy options. The discussion above around determining available health cadres in each country, which drew from prompts in step 1, also helped identify an appropriate set of preliminary options. To summarize, after it was determined which cadres were available in each country, through discussions with participants (i.e., country experts) at various meetings, each applicable recommendation was then worked through to see if the cadre was performing the specific intervention. If not, and the OptimizeMNH guidance suggested it could be safe to do so, then the Secretariat discussed what it would take to be able to have the cadre provide that intervention and what supports would be needed to do so. In addition, the workbook asked users to address potential benefits, harms and costs associated with each possible option.

Peru developed 3 possible policy options and Uganda developed 5 policy options for their draft documents. The preliminary options are listed here, but it is important to point out that neither government has endorsed any of these options at the time of this writing. As discussed previously, developing policy is complex and the policy dialogues, which could further shape these options and are outside of the realm of the workbook, have not yet taken place in either country.

Preliminary options for Peru included: 1) Conduct an assessment to identify actual and potential users of family planning methods, and to determine which health centres would be best placed to deliver services to these users, 2) Implement the use of a text message based reminder system for users of family planning methods, and 3) Optimize the roles of available health workers in order to increase access to family planning methods. Preliminary options for Uganda included: 1) Strengthen the community health worker cadre with a long-term plan for training, regulation and other supports; 2) Have nurses insert and remove IUDs and contraceptive implants; 3) Allow for midwives to administer corticosteroids for preterm labour and to perform vacuum extraction; 4) Train and support clinical officers to perform manual removal of placenta; and 5) Provide supports for medical officers having to perform ECV – external cephalic version

Experts who were familiar with the health system were needed for an understanding of the available health cadres and their roles. It was also found that using other sources of information, such as a table from the family planning Ministry directive from 2005 that described which health professionals were

responsible for / able to perform specific family planning interventions in Peru helped shape the policy options in Peru, especially as this also helped point to areas where national policy had not yet been implemented. Considering other factors, such as feasibility, impact of the proposed changes, and scope of the OptimizeMNH guidance, helped determine which options not to develop. One example of this was that in Uganda, aspirin was not routinely being given for women at high risk of preeclampsia / eclampsia as recommended in the OptimizeMNH guidance. However, as all cadres listed in the guidance could have provided aspirin in Uganda, this would be noted in the evidence brief but pursued through different channels in the country (i.e., not through policy change at the Cabinet level). Lastly, conducting key informant interviews with health workers in the country helped verify the options developed by the Secretariat in Uganda. The decision to carry out this step was not linked to the workbook but rather to the will of the Secretariat to ensure its recommendations were accurate and reflected the actual practice of the various health cadres in the country.

Identifying implementation considerations

The workbook asks the users to identify potential barriers to implementation at the healthcare recipient and citizen, healthcare provider, organizational, and system levels, and asks about strategies to overcome these barriers. It was found that discussions at meetings around clarifying the problem and considering the reasons why past policies had not been implemented helped identify implementation considerations. In addition, brainstorming while

developing the policy options, and using the OptimizeMNH guidance and other research evidence helped identify further implementation considerations. For example, the OptimizeMNH guidance provided general implementation considerations that had been found through the development of the recommendations, and targeted searches helped find cadre-specific or country-specific barriers and other considerations.

Identifying equity considerations

Questions surrounding issues of equity are asked at the end of steps 1, 2 and 3 in the workbook as they relate to clarifying the problem, framing the options and identifying implementation considerations. Because of the venue and topic selection process, equity was a focus in Peru throughout the development of the evidence brief by bringing attention to an area of high need, which was revealed through local data. Further equity considerations within Loreto would be expected to come out through meetings with health officials in Loreto. In Uganda, the topic was more general and equity considerations were specifically addressed by the workbook (which may have been missed without these prompts) and by the terms of reference. Brainstorming and using evidence helped identify high-risk groups in Uganda. These high-risk groups included: rural or remote, poor / urban poor, HIV positive, refugee / internally displaced, and incarcerated women.

Considering the broader health system context

The workbook prompts users to consider health system factors, including delivery, financial and governance arrangements. In addition, specific

considerations are provided for each health system arrangement. Several participants noted that these aspects of the workbook were very helpful and made it easy to understand, even for users without a health systems background. Generally, discussions of the health system context during meetings helped in: 1) determining the policy venue for the work, 2) developing the options, and 3) identifying implementation considerations. One example of this was that in Uganda, discussions around delivery arrangements included what facilities were located where (e.g., health centre II vs. hospitals) and who staffed these facilities. These discussions were especially helpful in focusing the options on where health professionals would be practicing on their own, and therefore where these intervention / cadre combinations were most needed. In addition, barriers at these levels were discussed. For example, even though every person in Uganda should live within about 5 km to a health centre II, there is variability in distance to and staffing of these health centres (39). In addition, non-existent or poor roads could make even 5 km for an ill person or a woman in labour an insurmountable barrier.

Considering the broader political system context

The workbook also provides political system factors, including institutions, interests, ideas and external factors, and it breaks down components of each one. Again, this was seen as helpful by the participants in that people without health systems and policy backgrounds would be able to understand the terms used. Discussions of the political system context during meetings, helped: 1) frame the problem, 2) develop the options, and 3) identify implementation

considerations. In Peru, during the development of the evidence brief, there was a high rate of turnover in administration within the Ministry of Health and in other departments, in Loreto, and elsewhere. These transitions made this part of the assessment difficult, since it was not known what the changes would mean for the work. In particular it was not known whether the new directors were interested in using research evidence to inform their decisions. However, more stable parts of the political system, such as prominent ideas and beliefs of the government and society, and past policies, played a role in defining the problem. For example, Peru's government was accused of promoting sterilization among the poor in the past, therefore, if options included permanent sterilization, this sensitive issue would have needed to be considered in its implementation. In Uganda, consideration to the political factors was given to each policy option in turn. Both barriers and facilitators to the implementation of each policy option were brought forth through this step. Overall, it was also noted that the role of NGOs and/or donors would need to be taken into consideration in the policy decision-making process in Uganda, as these organizations play a large role in funding and providing services within Uganda.

Refining the statement of the problem, options and implementation considerations in light of health system and political system factors

The workbook provides an area to write down a summary of findings from each of the above steps in order to refine the statement of the problem, options and implementation considerations. In both countries, this occurred in an iterative

manner throughout the process. As one part was developed, another would be modified based on the findings (e.g., problem definition in Peru based on political system considerations). So, this section served as a reminder to review all of the work (i.e., as in a checklist).

Anticipating monitoring and evaluation needs

Questions in step 7 of the workbook include: 1) Is monitoring necessary?; 2) What should be measured?; 3) Should an impact evaluation be conducted?; and 4) How should the impact evaluation be done? Examples are provided of types of results that could be measured and of useful properties of indicators. Monitoring and evaluation (M&E) were not addressed explicitly in Peru in the evidence brief. Monitoring systems were already in place (i.e., national surveys such as ENDES and ENESA). Even though gaps were found, these two national surveys provided much information related to the problem at hand, and they were expected to be conducted on a routine basis. In Uganda, this section was addressed in general terms (e.g. acceptability, effectiveness, numbers performed, etc.) in the terms of reference, where a section for M&E had been included for each option. It is expected that the M&E for each option will be developed further in both countries as more experts provide feedback on the draft documents.

Making national policy recommendations or decisions - developing the evidence brief and planning for a policy dialogue

The workbook does provide information on how to go about developing an evidence brief, planning for a policy dialogue, and engaging the public, where

applicable. Future work involves planning for a policy dialogue and revising the evidence brief in both countries. This section of the workbook was not used because both teams already had experience developing evidence briefs. This section would likely be more helpful for teams that have not produced evidence briefs or conducted policy dialogues in the past. Because of the administrative turnover in Peru and attention to other priorities by the Ministry of Health, the Secretariat is waiting for formal meetings to be set up by the Ministry of Health with health officials in Loreto in order to continue this work. However, the Institute of Health in Peru has budgeted for policy dialogues on this topic for 2015 (personal correspondence with Member of Secretariat in Peru). In Uganda, the draft terms of reference were written and feedback was obtained from the working group. There are plans to write an evidence brief and convene a policy dialogue, however, funding will still need to be obtained to conduct the policy dialogue in Uganda. In addition, involving the public has not been discussed thus far in either country. In Peru, this will likely not occur until health officials in Loreto are involved and their needs and priorities are determined.

Evaluating the process of using the workbook in Peru and Uganda

Seven main benefits, and four main challenges, in the process of using the workbook for developing evidence briefs were expressed by both countries (see table 3). It is important to note, however, that these comments reflect 3 changes to their usual processes of developing evidence briefs: 1) a workbook, which was specific to contextualizing the OptimizeMNH guidance, was provided, 2) two

authors of the workbook (and of this study) provided support throughout the process as participant-observers, and 3) the OptimizeMNH guidance was worked through systematically. According to country experts, it seemed that guideline recommendations from WHO were not generally applied systematically but were used more as reference at the national level and unknown for subnational levels. For example, if a priority topic aligned with a WHO guidance, then the recommendations were used as one input. However, in these cases, each relevant recommendation was worked through, in turn, and the topic of the evidence brief was based on a topic of the OptimizeMNH guidance. One participant speculated that the reason for the guidance being used systematically in this case was due to this being part of a research study and paying more attention to the details of using the workbook. Overall, the users of the workbook seemed pleased with the workbook and the process of using it, and several people in both Peru and Uganda stated they would use (or are already using) the workbook for other projects.

“I am using it. For another evidence brief ...I am using the workbook to help me gather the information I need.” (Member of Secretariat in Peru, Interview 2-01)

“I definitely think so. I mean, if a question came to me I do not know why I would suffer going through the usual stuff that we do, when the workbook is over here, there's no way. (laughter) There's no way.” (Member of Secretariat in Uganda, Interview 2-04)

Benefits

1) The workbook, which was specific for contextualizing the OptimizeMNH guidance and provided examples linking the questions to the guidance, made the process faster and easier when compared with prior processes. Both Peru and

Uganda had followed the SURE guides (or PAHO-equivalent guides for Peru) to develop evidence briefs in the past (11). The workbook and the SURE guides shared some underlying concepts as both were developed from the SUPPORT Tools. However, the SURE guides were general and not made to contextualize specific guidance documents.

“Because you know, with the SURE guides, you have a guide and then you know, it’s like a map ... to navigate your way through a forest – yeah. And with the workbook, I mean there are several roads through the forest, and so you choose depending on which of those would suit you or not, so it makes things a bit easier.” (Member of Secretariat in Uganda, Interview 2-05)

2) The structure of the workbook was seen as systematic, logical and user-friendly. It served as a tool for developing evidence briefs but also as a checklist for evaluating the work.

“...it was a good checklist, and since I did the quality control, I found it was user-friendly to make sure all the steps were followed.” (Member of Secretariat in Peru, Interview 2-02)

“I like the way it is put together; it is systematic and logical. For a person who has used it and even one who hasn’t...” (Member of Secretariat in Uganda, Interview 2-04)

There was a concern, however by one interviewee, that by including so many considerations and having it be so systematic, this might also limit peoples’ thinking about other considerations not listed in the workbook.

3) Examples in the workbook were seen as helpful. However, there was disagreement over whether there was a need for more examples in order to help those in areas with limited data (e.g., countries without a routine national demographic survey) or those who were not trained in health systems and policy.

In particular, the examples of which types of evidence could be used to answer various types of questions (e.g. about the problem) were especially helpful for those with a clinical-epidemiological background who were not as familiar with developing evidence briefs.

4) Prompts for what types of data to use for answering the various questions may have been helpful for highlighting gaps in knowledge and in practice. For example, factors that strongly affected indicators in the data were not reported along with the data. One example is that in Uganda only 38% of urban and 29% of rural births were registered from 2005-2012, which made the Secretariat unsure of how to interpret other findings for Uganda.

“Gaps in knowledge were found in Uganda, with discussion of cadres / interventions / barriers (e.g., where do women die in Uganda and from what?)” (Participant-observation in Uganda, June 13, 2014)

5) Outside of the workbook, country experts were helpful for both content and methods (i.e., evidence briefs). Both countries had a mix of health workers on their teams. Having country experts who understood the medical terminology used in the OptimizeMNH guidance and their respective health systems was helpful to the work as it required knowledge of available cadres and interventions performed by each cadre for developing the options. Having first-hand experience in the health system was also helpful for identifying implementation considerations. At first, this work seemed more difficult for those with only a clinical-epidemiological background, as evidence briefs draw on qualitative as

well as quantitative data, and the questions in the workbook are broader than typical quantitative research questions.

6) Also alongside the workbook itself, outside support was helpful for building capacity and focusing attention on the work. In Peru, outside support helped with the capacity to find evidence and to develop the evidence brief. In Uganda, everyone who worked on this project was volunteering his/her time and had many other priorities. Having outside support helped bring focus to this work.

7) The process of using the workbook helped evaluate the OptimizeMNH guidance and standardize thinking globally. The use and implementation of WHO guidelines are not usually evaluated. This process helped evaluate the guideline itself. Participants felt that the guideline was unclear about what countries could do when their health cadres or recommendations did not align with the information presented. However, even though some of the comments made by participants reflected a sense of what the guidance and the workbook should be able to do, it is important to address the expectations of this work, as neither the guidance nor the workbook could address the specific contexts of each country or region, although consideration could be given to having WHO regional offices and country offices support the development of regional or national guidance, nor direct how the country should or could make necessary changes (e.g., ensure a law is passed to support the changes). Also, there was no glossary to explain the medical terms used. According to participants, working through the guidance

could also be helpful for policymakers to look beyond their context and standardize their thinking with what is happening at a global level.

“...so if you’re talking about lay health workers, what exactly does this mean in your context and also in the outside context...” (Member of Secretariat in Uganda, Interview 2-04)

Challenges

1) The workbook was perceived to be too long and complex. In general, everyone reviewing the workbook stated that the workbook was dense or tedious because of the amount of sections and questions asked in the workbook. However, when asked which sections could be left out to make it shorter, there were no specific areas mentioned. This likely reflects the complexity of contextualizing guidance, as each section of the workbook captures different relevant information.

“The only problem I have with it is it looks quite big. The numbers of things you need to look for, if you’re going to respond to each of those, I don’t know how much time it would take. But the guidance is really good, not so sure which of those you can leave out and which of you can respond to.” (Member of Secretariat in Uganda, Interview 2-04)

2) The workbook had areas of redundancy and overlap, which was highlighted through the reflexive journal. However, because of the complexity of health system issues, this is likely a reality for this type of work. The main thing was not to focus too much on where to place the information, but rather how that information contributed to the topic. One example was that health systems arrangements were addressed in two separate sections, first in clarifying the problem and then again as a stand-alone section. However, the first was to help

define the general problem and to focus on what was contributing to the problem.

The latter was much more focused on the actual policy option to be developed.

3) The workbook had missing components: a glossary of medical terms and a section regarding advocacy considerations. There were medical terms used in the OptimizeMNH guidance which were not described. The interviewees expressed that for non-health workers, it would have been helpful to have a glossary of these terms to provide definitions. However, working with a team involving health workers helped bypass this problem. Also, although costs are addressed in the workbook they may need to come out more explicitly in the evidence brief since policymakers were very interested in cost. In addition, two issues arose through prior work as to points that might be missing in the workbook: advocacy and corruption. Selected interviewees in each country were asked about these elements. There was agreement that advocacy could be addressed in more detail, although it was also expressed that this may not be in the scope of developing an evidence brief. However, interviewees in both countries stated that corruption should not be addressed since Latin America and Africa have high levels of corruption, and it could be counter-productive if policymakers felt singled-out or felt defensive about being labeled as corrupt.

“Corruption, no, especially for Latin America. There is so much corruption, that no, I would not include anything about it. Everyone will be offended, so everyone will think you are talking about them and you would lose a lot of friends...” (Member of Secretariat in Peru, Interview 2-02)

4) The language used in the workbook could be difficult for those without training in health policy and systems to understand. Also, English terms could be difficult for some to understand. For example, there were some English concepts that could not be translated into Spanish or they were not exactly the same when translated. However, those involved in these processes in Peru and Uganda stated they did not have any problems with the language, as they were familiar with knowledge translation processes and had backgrounds in health systems and policy, including work with evidence briefs. In fact, several interviewees felt the workbook was easy to understand and that the terms were described well.

“The health systems jargon and the policy jargon seems to sort of work itself out within the book, and so for instance where they talk about, what example can I give...For instance where they talk about things like how do delivery arrangements, you know? You need to sort of have health systems jargon to have an idea of what that means, but then within the workbook, they actually go ahead and say ... who are you providing for, where are you providing it, you know, the care, or the intervention that you are talking about. Then what support is being provided. That sort of thing. They sort of go ahead to clarify what this is.” (Member of Secretariat in Uganda, Interview 2-04)

Discussion

Principal findings

Overall, the workbook was seen as useful by participants in both countries. Several interviewees stated they would use (or are already using) the workbook for developing other evidence briefs. Seven main benefits and four main challenges (see table 3) were found in the process of using the workbook, keeping in mind that the usual processes were also changed by having outside support and by systematically working through the OptimizeMNH guidance,

which is typically used more generally as a reference, according to several interviewees.

As can be seen, the way the problem and its causes are framed, potential policy options to address the problem and its causes, and implementation considerations for these policy options varied substantially between Peru and Uganda due to their contextual factors. For example, in selecting a topic, the starting point for both countries was the OptimizeMNH guidance, but because of priorities of the Ministry of Health in Peru, the work became narrowed down to specific interventions around family planning, while in Uganda, government priorities allowed for the topic to remain broad enough to consider all the interventions in the guidance. Further, the cadres that were available in each country, and the interventions performed by these cadres, varied significantly. For example, even though Uganda had community health workers, this cadre did not align well with WHO's definition of a lay health worker. Therefore, consideration had to be given as to how this cadre could be supported and strengthened over time. Finally, implementation considerations differed in each country based on epidemiological features (e.g., prevalence of HIV in Uganda), past policies (e.g., sterilizations of the poor in Peru) and other issue- and context-specific factors. This case is one example of how and why contextualization of guidance is important.

Strengths and limitations of the study and relation to other studies

There are six main strengths of this study. First, the use of an embedded case study design, including the use of multiple sources of data, allowed for an in-depth examination of the process of using the workbook and the context surrounding its use, both at an international level (i.e., global guidance around improving access to and use of key interventions to improve maternal and newborn health) and at a national level (e.g. health systems arrangements within each country). Second, studying the process of using the workbook in two countries allowed for comparisons between key findings in these different settings. Third, this was a prospective study, which allowed for events to be followed as they occurred, such as through participant-observation sessions, which would not have been possible within a retrospective study. Fourth, following with the previous point, the roles of the authors as participant-observers added to the richness of the findings in that the researchers had a first-hand account of the process. For example, EA was not only privy to guidance-development processes, but also participated in working through the workbook, which gave the team a greater understanding of facilitators and barriers faced in the process. Fifth, using peer debriefing helped refine the concepts and themes for the workbook and for the process.

Sixth, the reflexive journal helped ensure that the investigator's biases could be reflected on in terms of how this influenced data collection, analysis and interpretation. These biases included that both EA and JL were involved in

developing the workbook and both believe that health systems guidance and the contextualization of guidance recommendations hold promise in helping to strengthen health systems. Furthermore, the use of research evidence to inform policymaking is another value held by both investigators. These beliefs and values could have led to interpreting the data to support the positive aspects of the findings. However, these biases were recognized, and several methods were used to try to mitigate their influence, including asking for feedback on both positive and negative aspects of the workbook during the semi-structured interviews, and using peer review with people who had not been involved in the process of using the workbook. Due to the sampling strategy, which included people who were involved in the use of the workbook, these biases cannot be fully removed as all the participants may hold similar beliefs. At a broader level, it is also important to note these biases and how they may influence initiatives globally.

There is one main challenge of this study, which involves the development processes for evidence briefs, and one noted limitation of the case study methodology, which involves the generalizability of the findings. The main challenge is that the workbook is used for a defined purpose and time in the development of evidence briefs, which means that the rest of the process of convening policy dialogues, developing policy which is informed by the evidence brief and policy dialogue summary (i.e., in the case for Uganda), implementing that policy, and evaluating the impact of the policy on the population's health is outside of the scope of this study. It has been suggested by a participant that there

could be workbooks developed for the purposes of facilitating these other steps in the policymaking and implementation processes. Therefore, how the contextual factors and components of the processes found in this study affect the ultimate policy decisions and their implementation is not known. For example, is it better for a country to have an EVIPNet team with direct organizational ties to the Ministry of Health, such as in Peru, or is it better to have a broader participatory process, such as in Uganda? The implications of this and other differences found need further examination. While some of the findings are transferable to other contexts, one limitation of a case study approach is that findings cannot be generalized from these to other cases, as the context of where and how the work is done may be unique. Therefore, readers would need to consider their own contexts before applying these findings to their settings. For example, if a country does not have an established EVIPNet or similar entity, work may be required to set up connections with policymakers before attempting to use the workbook to develop evidence briefs.

This study builds on the work in the field of clinical guidelines and health systems and policy. Context has been found to be important in developing and implementing guidelines and knowledge translation tools to help bridge the gap between research evidence and its practical use (42,43). Much work has been done in the field of clinical guideline implementation, with many frameworks and tools available to help users (44–51). One example is that specific and actionable recommendations are more likely to be implemented. (48) While WHO produces

general guidance, it is up to each jurisdiction to tailor these recommendations to fit their own needs and realities, which is where the workbook can be used. However, one must also note that the contextualization process is aimed at developing policy or guidance for a national or subnational setting, which still aims to keep the recommendations generic enough to fit multiple settings, such as various clinics or hospitals. Contextualization is one step in the shaping of global recommendations to make them more specific and actionable to these settings, but further work would still be needed in order to implement the recommendations created through national/subnational guidance or policies. Chapter 4 addresses these pathways in more detail. In addition, a study by Gagliardi et al (45) showed that one of the preferred approaches of clinical guideline developers was to include information within the guideline that would help users implement it. That was a feature of the workbook that was also liked by participants in this study, especially when compared to other existing tools, which are more general.

In the field of health systems and policy, the SUPPORT Tools and SURE guides help build on the use of evidence briefs and policy dialogues as tools for evidence-informed policymaking (9,11). The workbook adds to this emerging field by helping users contextualize a specific guidance document to their settings by addressing the health system arrangements and political system considerations in policy development and implementation. It was found through this study that having a workbook may support groups or build capacity by systematically presenting considerations to many factors in the contextualization process and

what types of evidence could be sought to help answer particular questions.

However, this process is also complex, and there is a concern that it could potentially be seen as too prescriptive. In addition, as pointed out previously, the link between these contextual factors and health outcomes are yet to be determined.

Implications for policy and practice

There are five implications for policy and practice that were found through this study. First, the workbook was seen as helpful for contextualizing global guidance in two, quite different, settings. The participants in both of these countries felt this workbook made the process easier even though they had done prior work with evidence briefs. Therefore, organizations which produce global guidance, such as WHO, need to consider institutionalizing the development of workbooks (or other tools) into their guidance development processes to help users at the national / subnational level contextualize each guidance document. Second, as noted previously, it is important for countries (or subnational health authorities, such as provinces in a decentralized system) looking to use this workbook to consider their own contexts first (e.g., having an established EVIPNet or equivalent forum to support evidence-informed policymaking). Third, having a team of country experts who understood the health system and the priorities of the government or Ministry of Health was helpful at multiple steps of the process. It seems this would be an important consideration for countries that are looking to establish an EVIPNet or that have not already incorporated these

country experts into their current processes. Fourth, related to the prior point and as can be seen through the findings, contextualizing health systems guidance is a time- and resource-intensive process. There are multiple steps in the process and many elements need to be considered. While the workbook may simplify this process by providing a systematic tool, it cannot replace the work required by a team of methods and content experts, and support for this work needs to be secured at the national / subnational level. Fifth, many low-and middle-income countries have little capacity for local health and political system analysis, for linking research to problems, options and implementation considerations, and for embedding this work into their policymaking processes. WHO and partner organizations may have a role to play in helping countries build this capacity.

Implications for research

There are three implications for research that were found through this study. First, as mentioned above, how the contextual factors and components of the processes found in this study affect the ultimate policy decisions and their implementation is not known. Chapter 4 lays the foundation for studying what and how contextual factors might affect the contextualization process and implementation of global guidance recommendations. However, empirically testing these assumptions by analyzing these various stages will be helpful for understanding the implications of the factors. Setting up an inventory of briefs and policies arising from global guidance may also be useful in this endeavor. Second, the process of using the workbook helped evaluate the OptimizeMNH

guidance as well as helped find gaps in data. Feedback mechanisms need to be established so that these findings can be taken into consideration during guidance development and during research priority-setting processes. With the outcome of strengthening health systems in mind, it is important to have these feedback loops in order to improve these processes by understanding the needs of those using the guidance. Establishing and evaluating possible feedback mechanisms could be a fruitful area of study. Third and last, evaluating how the workbook was used in this process provided feedback on the workbook itself and ways to improve it. See chapter 5. Further empirical work testing the workbook would help tailor this tool for its use in various settings and for different topics.

Acknowledgements

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Figure 1. Timeline of events in the process of using the workbook for contextualizing health systems guidance recommendations in Peru and Uganda

Peru	2012	Uganda
Development of workbook	April - November	Same as Peru
Discussions around evaluating the use of the workbook in 2-3 countries		
Workbook published online with WHO OptimizeMNH guidance	December	Same as Peru
HIREB ethics approval obtained / initial contact with country / approval from National Institute of Health & Ministry of Health to move forward with study	2013 March - April	HIREB ethics approval obtained / initial contact with country / preliminary approval from REACH/SURE team to move forward with study
Work started on evidence brief with 1 st topic of institutional delivery (venue, problem definition) / awaiting meeting with Ministry to clarify problem	May - July	Discussions with team in Uganda regarding purpose of work, make-up and roles of Secretariat, timelines, and structure of terms of reference
Main author of evidence brief off for maternity leave	August - September	
	October	Final approval received from REACH/SURE team
Awaiting meeting with Ministry to review work	November December	Discussions around topic selection, potential working group members and ways to reach them, preparation for fieldwork, background research, and ethics application
	2014	
Meeting with Ministry to review work – new directors at the Ministry with different priorities	January - February	
Formal document from Ministry with priority topics	March	
Developed evidence brief (all sections) with 2 nd topic of access to and use of modern contraceptives in Loreto, Peru	April	SOM-REC ethics approval obtained
	May	Preparation for fieldwork
	June	Fieldwork (2 weeks) – drafted terms of reference (all sections), met with working group
Draft evidence brief completed	July	
Feedback from Secretariat obtained and evidence brief revised	August - September	Feedback from working group obtained / Research assistant hired
	October	Report submitted by research assistant
Waiting for Ministry to formally connect the Secretariat with health officials in Loreto	November December	Further discussions around evidence brief and policy dialogue

HIREB - Hamilton Integrated Research Ethics Board, Hamilton, Ontario, Canada

REACH - Region of East Africa Community Health Policy Initiative

SOM-REC - School of Medicine Research and Ethics Committee, Makerere University College of Health Sciences, Kampala, Uganda

SURE – Supporting the use of research evidence for policy in African health systems, a collaborative project involving researchers and policymakers in seven African countries, lasting 5 years. SURE was funded by the European Commission's 7th Framework Programme and was supported by research teams in Europe and Canada

WHO – World Health Organization

Table 1. Health care cadres addressed by WHO’s OptimizeMNH guidance and their equivalents in Peru and Uganda

Health care cadres – WHO	Peru	Uganda
Non-specialist doctor	Médicos cirujanos generales (general surgeons) Médicos de familia (family doctors) Medico general no calificado en AQV (Anticoncepción Quirúrgica Voluntaria) (general doctor not certified in voluntary surgical contraception, or sterilization and vasectomy) Médicos calificados en provision de anticonceptivos incluido AQV (doctors certified in the provision of contraceptives including voluntary surgical contraception, or sterilization and vasectomy)	Medical officer
Advanced level associate clinician	Does not exist in Peru	Does not exist in Uganda
Associate clinician	Does not exist in Peru	Clinical officer
Midwife	Midwife (Obstetriz)	Midwife; there is some cross over with nurses (see below). They have 2 levels – enrolled and registered (see below)
Nurse	Nurse (Enfermero(a))	Have 2 main levels of nurses: - enrolled nurses - certificate - registered nurses - diploma (more training than enrolled nurses). Other levels: - nurses with bachelors degree - “comprehensive” or “double-trained” nurse with training in both nursing and midwifery
Auxiliary nurse	Nurse technician (Técnico de enfermería)	Uganda used to have nurse assistants, but they are no longer being trained or recruited. They still exist but are no longer officially recognized. It would take time to train this cadre again as training programs have stopped.
Auxiliary nurse midwife	Does not exist in Peru	Uganda used to have this cadre as part of the auxiliary nursing group but they are no longer recognized.
Lay health worker (LHW)	Health promoter (Promotores de salud)	Community health worker (CHW). However, in Uganda, CHWs tend to be volunteers in the community and may not have any health training or be literate.

Table 2. Main findings in the process of using the workbook to develop an evidence brief in Peru and terms of reference in Uganda

Key steps in the process	Main findings
Using the workbook in the process	<ul style="list-style-type: none"> - Used as a methodology for developing evidence briefs - Used to refine the template for the terms of reference in Uganda - Used to develop the timeline in Uganda
Selecting the topic Peru - Increasing access to modern family planning methods in Loreto, Peru Uganda - Optimizing health workers' roles to increase access to and use of key interventions to improve maternal and newborn health	The workbook did not explicitly address selecting the topic Factors used in selecting the topic: <ul style="list-style-type: none"> - Alignment with priorities of the government / Ministry of Health - Alignment with the OptimizeMNH guidance - Consideration of priority regions / populations - Preliminary consideration of OptimizeMNH recommendations
Identifying the venue for the evidence brief Peru – Health officials at the regional level – Loreto, Peru Uganda – National Ministry of Health	The workbook prompted users to consider the venue to identify the target audience, format and language for the evidence brief Factors considered in selecting the venue: <ul style="list-style-type: none"> - Level of government responsible for health policy and/or implementation - Government's commitment to evidence-informed policymaking - Professional connections - Type of research evidence available within the country - Other considerations, such as prior laws or level of authority for regulations around the training of health workers
Clarifying the problem	<ul style="list-style-type: none"> - Using the OptimizeMNH guidance and the workbook helped clarify the problem - Using the workbook helped identify gaps in policy - Using the workbook helped identify gaps in data - Working with a team helped frame the problem
Framing the policy options Peru: 3 preliminary options Uganda: 5 preliminary options	<ul style="list-style-type: none"> - Working through the prompts provided in the workbook and the cadre equivalents and interventions in the OptimizeMNH guidance with health experts from the country helped develop the policy options - Using other sources of information helped shape the policy options in Peru - Considering other factors, such as feasibility, impact, and scope of the OptimizeMNH guidance, helped determine which options not to develop - Performing key informant interviews with health care cadres in Uganda helped verify the options developed by the Secretariat
Identifying implementation considerations	<ul style="list-style-type: none"> - Clarifying the problem and considering the reasons why past policies had not been implemented, which were prompted by the workbook, helped identify implementation considerations - Brainstorming while developing policy options also helped identify implementation considerations - Using the OptimizeMNH guidance and other sources of evidence helped identify further implementation considerations
Identifying equity considerations	Prompts in the workbook, brainstorming, and using local evidence helped identify high-risk groups
Considering the broader health system context	The workbook provided a framework for the health system context, including governance, financial and delivery arrangements. Discussing the health system context helped to: <ul style="list-style-type: none"> - determine the policy venue for the work - develop the options - identify implementation considerations
Considering the broader political system context	The workbook provided a framework for the political system context, including institutions, interests, ideas and external factors. Discussing the political system context helped to: <ul style="list-style-type: none"> - frame the problem - develop the options

	- identify implementation considerations
Refining the statement of the problem, options and implementation considerations in light of health system and political system factors	Using this section helped serve as a reminder to review all of the work (i.e., as in a checklist) to make sure details were not missed, since refining the statement of the problem, options and implementation considerations occurred iteratively throughout the work in both countries.
Anticipating monitoring and evaluation needs	The workbook addresses considerations for monitoring and evaluation (M&E) and provides examples of measurable results and possible indicators for M&E. These needs varied in each country depending on available sources of evidence and having a structured template for the terms of reference. It is expected that the M&E for each option will be developed further as more experts provide feedback on their respective draft evidence brief.
Making national policy recommendations or decisions - developing the evidence brief, planning for a policy dialogue, and engaging the public	These processes are discussed in the workbook. However, as both countries had developed evidence briefs in the past, this section was not used. Although this section could be helpful for people not as familiar with these processes. Engaging the public has not been discussed in either country yet, but this may still occur based on the country's processes.

Table 3. Evaluating the process of using the workbook in Peru and Uganda

<p>Evaluating the process of using the workbook: Main findings</p> <p>Overall, these findings reflect 3 changes in the process of developing evidence briefs:</p> <ol style="list-style-type: none"> 1) A workbook, which was specific to contextualizing the OptimizeMNH guidance, was provided. 2) Two authors from Canada provided support throughout the process. 3) Each relevant recommendation from the OptimizeMNH guidance was worked through systematically for developing policy options for the evidence briefs, which according to country experts, is not how guidelines are typically used, and are instead used more generally as a reference.
+ Participants in both countries plan on using or are already using the workbook for other, unrelated, work.
+ The workbook, which was specific for contextualizing the OptimizeMNH guidance, made the process faster and easier when compared with prior processes.
+ The workbook was systematic, logical, and user-friendly. It served as a tool for developing evidence briefs but also as a checklist for evaluating the work. There was a concern raised, however, that because it is so systematic, it could also limit peoples' thinking about the problem or how to address it.
+ Examples in the workbook were seen as helpful, however, there was disagreement over whether there was a need for more examples to help those in areas with limited data or those who were not trained in health policy and systems.
+ Country experts were helpful for both content and methods (i.e., evidence briefs).
+ Outside support was helpful for building capacity and focusing attention on the work.
+ The process of using the workbook helped find gaps in knowledge and in practice.
+ The process of using the workbook helped evaluate the OptimizeMNH guidance and standardize thinking globally. Even though some of the comments made by participants reflected a sense of what the guidance and the workbook should be able to do, it is important to address the expectations of this work, as neither the guidance nor the workbook could address the specific contexts of each country or region (although consideration could be given to having WHO regional offices and country offices support the development of regional or national guidance) nor direct how the country should or could make necessary changes (e.g., ensure a law is passed to support the changes) nor replace the tacit knowledge of people at the country level.
- The workbook was too long and complex. In general, everyone reviewing the workbook stated that it is too dense or tedious because of the amount of sections and questions asked in the workbook. However, when asked which sections could be left out to make it shorter, there were no specific areas mentioned.
- The workbook had areas of redundancy and overlap
- The workbook had missing components: glossary of medical terms, advocacy Also, although costs are addressed in the workbook they may need to come out more explicitly in the evidence brief since policymakers are very interested in cost.
- The language used in the workbook could be difficult for those without training in health policy and systems to understand. Also, English terms could be difficult for some to understand. This was not the case for those involved in these processes in Peru and Uganda because they had the appropriate training, but they felt others may have difficulty with the language. On the other hand, several interviewees felt the workbook was easy to understand and that the terms were described well.

Appendix 1. Participant-observation guide

Participant-observation guide – February 19, 2014

Date _____
 Location _____ Researcher _____
 Start time _____ End time _____ Date of informed consent _____
 OK to record: Y / N
 Participant's name(s) and positions _____
 Participant's name(s) and positions _____
 Participant's name(s) and positions _____
 Participant's name(s) and positions _____
 Participant's name(s) and positions _____
 Participant's name(s) and positions _____

Observations: who, what, when, why	Other information/ thoughts: layout of room, tone of voices, questions that arise, etc.
Time:	

Appendix 2. Semi-structured interview guide

Semi-structured interview guide (15-45 minutes) – February 19, 2014

Participant ID _____ Date _____
Location _____ Researcher _____
Start time _____ End time _____ Date of informed consent _____
OK to record: Y / N

-Thank you for agreeing to be part of this study. Have you had a chance to look over the interview questions that I sent you beforehand? I will first ask you some broad questions, and at the end, I will ask you some personal questions to help understand the context of this work-

Semi-structured interview questions

1) What is/was your role with regards to the use of the workbook for health systems guidance?

Probes – researcher, policymaker, stakeholder; active involvement; decision for use of the workbook

2) Can you describe the process of using the workbook?

Probes – Who was involved? Where did the work take place? How was it arranged? What information was used?
Need for the workbook – discussions, rationale

3) Overall what was your impression of using the workbook to develop policy recommendations or policy decisions?

4) What were the most useful components of the workbook?

5) What components would you change and why?

6) Was there “buy-in” from policymakers and stakeholders for the use of this workbook/ contextualization process? Was there personal buy-in from yourself?

Probes – Did people feel it would be useful and were willing to use the workbook or was there push-back

7) Are you and others who used the workbook familiar with efforts to support evidence-informed policymaking?

Probes – Knowledge transfer and exchange, working with researchers/policymakers

8) How were people selected to work on this project? Did you feel there was diversity within the group using this workbook?

Probes – Position, knowledge; researchers, policymakers, stakeholders

9) Were any high-level officials involved in the process of using the workbook, and if so, did you feel that helped or hindered the process?

Probes – Trying to satisfy high-level official and not being able to share own views; improved buy-in

10) How much time was dedicated for the process of using this workbook to develop policy recommendations or policy decisions? Do you feel this was sufficient time?

Probes – Concentrated effort with dedicated time vs. piecemeal

11) Is there any other information you feel I have left out which you would like to tell me about regarding the workbook for health systems guidance?

- Before ending this interview, I need to gather some personal data for contextual factors -

Demographic information

Age_____ Gender: F / M Country_____

Current professional designation_____ Length of time at current position _____

Other professional designation(s)_____

Other professional designation(s)_____

Thank you for your time. Is it ok to contact you again if I need any clarifications or have other questions? Thanks again!

OK to contact for further interview: Y / N

Appendix 3. Informed consent form for participant-observations



Participant-observation letter of information/consent

Title of study: Examining the process of using a health systems guidance workbook to support the contextualization of the World Health Organization's 'Optimizing the delivery of key interventions to attain Millennium Development Goals 4 and 5' (OptimizeMNH) guidance at the national or subnational level

Principal investigator: Elizabeth Alvarez, MD, MPH, PhD (Candidate)

Co-investigator(s): John N. Lavis, MD, PhD

Funding sources: International Development Research Centre (IDRC)
International Research Chair in Evidence-Informed Health Policies and Systems

Government of Canada: Vanier Canada Graduate Scholarship

You are being invited to participate in a research study. The purpose of the study is to understand the process of using a workbook for the contextualization of the WHO's 'Optimizing the delivery of key interventions to attain Millennium Development Goals 4 & 5' (OptimizeMNH) guidance to help with policy development and implementation at the national or subnational level. Specifically, you are being asked to allow a researcher to observe and/or participate in a guidance or policy-making session in which the individual will observe and record events surrounding the use of the workbook in the process of developing policy recommendations or policy decisions. This is a student research project conducted under the supervision of Dr. Lavis. The study will help the student learn more about the topic area and develop skill in research design, collection and analysis of data, and writing a research paper.

Your participation in this research study is voluntary. You may refuse to participate in the research study and you may choose to withdraw from the study at any time. We cannot promise any personal benefits to you from your participation in this study. However, a possible benefit includes helping improve global efforts to support the use of global guidance recommendations to strengthen health systems.

Any information gathered from the session or in the form of documents that are not in the public domain will be treated as confidential. With your permission, the session will be audio-recorded and transcribed and personal identifiers will be assigned to each digital file and transcript by us. If you or other session participants do not provide your consent, the segments of the audio-recordings that involve you speaking will be deleted, not transcribed and not used as part of the study. We will ensure that the transcript and any confidential documents are kept in a locked

cabinet, the digital files containing the audio-recordings and transcripts are stored on a security protected computer, and the digital files, transcript and confidential documents are destroyed 10 years after the last publication of our findings. We will make the summary of our findings publicly available for use by others interested in improving their efforts to support policy development using global guidance in health systems policymaking.

Your anonymity as a research study participant will be safeguarded. We will ensure that the list of study participants and their participant numbers will be stored in a different locked cabinet or security protected computer from those where the digital files, transcripts and confidential documents are stored. Every effort will be made to report information in a way which will not identify individual respondents or departments; however, there is a slight chance that someone may be recognizable by his/her role or comments.

Please check yes or no to the questions below to indicate whether you consent to participate in our study and, if so, whether you are willing to have your name and position appear in the study acknowledgements and whether you would like to review and comment on the draft case report. We would be pleased to provide you with additional information about our study and your potential participation. For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Integrated Research Ethics Board may consult your research data. However, no records which identify you – be it name or initials will be allowed to leave the university. By signing this consent form, you authorize such access.

Request for consent	Yes	No
1. I am willing to partake in this training session or allow one person to observe and/or participate in a policymaking session as part of this study.		
2. I am willing to have the session audio-recorded.		
3. I am willing to have my name and position appear on the study acknowledgement list as one of the respondents.		
4. I would like to review and comment upon the draft case report.		
5. Please contact me. I would like additional information about the study and/or my participation.		

I will receive a signed copy of this form.

Participant

Print name: _____ Signature: _____

Date: _____

Person obtaining consent

Print name: _____ Signature: _____

Date: _____

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB), and the research ethics board in (insert name of country here). The HIREB is responsible for ensuring that

participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call The Office of the Chair, HIREB at +1-905-521-2100 x 42013 or (insert contact information for country REB here).

Sincerely,

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Appendix 4. Informed consent form for interviews



Interview - Letter of information / consent

Title of study: Examining the process of using a health systems guidance workbook to support the contextualization of the World Health Organization's 'Optimizing the delivery of key interventions to attain Millennium Development Goals 4 and 5' (OptimizeMNH) guidance at the national or subnational level

Principal investigator: Elizabeth Alvarez, MD, MPH, PhD (Candidate)

Co-investigator(s): John N. Lavis, MD, PhD

Funding sources: International Development Research Centre (IDRC)
International Research Chair in Evidence-Informed Health Policies and Systems

Government of Canada: Vanier Canada Graduate Scholarship

You are being invited to participate in a research study. The purpose of the study is to understand the process of using a workbook for the contextualization of the WHO's 'Optimizing the delivery of key interventions to attain Millennium Development Goals 4 & 5' (OptimizeMNH) guidance to help with policy development and implementation at the national or subnational level. Specifically, you are being invited to participate in an interview about the process around the use of this workbook and your role in this process. Your involvement would mean participating in a 45-minute (approximately) semi-structured telephone or in-person interview to be scheduled at your convenience. During the interview, I will ask you questions about your role in the process of using the workbook, the process itself, and specific questions about how factors surrounding the use of the workbook might help or hinder its usefulness (e.g. the mix of people using the workbook to develop policy recommendations or policy decisions in your country). This is a student research project conducted under the supervision of Dr. Lavis. The study will help the student learn more about the topic area and develop skill in research design, collection and analysis of data, and writing a research paper.

Your participation in this research study is voluntary. You may refuse to participate in the research study and you may choose to withdraw from the study at any time. We cannot promise any personal benefits to you from your participation in this study. However, a possible benefit includes helping improve global efforts to support the use of global guidance recommendations to strengthen health systems.

Your interview and any information provided in the form of documents that are not in the public domain will be treated as confidential. With your permission, the interview(s) will be audio-

recorded and transcribed and personal identifiers will be assigned to each digital file and transcript by us. We will ensure that the transcript and any confidential documents are kept in a locked cabinet, the digital files containing the audio-recordings and transcripts are stored on a security protected computer, and the digital files, transcript and confidential documents are destroyed 10 years after the last publication of our findings. We will make the summary of our findings publicly available for use by others interested in improving their efforts to support policy development using global guidance in health systems policymaking.

Your anonymity as a research study participant will be safeguarded. We will ensure that the list of study participants and their participant numbers will be stored in a different locked cabinet or security protected computer from those where the digital files, transcripts and confidential documents are stored. Every effort will be made to report information in a way which will not identify individual respondents or departments; however, there is a slight chance that someone may be recognizable by his/her role or comments.

Please check yes or no to the questions below to indicate whether you consent to participate in our study and, if so, whether you are willing to have your name and position appear in the study acknowledgements and whether you would like to review and comment on the draft case report. We would be pleased to provide you with additional information about our study and your potential participation. For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Integrated Research Ethics Board may consult your research data. However, no records which identify you – be it name or initials will be allowed to leave the university. By signing this consent form, you authorize such access.

Request for consent	Yes	No
1. I am willing to participate in a 45-minute (approximately) in-person or telephone interview to be scheduled at my convenience.		
2. I am willing to have the interview audio-recorded		
3. I am willing to have my name and position appear on the study acknowledgement list as one of the respondents.		
4. I would like to review and comment upon the draft case report.		
5. Please contact me. I would like additional information about the study and/or my participation.		

I will receive a signed copy of this form.

Participant

Print name: _____ Signature: _____

Date: _____

Person obtaining consent

Print name: _____ Signature: _____

Date: _____

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB) and the ethics review board in (insert name of country here). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call The Office of the Chair, HIREB at +1-905-521-2100 x 42013.
Sincerely

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Appendix 5. Documents reviewed for the study

Date(s)	Document Title	Document Type	Source	Author
Revised 2001	Health services system profile of Peru	Document	Internet search	PAHO
2005	Norma técnica de planificación familiar	Document	Personal email	MINSA
2009	Uganda's health care system explained	Document	Internet search	Kavuma
2010	An evidence-based policy brief: Task shifting to optimise the roles of health workers to improve the delivery of maternal and child healthcare	Document	Personal email	Nabudere, Asiimwe & Mijumbi
2011 (Updated)	SURE guides for preparing and using evidence-based evidence briefs	Website	Interviewee	WHO / SURE
2012	OptimizeMNH: Optimizing health worker roles to improve access to key maternal and newborn health interventions through task shifting	Document	Interviewee	WHO
2012	Annex 8. Contextualizing the guidelines - workbook	Document	Principal investigator, online search	WHO
2012	Encuesta a Establecimientos de Salud con Funciones Obstétricas y Neonatales. ENESA 2009-2012	Document	Personal email	Instituto Nacional de Estadística e Informática
2012	Encuesta Demográfica y de Salud Familiar – ENDES	Document	Personal email	Instituto Nacional de Estadística e Informática
2012	Uganda Health System Assessment	Document	Internet search	Ministry of Health, Health Systems 20/20, & Makerere School of Public Health
2012	Uganda Demographic and Health Survey	Document	Internet search	Uganda Bureau of Statistics (UBOS) and ICF International Inc.
2013, Jun	Nota técnica (Peru) – Interventions to increase institutional delivery through optimizing health worker roles following WHO's 2012 recommendations (Intervenciones dirigidas a fortalecer el acceso al parto institucional a través de la optimización de las funciones del trabajador de salud empleando la guía de recomendaciones de la Organización mundial de la Salud de 2012) Only final draft listed, but multiple earlier drafts and parts of drafts reviewed	Document	Personal email	Secretariat for evidence brief in Peru
2013	UNICEF – Statistics, Peru	Website	Internet search	Unicef
2013	UNICEF – Statistics, Uganda	Website	Internet search	Unicef
2014	WHO - Peru	Website	Internet search	WHO

2014	WHO - Uganda	Website	Internet search	WHO
2014	Policy briefs - SURE	Website	Internet search	WHO
n.d.	The world factbook - Peru	Website	Internet search	CIA
n.d.	The world factbook - Uganda	Website	Internet search	CIA
2014, Mar 13	Letter from Peru's Ministry of Health (MINSA) to Peru's National Institute of Health (INS) on priorities	Document	Personal email	MINSA
2014, May 28	Feedback on draft evidence brief	Document	Personal files	Principal investigator
2013, Apr	Health in the Americas – Peru	Website	Internet search	PAHO
2014, Jun 18	Cover letter for working group meeting (Uganda)	Document	Personal files	Secretariat for evidence brief in Uganda
2014, Jun 18	Agenda for working group meeting (Uganda)	Document	Personal files	Secretariat for evidence brief in Uganda
2014, Jun 18	Power point presentation for working group meeting (Uganda)	Document	Personal files	Secretariat for evidence brief in Uganda
2014, Jun 18	Terms of reference for evidence brief in Uganda (Uganda) - Working paper – most updated draft listed, but multiple earlier drafts and parts of drafts reviewed	Document	Personal files	Secretariat for evidence brief in Uganda
2014, Jul 8	Timeline for work in Uganda - Working paper – most updated draft listed, but multiple earlier drafts and parts of drafts reviewed	Document	Personal files	Secretariat for evidence brief in Uganda
2014, Jul 18	Nota técnica (Peru) – Interventions to decrease barriers in accessing modern family planning methods at the regional level (Intervenciones dirigidas para disminuir las limitaciones de acceso a métodos modernos de planificación familiar a nivel regional) - Working paper – most updated draft listed, but multiple earlier drafts and parts of drafts reviewed	Document	Personal email	Secretariat for evidence brief in Peru
2014, Aug 20	Letter of information for health workers (Uganda)	Document	Personal files	Secretariat for evidence brief in Uganda
2014, Oct 20	Report from health centres (Uganda)	Document	Personal email	Research Assistant
2015	Evidence briefs / issue briefs	Website	Internet search	McMaster Health Forum
2014, May 2 2014, May 28 2014, Jun 20 2014, Jul 30	Meeting notes / Participant-observations – Peru – multiple: Gmail chat transcription with Secretariat Skype meeting with Secretariat Gmail chat transcription with Secretariat Skype meeting with Secretariat	Documents	Participant-observations	Principal investigator / Secretariat for evidence brief in Peru

2013, Oct 24 2013, Dec 19 2014, Apr 30 2014, May 8 2014, May 15 2014, Jun 10 2014, Jun 13 2014, Jun 16 2014, Jun 18 2014, Jun 19 2014, Jun 20 2014, Jul 8 2014, Aug 1 2014, Aug 13 2014, Nov 5	Meeting notes / Participant-observations – Uganda – multiple: Skype meeting with contact in Uganda Notes from meeting of Uganda team Skype meeting with Secretariat Skype meeting with Secretariat Skype meeting with Secretariat Guidance development session Guidance development session Guidance development session Guidance development session Guidance development session Guidance development session Skype meeting with Secretariat Skype meeting with Secretariat Skype meeting with Secretariat Skype meeting with Secretariat	Documents	Participant-observations	Principal investigator / Secretariat for evidence brief in Uganda
2012, Mar 3 – 2013, Nov 19	Reflexive Journal I (Workbook)	Reflexive Journal – 195 pgs,	Principal investigator	Principal investigator
2013, Nov 20 – 2014, Jun	Reflexive Journal II (Workbook)	Reflexive Journal – 127 pgs	Principal investigator	Principal investigator
2014, June 5 – 2015, Jan 23 (ongoing)	Reflexive Journal III (Workbook)	Reflexive Journal – 93 pgs	Principal investigator	Principal investigator
2012-2014		Personal correspondence	Personal emails	Multiple

Does not include documents reviewed for developing the evidence brief in Peru or terms of reference in Uganda

Appendix 6. Select demographic, social, economic, epidemiological, and health system contextual factors and background for evidence-informed policymaking for Peru and Uganda

Contextual factors	Peru	Uganda	Comments
Total area	1,285,216 sq km	241,038 sq km	Peru is 5 times larger than Uganda
Administrative divisions	25 regions and 1 province (Lima)	111 districts and 1 capital city	Uganda has over 4 times the administrative divisions of Peru
Total population (2012)	29,988,000	36,346,000	Relatively similar population
Urbanized population (%), 2012	78	16	Delivery of services is greatly impacted by where people live
Birth registration (%), 2005-12, urban/rural	96/94	38/29	Monitoring and evaluation activities need to reflect differences in reporting and account for where and how measurements are made (e.g., community level vs. national level, self-reported vs. household survey)
Gross National Income per capita (PPP international \$, 2012)	10,090	1,120	Peru's GNI per capita is 9 times greater than Uganda's
Total expenditure on health per capita (Intl \$, 2012)	555	108	Peru's total expenditure on health per capita is 5 times greater than Uganda's
Total expenditure on health as % of Gross Domestic Product (2012)	5.1	8.0	Uganda spends more on health as a percent of its GDP
Life expectancy at birth m/f (years, 2012)	75/79 life expectancy ranges from 72-77 years for Lima, Callao, and certain coastal departments, to 57-63 years for the Andean departments	56/58	People in Peru have a life expectancy of 20 years over that of people in Uganda. However, variations exist within countries as well.
Adult HIV prevalence (%), 2012	0.4	7.2	HIV prevalence affected the recommendations regarding external cephalic version (ECV) in Uganda

Total fertility rate (TFR), 2012	2.4 2.3 for urban areas and 4.6 for rural areas; variance depending on the educational level of women, with TFRs of 6.9 for women without education, 5.0 for women with primary education, 3.0 for women with secondary education, and 2.1 for women with higher education	6.0	Uganda has a higher total fertility rate than Peru, but wide variation exists within Peru based on urban/rural dwelling and women's educational level. These are important considerations for equity.
Births with skilled attendant present (%), 2008-2012	87	57	Having a skilled attendant at birth is one of the most important ways to decrease maternal mortality. Improvements in this indicator need to consider cultural preferences and the urban/rural distribution of the population and of health human resources.
Lifetime risk of maternal death (2010)	1 in 570 More than 50% of maternal deaths are concentrated in eight regions: Cajamarca, Puno, La Libertad, Loreto, Piura, Junín, Huánuco, and Cusco – (PAHO, 2013)	1 in 49	1 in 5,200 in Canada
Under-5 mortality rate, 2012	18	69	4 times greater in Uganda
Infant mortality rate (under 1), 2012	14	45	3 times greater in Uganda
Neonatal mortality rate, 2012	9	23	3 times greater in Uganda
Health system			
Governance arrangements	The Ministry of Health is responsible for policy in the health sector. Each region is responsible for modifying policy to fit its needs and implementing policies and programs.	The Government of Uganda, through the Ministry of Health (MoH), is responsible for developing policies and frameworks for delivering health services. Either the MoH, or parliament, can initiate	

		<p>policies. Multiple players, including other ministries and outside donors, contribute to health policy. Uganda has a decentralized system in which power, authority and resources are distributed from the central government to the districts. However, some of the districts lack the personnel, resources and training to carry out their duties.</p>	
Financial arrangements	<p>Mix of public and private financing. Each region is allocated a budget from the central Ministry and is accountable for finances regarding health. Three types of health insurance exist: social security (ESSALUD), the Armed Forces and National Police, and private insurance. Donor financing is about 2% of total health expenditure.</p>	<p>Mix of public, private, and donor-funded (32-over 50%) financing. Each region is allocated resources from the central government but resources are often not enough to support implementation of policy and programs.</p>	<p>Regulations within the public sector and the private sector need to be considered. Also, the role of NGOs cannot be discounted in the policymaking process.</p>
Delivery arrangements	<p>The public sector is made up of the Ministry of Health, ESSALUD (Social Security), and the services of the Armed Forces and the National Police. The public subsector has 51% of total hospitals, 69% of health centers, and 99% of health posts, located in remote rural areas and marginal urban areas.</p> <p>The private subsector mainly operates in the larger cities and is made up of clinics, physician's offices, and NGOs.</p>	<p>Service delivery is provided by public and private sectors (about 50% each). The public sector includes Village Health teams (or Health Centre I – HCI) within the communities and tiered levels of care at the district level (HCII, HCIII, and HCIV) up to general hospitals (formerly district hospitals). The regional and national hospitals are semi-autonomous, while the district health services and general hospitals are managed by local governments.</p> <p>Private health service providers comprise private not-for-profit organizations, private for-profit health care providers (or commercial health care providers), and</p>	<p>There is poor coordination between the public and private systems in both countries</p>

		<p>traditional and complementary medicine practitioners.</p> <p>Staffing of these facilities are variable, especially at the HCII level where there are “fill rates, ranging from 0 percent to well over 100 percent. The 2011 Audit Report noted that “most of the HC IIs have the Nursing Assistants/Aides as the in-charges which compromises the quality of care provided at these service delivery points” (Ministry of Health, Health Systems 20/20, & Makerere School of Public Health, 2012, pg.47)</p>	
Capacity for knowledge translation and evidence-informed policymaking			
EVIPNet (Evidence-informed policy network) equivalent	The unit for analysis and evidence production for public health (UNAGESP) within the National Institute of Health (INS), which supports the Ministry of Health (MINSA) in using evidence in policymaking.	<ul style="list-style-type: none"> - The Region of East Africa Community Health (REACH) Policy Initiative set up years ago between multiple countries in East Africa to help use evidence in developing policy. - SURE project (Supporting the use of research evidence for policy in African health systems) lasted for five years and was funded and supported through the European Commission’s 7th Framework Programme to develop and evaluate knowledge translation strategies. 	Both countries have formal processes in place to support evidence-informed policymaking. Peru’s structure is more formalized as it has direct links with the Ministry of Health through its directives and funding sources. Uganda has more informal channels to the Ministry and usually reaches policymakers at the Ministry through professional contacts and involvement of these contacts in the working groups for developing evidence briefs.
Complementary initiatives focused on health system issues	None found	- Rapid response system started in Uganda under SURE project and is	

		now being adapted by other countries - Uganda Clearinghouse for Health Policy and Systems Research - Africa Centre for Systematic Reviews and Knowledge Translation	
Affiliation with academic centres	No	Yes – based within Makerere University in Uganda with linkages to universities in Canada and Norway	Affiliation with academic centres often grants people access to sources of evidence, such as research databases. This is an important consideration for the capacity to find and use evidence in decision-making.
Number of prior evidence briefs and rapid response reports	2	5 evidence briefs and 71 rapid response reports (as of January 22, 2015 – personal correspondence) under the SURE project. Uganda completed an evidence brief on a similar topic in 2010, prior to the release of the OptimizeMNH guidance and the workbook	Peru has less experience in developing evidence briefs than Uganda.
Usual process for developing evidence briefs and holding policy dialogues			
Selecting a topic	1) A topic is brought forward by the Ministry of Health or 2) A need is determined by an expert (e.g., the case of micronutrient powders in Peru)	1) Priority-setting process under the SURE project involving interviews with stakeholders and determining priorities or 2) Policymaker asks for evidence on a particular topic for a rapid response	
Developing an evidence brief	One or several people draft the evidence brief (equivalent to evidence brief) by using evidence to help define the topic, develop policy options and look at implementation considerations. This work is presented to the Ministry to ensure it meets their	A team of authors determine a search strategy and develop terms of reference section-by-section (clarify the problem, develop policy options and identify implementation considerations). The authors revise each section based on feedback from the working group and use the terms	

	needs and to keep them aware of the work.	of reference to write the evidence brief.	
Using guides in the development of evidence briefs	Worksheets, developed by the Pan-American Health Organization (PAHO) and which are similar to the SURE guides, are followed to develop the evidence brief.	The SURE guides are used to develop the sections of the terms of reference or to act as a checklist to ensure all items have been considered for the evidence brief.	
Involving experts, policymakers, stakeholders and researchers	1) May be included in the development of the evidence brief, depending on the topic, but mainly occurs during the policy dialogue. 2) Written feedback is concurrently obtained from experts who are not in attendance at the policy dialogue	1) A working group made up of policymakers, stakeholders and researchers provides input throughout the process. 2) The brief is sent out to 3-4 external reviewers (academics and policy practitioners and implementers) and feedback is incorporated prior to the policy dialogue 3) Experts, policymakers, stakeholders and researchers are included in the policy dialogue	
Convening a policy dialogue	30-40 policymakers, stakeholders, representatives of groups and researchers discuss the implications of the evidence brief and provide their opinions and tacit knowledge. A series of dialogues may be held and recommendations are made.	15-20 policymakers, stakeholders and researchers discuss the implications of the brief and refine the work based on the larger groups' perspectives and knowledge, and to sensitize the group on this particular problem and potential solutions.	
Making policy recommendations	The Ministry of Health then decides whether to adopt the recommendations, and, if adopted, supports the implementation of the recommendations	Usually, a champion is sought during the policy dialogue to help move the work forward within policymaking circles	
Time to develop evidence brief	4-6 months	6-8 months	

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Chapter 4 - Preface

Chapter 4 systematically reviews literature in a wide range of fields in order to better define ‘contextualization’ and to identify contextual factors that are used in adapting global guidance at the national or subnational level. Two theoretical models were created. The first model describes the processes by which guidance can be shaped to fit a particular setting and how context relates to these processes and to the implementation of recommendations. The second model shows what factors influence the guidance contextualization process. In addition, mechanisms by which contextual factors may affect the chances of policy being implemented are presented. The critical interpretive synthesis method allowed for related concepts to be examined (e.g., terms used to describe how guidance is shaped in order to be implemented, and what contextual factors are used in contextualizing guidance), but also allowed for relationships to be built between the concepts (e.g., how do contextual factors affect the contextualization process). In addition, a template-style of data organization facilitated data collection and analysis. Lastly, incorporating theories from various fields allowed for the development of models that could be applicable to a multitude of domains incorporating guidance in the use of research evidence for informing policy decision making. The methods are described in detail, which could help others who would want to apply them. Further recommendations for improving the workbook are presented in chapter 5.

As highlighted in chapter 1, the three studies in this dissertation occurred concurrently, and information from each study was compared and contrasted to findings in the other studies. Specifically for this chapter, concepts from chapters 2 and 3 were looked at to see whether and how they were defined in the literature and how they played a role in the contextualization of guidance. Information from all three chapters were further synthesized to strengthen the recommendations made for improving the workbook.

I was responsible for conceiving of the design of the study with my supervisor, Dr. John Lavis, and for completing all data collection and analysis. Dr. Lavis also contributed to the analysis through feedback on the concepts and presentation. I drafted the chapter, and Dr. Lavis, Dr. Brouwers and Dr. Schwarz provided comments and suggestions that were incorporated into subsequent revisions.

Integrating contextual factors as a strategy to improve health systems guidance implementability

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Keywords: guidance; guideline; contextualization; knowledge translation; health system strengthening; political system; evidence brief; qualitative research

Word count: 15,434 including title to references (with tables and appendices included); 8,252 text without title, authors, keywords, references, tables or appendices (abstract 503)

Abstract

Introduction: Strong health systems are needed in order to implement clinical and public health interventions. Global evidence-informed health systems guidance (e.g., World Health Organization guidance) has been used to help strengthen health systems. However, global guidance needs to be contextualized or adapted to fit the needs and realities of a particular setting. The contextualization process has not been clearly defined in the literature. In addition, in order for guidance to have an impact, it needs to get on the government's agenda, inform policy development, and be implemented. Evidence briefs have been used as a method of incorporating evidence to inform policymaking, but influencing the stages of the policy process is complex and needs to take into account contextual factors. This study set out to more clearly define the meaning of “contextualization” especially in relation to other similar terms used for, and as part of, the process of shaping and implementing guidance in different contexts. In addition, the study looked at what, and how, factors influenced the contextualization process.

Methods: A critical interpretive synthesis method was used to review empirical and conceptual documents in a variety of fields. Multiple electronic databases were searched to encompass various types of literature, such as peer-reviewed and grey literature, and a variety of fields. These included general bibliographic databases - CINAHL, Embase, HealthSTAR/Ovid Healthstar, Medline, PsycINFO, Pubmed, Social Sciences Abstracts, Teacher Reference Center, and Web of Science; databases mainly containing systematic reviews – Health Systems Evidence, and Joanna Briggs Institute EBP database; and databases also containing grey literature – AgeLine, Global Health, Health and Psychosocial Instruments (HAPI), and OECD iLibrary – Papers. A template-style of data organization using NVivo10 and a constant comparative method were used for data collection and analysis.

Results: Of 3,124 unique documents retrieved through the electronic database searches, 2,934 were excluded using explicit criteria, leaving 190 potentially relevant documents. Thirty-eight documents were purposively sampled for inclusion, and another 23 documents were found to help fill conceptual gaps during data analysis. Therefore, 61 documents were reviewed for this study. Models were developed of: 1) the processes by which guidance can be changed to fit the needs and realities of a specific setting in order to be implemented, and 2) contextual factors influencing the guidance contextualization process.

Discussion: Integrating contextual factors as part of the development of evidence briefs can be used as a strategy to maximize the implementability of guidance

recommendations at the national / subnational level. Contextual factors to be considered include: local evidence, health systems arrangements (delivery, financial, and governance arrangements), and political system factors (institutions, interests, ideas, and external factors), along with other implementation considerations for a particular intervention. Four mechanisms are suggested for how these contextual factors may increase the implementability of the recommendations: 1) determining relevance, 2) aligning with government priorities, 3) selecting policy options that are technically feasible, fit with dominant values, and are workable from a budget perspective, and 4) integrating contextual factors as a strategy for implementation (e.g., involving end users or other stakeholders as a strategy for advocacy).

There are many known simple, yet effective, clinical and public health interventions that can greatly impact on the quality and quantity of people's lives. However, a strong health system is required in order to deliver these interventions to those who need them. (1) Even though some progress has been made, many countries, especially low- and middle-income countries (LMICs), have not achieved the Millennium Development Goals (MDGs). (1) The MDGs are eight goals that United Nations Member States agreed to try to achieve by 2015 to address issues of poverty, hunger, disease, illiteracy, environmental concerns and discrimination against women. (2) Because of the realization that strong health systems are needed in achieving health targets, there has been an emphasis placed on prioritizing health systems research to understand how to strengthen health systems in various contexts. (1,3)

International organizations, such as the World Health Organization (WHO), have been developing guidelines and health systems guidance to help countries use evidence in informing decisions for policy and practice. (4) Global guidance recommendations can help support guidance development at the national level as well as policy development at the global and national levels. (4) But, developing health systems policy is a complex process. (4) Characteristics of the problem, options for addressing the problem, implementation considerations, health system arrangements, and political system factors influence political agenda-setting and policy development and implementation. (4) Evidence briefs have been used as a method of incorporating evidence to inform policymaking,

but influencing the stages of the policy process is complex and also needs to take into account contextual factors. (4,5) An evidence brief is a document created at the national or subnational level that presents research evidence on the problem and its causes, possible policy options, and implementation considerations. (4,5) The evidence brief can then be used to inform a policy dialogue. A policy dialogue is organized to elicit the views, experiences and tacit knowledge of policymakers, stakeholders and researchers who are involved in or affected by decisions surrounding the topic and possible policy options at hand. A summary of the policy dialogue can help inform agenda setting, policy development and/or policy implementation. (4,5)

Global guidance needs to be contextualized or adapted to fit the needs and realities of a particular setting. (4) Countries have found that evidence-informed guidance recommendations are not sufficient for developing and implementing national or subnational policies in their settings. (4,6,7) For example, Peru recently tried to implement a micronutrient supplementation program but found no evidence to support an improvement in nutritional status. (8) After investigating reasons for these findings, it was determined that there was a lack of education on how to use the micronutrient supplements. Once this critical component was addressed, the program was more effective and was able to be scaled up to other jurisdictions in Peru. (8)

If context-related factors (9) can be addressed during the policy development process, then the policy recommendations or policy decisions should

be designed to fit the specific local needs of policymakers and stakeholders grappling with these issues within their countries while still being faithful to the principles of the global recommendations.

With the advancement in the fields of health systems and policy and in knowledge translation, it is a good time to *critically review* work on the contextualization of guidance recommendations within the health systems field as well as beyond it (e.g. clinical, public health, environment) to provide comprehensive insights into this process. While it is known that guidance needs to be contextualized in order to fit the needs and realities of particular settings, there is no clear definition of what contextualization means, especially in relation to other terms used, such as adaptation and implementation. Examining these terms and how they are defined can help not only build a better understanding of how they relate to each other in order to bridge the work done in a variety of fields, but it can also clarify the processes of how guidance is shaped and implemented in different contexts. In addition, the study will examine what, and how, factors influence the contextualization process. This will help lay a foundation to explore how contextual factors play a role in guidance contextualization across multiple fields for both research and practice.

Methods

Many types of knowledge synthesis methods exist. (10) However, the critical interpretive synthesis method developed by Dixon-Woods et al (11) seemed the most fitting for the purposes of this study. Critical interpretive

synthesis is an approach to an entire process of review and uses an iterative approach to refining the research question, searching and selecting articles from the literature, and defining and applying codes and categories. (10) This interpretive approach allows for the re-interpretation and re-analysis of textual evidence in order to generate new conceptual understanding. (12) In addition, as Dixon-Woods et al (11) specify, few interpretive reviews have attempted to apply an interpretive approach to the studies reviewed as well as to the final work. This study was strengthened by the ability to critically appraise the literature and to ask in-depth questions about how these studies add to or miss critical elements of health systems guidance contextualization. Because of the ability to purposively sample relevant evidence, to iteratively refine the research question and the search terms as the study progressed, to explore related fields for similar work, to critically examine the information encountered in an iterative fashion as well as the diversity of the field and the variety of the literature addressing contextualization of health systems guidance (e.g. grey literature, conceptual or opinion work, etc.), critical interpretive synthesis was the method chosen for this work. In addition, critical interpretive synthesis has been used before in the field of health systems and policy. (9)

In critical interpretive synthesis, the research question helps direct the initial line of study, but the research question itself can be shaped iteratively as the work progresses. Therefore, the question serves as a "compass." (11) For this study the compass question was "What does contextualization mean in regards to

policy development based on, or implementation of, health systems guidance?”

Three sub-questions to answer were: 1) what tools are available for contextualizing or adapting guidance, guideline or policy recommendations (henceforth “recommendations”), and what are their components, 2) what context-related factors are being proposed for the contextualization (or adaptation) of health system guidance recommendations at the national or subnational level and 3) if work was done outside of the field of health systems and policy, how could this work be applied within health systems guidance contextualization?

Document identification

A number of strategies were used in finding literature for this critical interpretive synthesis, including an initial systematic search of electronic databases, reference chaining (e.g., searching the bibliographies of included papers to identify further relevant documents), and identification of other documents to fill knowledge gaps during the analysis phase.

Because of the diversity of the terms used in the literature around guidance or policy contextualization, adaptation, and implementation, pilot testing was conducted in the summer of 2014 to develop the search strategy. A table was created with Boolean-linked keywords and synonyms, and various search strategies were tested. The goal was to develop a search strategy that would identify relevant documents while limiting the search to a manageable amount. In addition, several known relevant articles were used to test the search strategies to

ensure these articles were captured in the searches. Databases were selected that would represent health systems and policy, clinical, and other fields, including education, environment, and economics. The refined searches used for this study were conducted in October 2014. See appendix 1 for the databases and search terms used for the electronic database search. Additional documents were included in 2015 during data extraction through reference chaining and during data analysis to fill in knowledge gaps.

Databases searched (see appendix 1)

Multiple electronic databases were searched to encompass various types of literature, such as peer-reviewed and grey literature, and a variety of fields. These included general bibliographic databases - CINAHL, Embase, HealthSTAR/Ovid Healthstar, Medline, PsycINFO, Pubmed, Social Sciences Abstracts, Teacher Reference Center, and Web of Science; databases mainly containing systematic reviews – Health Systems Evidence, and Joanna Briggs Institute EBP database; and databases also containing grey literature – AgeLine, Global Health, Health and Psychosocial Instruments (HAPI), and OECD iLibrary – Papers. No time limits were placed on the searches since key conceptual works were sought.

Key terms searched (with modifications made for the various databases)

context* OR local* OR adapt* OR appl* OR implement* OR link* OR poli*
guideline OR guidance OR recommend*
tool OR decision support OR support tool OR framework OR factor OR countr*

Document selection

Excluding irrelevant articles

An explicit set of exclusion criteria was developed to help remove articles that were not relevant to this study. Some of the exclusion criteria were developed in an emergent fashion as patterns of irrelevant articles were encountered, and they reflect the diversity in the fields included in the study. The titles, abstracts or full texts of documents identified through the electronic database searches were reviewed for this step. Exclusion criteria included: 1) patient-specific guidelines, where the focus was on point-of-care issues or the clinical guidelines themselves, 2) topic-specific adaptation (e.g. climate adaptation, genetics, career guidance, context-aware technology, user recommender systems for technology) unless the focus was on adapting recommendations on these topics for particular settings, 3) implementation of a program or intervention, unless factors affecting implementation were discussed, 4) measurement of specific outcomes, including disease-specific outcomes, implementation/non-implementation of recommendations, or evaluation of policies without looking at factors for the results, 5) creation of guidelines, frameworks or recommendations, unless factors affecting the adaptation or implementation of these were also discussed, 6) research processes, such as priority-setting for a research agenda or patient involvement in research, 7) contextual descriptions that described the context of an issue without discussing how these factors played a role in the development or implementation of policies or programs, 8) programming of electronic clinical decision support systems where the focus was on the programming aspects of

electronic guideline development, such as how to incorporate patient factors, as opposed to finding out which factors were important in developing guidelines,

Purposive sampling for inclusion of relevant papers

Once irrelevant papers were excluded, the documents found through the electronic database searches were purposively sampled for inclusion. Titles, abstracts and full texts were reviewed, as needed, for this process by the principal investigator (EA). Tools (frameworks, etc.) were prioritized as it was felt these would include factors found in prior literature. For a similar reason, more recent articles were prioritized. Because the focus of the study was around health systems and policy, documents covering topics from this field were prioritized. This was especially relevant since most of the documents related to clinical guidelines. Lastly, information from other fields, such as public health, environment and economics, was prioritized in order to expand the knowledge base used in the analysis. This sampling approach, along with inclusion of documents found through searching the bibliographies of these papers or through further searches for documents to help fill conceptual gaps (i.e., concepts emerged but did not include sufficient explanation), was used until saturation of the themes was achieved.

Data extraction and analysis

Because the foci of this study were to clarify how contextualization differed or was the same as other terms used in the process of shaping recommendations to improve implementation, and to find out what and how

contextual factors could influence this process, several approaches were taken with these ends in mind while collecting and analyzing the data. First, to facilitate data extraction, a preliminary code structure was developed based on the objectives of the study using 1) terms that had been previously identified during the database search process (e.g., implement/implementation, adapt/adaptation), 2) tools that were known to the authors through prior work for developing, assessing or implementing guidance or guidelines (e.g., GRADE, AGREE II), and 3) context-related factors used in contextualizing guidance or guidelines known to the authors both through prior work and through the development of the workbook. The authors had collective experience in the fields of clinical practice, public health, health systems and policy, clinical guideline development and implementation, and political studies. Coming from this lens, a prominent classification of factors known to influence the policymaking process used in the fields of political studies and health systems and policy research includes institutions, interests, ideas (“3 Is”) and external factors. (4,9) Institutions include government structures (e.g., unitary or centralized vs. federal or decentralized systems), policy legacies (e.g., past policies shaping current structures), and policy networks (e.g., some interest groups have greater access to the policy process). (4,9,13,14) Interests include groups of people who may benefit or be harmed by a policy decision and may mobilize politically for or against this decision (e.g., patient groups, civil society). (9,15) Ideas include values and beliefs of policymakers and the public, and research evidence. (4,9) Lastly,

external factors, such as economic changes or media coverage, can either bring attention to or away from other topics. (4,9) In addition, health and public health interventions as well as policy directives are instituted within a health system. Therefore the context of the health system also needs to be considered. As one commentator noted:

“New trends in health systems thinking advocate the construction of conceptual pathways that look at the interventions from a systems perspective, making explicit how interventions may trigger reactions in related components of the health system that may produce unintended consequences.” (1)

A widely used framework distinguishes delivery arrangements (e.g. who provides the care, where is the care provided), financial arrangements (e.g., financing mechanisms, remunerating providers) and governance arrangements (e.g., policy authority, commercial authority) within health systems. (4,16) In addition, potential factors from the previous studies were included (e.g., advocacy, corruption). This code structure, however, was modified throughout data analysis and was open to including new concepts as they arose.

Second, a data extraction sheet was developed based on these factors to help guide data extraction and coding (see appendix 2). The data extraction sheet also included information on the document, such as title, field (e.g., clinical, public health, health systems and policy, environment, education, etc.), year

published, journal/publisher, authors, type of document (i.e., empirical or conceptual), and methods used for empirical papers.

Third, articles were read and coded, with notes made throughout the process during which time concepts first emerged. Data were organized following a template-organizing style (i.e., based on the preliminary code structure) (17,18) using NVivo10 (19) software to help with the coding process and organization of data. As described earlier, codes were modified and new codes were added as guided by the data during this process. In addition, codes were made for relationships found amongst the codes. A constant comparative method was used where new data were compared with previous data to see if they represented convergent or divergent concepts. This part included reflection on: 1) the names and terms used to describe concepts, 2) concepts themselves (e.g., is the concept of patient preferences similar to or different to the concept of the public's values and personal experiences), and 3) relationships amongst the concepts (e.g., how government structures (i.e., institutions) relate to problems of confusion over guidelines when there is no coordination amongst programs (i.e., a delivery or governance arrangement) serving the same populations).

Fourth, all the information organized under each code was reviewed and further notes were made. Concepts continued to emerge during this phase of analysis. In addition to the initial coding of the data, using NVivo10 software allowed for text queries to be conducted in order to supplement the information found through the initial coding process. Once the data had been reviewed and

coded, these text queries were run to ensure completeness of the data and to ensure all sources describing a particular concept were reviewed.

Fifth, concepts that emerged throughout these early stages of analysis were linked into themes. These themes were further reviewed in a critical interpretive manner to see if, and how, concepts from outside of the health systems and policy field could be applied to this field.

Sixth, two additional methods were used in order to ensure completeness of the findings. First, three additional papers from the database searches were reviewed in order to make sure no new themes or contradictory concepts emerged. Second, peer-review was conducted with experts in the health systems and policy and the clinical guideline fields to ensure these concepts resonated with current scholarly work in these fields. This was especially important since these were the fields in which health policy, guidance or guidelines would be contextualized for a particular setting.

Ethical considerations

As this study was a synthesis of literature available to the public, no ethical approval was required.

Results

Search results and article selection

In total, 3,124 unique documents were retrieved through the electronic database searches (see2). Of these, 2,934 were excluded after reviewing titles, abstracts or full texts, using the explicit set of criteria described above, leaving

190 potentially relevant documents. Thirty eight documents were purposively sampled for inclusion, and another 23 documents were found to help fill conceptual gaps during data analysis. Therefore, 61 documents were reviewed for this study. It was found that many of the documents overlapped fields (e.g., public health and health systems and policy), but for the purposes of this study, they were categorized by the primary field of focus (see table 1). The majority of included documents were from the health systems and policy field (n=28, 46%), followed by documents from the clinical guidelines field (n=23, 38%). Two documents were included from each of the fields of public health, general public policy, environment, economics, and management/administration/organization. Thirty one documents (about half) were published after 2010, 14 documents were published between 2006-2010, 8 documents were published between 2001-2005, 4 documents were published before 2001, and 4 were not dated (e.g. websites). Of the 61 documents, about half were conceptual papers (n=32, 53%) and half were empirical papers (n=29, 48%). Of the empirical papers, most used mixed methods (n=13) but there were a variety of other methods employed, including systematic reviews (n=3), case study (n=6), other qualitative approach (n=2), and other methods (e.g., cost analysis) (n=5).

Terms used in the process of guidance adaptation/contextualization and implementation

Implementation as the main goal for health interventions, public health interventions, policy interventions or guidance recommendations

Table 2 lists the various terms used for shaping recommendations for implementation in a particular setting. It became clear early on that the main goal for all of these processes was to “implement” clinical, public health or policy interventions or guidance recommendations. However, “implementation” was described in different ways. In some documents, implementation was the last step, or a step, in the knowledge translation continuum. (20–23) In other documents, however, implementation was seen as the entire process leading to the use of evidence. (20,24,25) Further still, there were attempts to see this process as a strategy for improving implementation by influencing behavior (e.g., including end users in the process for a sense of ownership and advocacy) and by ensuring the recommendations fit the realities of the specific setting (e.g., including end users to identify implementation considerations). (26–28) In addition, context was related to multiple points in the implementation process in that the effectiveness of an intervention was dependent on context (both where the original study took place and the setting into which it was being implemented) and selecting an implementation strategy was dependent on context. (20,29,30)

Potential processes to change guidance for implementation in a specific setting

There were also six general processes by which guidance or guidelines could be changed (or not) before being implemented in a new setting. First, the most commonly used term was “adaptation,” which was described as the “systematic approach to considering the use and/or modification of (a) guideline(s) produced in one cultural and organizational setting for application in

a different context.” (28) This was contingent on having (an) existing guideline(s) on a particular topic and needing to customize it (them) to suit the local context. (28) Adaptation was seen as a process to enhance implementation (23,31), but also as a product to establish relevance and feasibility (i.e., the adapted guideline). (28,31,32) However, there were also concerns over adapting guidelines too much to local circumstances and thereby limiting the effectiveness of the intervention(s) as found in the original studies. (28,33) Second, “adoption,” which was also commonly used, was at times described as an alternative to adaptation and at times as a complement to adaptation, in that guidance or guidelines could first be adapted but still needed to be adopted. (24,28) Third, “contextualize” was not differentiated clearly from “adaptation,” however, the term was related to developing guidance or policy from already existing global guidance (e.g., WHO guidance) and highlighted the importance of considering context in this process. (4,16,34,35) The concept of “context” was very prominent overall and was noted in the literature as an important consideration to determining if, and how, guidance should be changed or taken up as is in a particular setting. Specifically, context was noted to influence the process of guidance development (1,4,28,30,34,36–38), the process of policy development (4,9,16,34,35,39,40), implementation considerations (4,16,28–30,34,35,40–43), and the effectiveness of interventions. (28–30,37,40) Fourth, “customize” was sometimes used synonymously with “adapt” and was explicitly stated to require both methods and content experts. (31) Fifth, “transfer” was highly linked to the contextual factors

of the different settings (i.e., transferring and borrowing countries) and could be related to both adaptation and adoption. (40,44) Sixth and last, outside of the term “knowledge translation,” “translation” was used to describe a change in recommendations in terms of format (e.g., an instrument or toolkit, electronic decision-support system, awareness into action) (21,24,45) or in terms of language. (46)

Implementability - Characteristics to enhance implementation of guidance recommendations

Several documents discussed “implementability,” which was defined as “the characteristics of guideline recommendations that may enhance their implementation...” (32) In addition, implementability was differentiated from guideline quality.

“Quality assessments relate primarily to determining the scientific validity of guidelines and, generally, quality is assessed for the guideline as a whole. Implementability, on the other hand, is one component of guideline quality, but its assessment is applied largely to individual recommendations within a guideline.” (27)

Both intrinsic features of implementability (i.e., qualities of the guideline recommendations themselves, which guideline developers can control) and extrinsic features of implementability (i.e., largely site-specific) were noted. (26–28,32,42) In addition, several tools to help improve guideline implementability were found. (26,27,32,42) The most noted terms used as implementability

features were acceptability, applicability, feasibility, generalizability and transferability. However, there was quite a bit of overlap between these terms and many were used synonymously, depending on the source, therefore a full discussion of these will not be elaborated here (see table 2 for definitions).

Examining the role of context in the knowledge translation continuum

A model of knowledge translation processes was created based on the data and presented as figure 2. Since the ultimate goal of knowledge translation is to implement evidence-based or evidence-informed clinical, public health and health systems interventions or guidance recommendations, one could view evidence (A) as a starting point and implementation (L) as the end point. Even though it was understood by the authors that a single study could change policy or practice, the focus for this study was on developing guidance to bring together evidence as an intermediate output in the knowledge translation process. However, there were two separate processes described for the development of guidance. First, the question was often whether to develop guidelines de novo or adapt existing guidelines because of the time and resource-intensive nature of developing guidelines. (28) In this case, guidelines were first developed for a particular setting (B) to create “contextualized” guidance or guidelines (D), and other settings then needed to decide whether to use these guidelines or develop their own. In a second scenario, which was seen more prominently at the global level (e.g., WHO guidance), guidance was developed for use in multiple settings (C) and led to “decontextualized” guidance (E).

Following the first scenario, and as noted previously, “transfer” (F) was described as taking one guideline or policy from one setting and putting it into another setting. However, the contexts could be similar, in which case, the recommendations could simply be “adopted” (G). Or, if the contexts were significantly different, then the recommendations may not be able to be implemented in that setting (30,40), or they may need to be “adapted” “customized” or “contextualized” (H) before being adopted. In the second scenario, “decontextualized” guidance (E) first needed to be “contextualized” (I) as part of the process of national guidance development or national / subnational policy development in order to make it fitting for that particular setting. Processes H and I lead to a(n) adapted, customized or contextualized guidance or policy (J). Before adoption (G) of any of these recommendations, these could also be translated (K) into a different format (e.g., electronic decision support tools) or into a different language. It is to be noted that this process could be straightforward, as in following one of these paths, or there could be multiple steps in the process (e.g., developing national guidance, developing provincial policy and then developing hospital procedures). However, it seems to the authors that each iteration of the recommendations could be placed back into the positions of D or E, and the process could continue as often as needed prior to implementation (L).

As described previously, implementation could be seen as: 1) the end point in the knowledge translation continuum; 2) as one of the last steps followed

by monitoring and evaluation (M&E) and sustainability or institutionalization (34); or 3) as an entire process of implementation. One can imagine that if implementation is seen as the end point or one of the last steps, then little emphasis might be placed on the role of context and/or implementation considerations during guidance development, or during the adaptation or contextualization processes. It is important to highlight that context has been shown to affect every part of the knowledge translation process. For example, evidence is often gathered within a particular context (e.g., high-income country, free access to medications and providers for the purposes of the study). Not reporting this context within original studies has been noted as a problem for identifying the ability to transfer or generalize findings from one context to another. (29) In addition, guidance or policy development processes are all performed within specific contexts (e.g., number and skill mix of guideline developers, funding and resources available for conducting the work). (4,28,34,35) And, implementation occurs within a particular context (4,16,28–30,34,35,40–43), which can even affect the effectiveness of the intended intervention. (28–30,37,40)

Following what was learned about implementability and how intrinsic and extrinsic features could affect the implementation of recommendations, then one could assume that not incorporating considerations of context until this late stage might lead to lower implementability potential of the recommendations. If, on the other hand, one views the whole process as a way to enhance adoption of existing

recommendations, and incorporates considerations of context throughout the process, then the literature suggests that the intrinsic and extrinsic implementability features may be improved as already highlighted. However, the literature also suggests that this process can be further looked at as a strategy to integrate contextual factors in order to maximize the implementability of recommendations, such as including end users as a means to improve recommendations and increase credibility. (26) Even though thinking strategically about implementation of recommendations is not new, the authors did not come across any documents describing how entire processes could be used as strategies, but instead found narrow areas of focus around one or two implementability features.

One last note is that implementation was not seen only as the ultimate goal, but rather that monitoring and evaluation be incorporated to see if the process and outcome(s) of implementation are meeting expectations.

(16,41,45,47) In addition, it was noted in chapters 2 and 3 that there is further need to incorporate feedback mechanisms between monitoring and evaluation to inform research priority-setting, guidance development, and implementation processes.

Contextual factors influencing the contextualization process and their relationships with other factors or steps in the process of developing evidence briefs

Because the focus of this study was on the contextualization of global health systems guidance (step “I” in figure 2), this particular step in the process of knowledge translation was looked at to see: 1) what, and how, contextual factors played a role in this process (addressed in this section), and 2) how integrating contextual factors into the contextualization process could maximize the implementability of the guidance as a strategy (addressed in the next section). One of the methods for contextualizing guidance, which has been used and researched globally in both high-income and low- and middle-income countries (LMICs), is the development of an evidence brief (see introduction section). (4,5,9)

Contextual factors found to influence the process of contextualizing guidance or adapting guidelines fit well with the frameworks described in the data extraction and analysis section above around health system contexts (delivery, financial and governance arrangements) and political system contexts (institutions, interests, ideas and external factors). However, an additional contextual factor that arose from the data was local evidence, which is evidence specific to the jurisdiction of focus, including the availability, type (e.g., quantitative, qualitative), and levels or settings (e.g., national or district, hospital or prehospital) of data (see appendix 3). Many terms were found to represent the concepts within each of these categories, however, many of the terms were non-specific and did not have analytical power. For example, “political environment” is very broad and can encompass multiple concepts such as past policies, interest

groups and the use of evidence in decision-making, among others. (4) Relevant themes found for each factor, and relationships found amongst the factors (i.e., ways in which the contextual factors influenced each other), are also shown in appendix 3. As can be seen, there were many ways in which contextual factors interacted (e.g., interest groups forming around ideas and also pushing for certain views or ideas). (9,47)

The process was also broken down in order to understand what contextual factors might affect each step in the contextualization process through the development of an evidence brief. Multiple steps, drawn from the workbook and chapters 2 and 3 and refined through the data, were examined in this process: 1) selecting the topic, 2) identifying the venue, 3) developing advocacy strategies, 4) clarifying the problem and its causes, 5) framing options for addressing the problem (including considerations of benefits, harms and costs), 6) identifying implementation considerations (including assessments of the health system and political system), 7) identifying equity considerations, 8) developing dissemination strategies, and 8) anticipating monitoring and evaluation needs. (4,9,16,34,35,39) Appendix 4 illustrates how each contextual factor can affect these steps, and how one factor may, in concert with (an)other contextual factor(s), affect particular steps in the process (i.e., across dimensions).

Figure 3 shows the influence of local evidence, health system arrangements, and political system factors on the process of contextualizing guidance through the development of an evidence brief. There are seven main

points to highlight. *First*, depending on the availability and level (or setting) of local data (e.g., district vs. national, hospital vs. prehospital setting) for the selected venue, there may be an increase (i.e., if more data are available) or decrease (i.e., if less data are available) in certainty with regards to recommendations made for that particular setting (e.g., will this specific population accept services provided by an auxiliary nurse?). (35,37,47–50) If there is an abundance of data for that particular, or a similar, setting, then making decisions may be able to rely more on this evidence. (48) However, when there is scant local evidence on a topic, there may be more room for the status quo of health systems arrangements to be relied on for decision making (e.g., there are currently lactation consultants in hospitals, therefore, interventions are targeted at the hospital level) (51) or for political system factors to play a role in decision making (ideas of policymakers and the public and interest groups). (9,51) Local evidence as a contextual factor is reinforced by findings in chapter 3 where the level of data available was used to determine the venue for the work done in Peru and Uganda. *Second*, selecting the topic is highly influenced by political system factors. While the impetus for change might be driven by an external factor (e.g., release of guidance by WHO) or by other, more internal, factors (e.g., indicators show there is a problem with the current provision of services), a government response is likely to be needed. This makes sense if one considers that when large-scale changes (i.e., changes in practice as guided by guidance within a province or country) are needed within a publicly funded or government-run

health system, which is the setting where evidence briefs have generally been used, then the government will be involved in funding, regulating and/or even delivering the intervention and supports for its widespread use. Therefore, the government or Ministry of Health, depending on the setting, will need to decide on approving such a change. (4,35) *Third*, a choice can be made in the selection of where the recommendations are to be implemented (e.g., regional or national level, or at a single hospital or region, as in a pilot study). (16,35) This will make a difference for the target audience (e.g., parliamentary representatives, hospital administrators), the format (e.g., evidence brief), the language, etc. but it will also make a difference for the context to be considered in the process. *Fourth*, thinking about advocacy strategies once the venue has been selected could help determine who to involve in the process (e.g., end-users) keeping in mind that these participants may also bring their own viewpoints to bear in how the problem is framed, and therefore, also in the solutions to be considered in solving the problem. (26,47) *Fifth*, whenever an intervention is new to a setting, there are going to be implementation considerations at multiple levels (i.e., healthcare recipient, provider, organization, and system levels). However, it is important to keep in mind that healthcare recipients and providers do not necessarily play a single role within any given system (4,24,26,51–53) As one example, there are interactions between healthcare recipients and the intervention (e.g., drug side effects), between healthcare recipients and providers (e.g., speaking the same language), between healthcare recipients and organizations (e.g., distance),

between healthcare recipients and system-level factors (e.g., ability to pay for services as a financial arrangement, involvement in a politically-organized interest group). Each of these interactions could facilitate or create barriers to successfully implementing the intervention. *Sixth*, specified dissemination strategies (e.g., publishing in journals, conferences), along with advocacy strategies, are important to include in order to ensure there is uptake of the recommendations. (24)

Seventh, equity issues are considered in multiple steps in the process of developing an evidence brief and are therefore not addressed as a separate step in figure 3. However, as is shown in appendix 4 and reinforced in chapter 3, equity considerations can help shape how the problem is defined and in identifying implementation considerations.

Integrating contextual factors into evidence brief development as a strategy to maximize the implementability of recommendations

Another way to look at the above information is to organize the data by each step in the process of developing an evidence brief, identify the themes that are important within each step, and consider what contextual factors play a role in each. This analysis is represented in table 4. There appear to be four unifying mechanisms by which these factors may play a role in developing implementable recommendations: 1) determining relevance, 2) aligning with government priorities, 3) selecting policy options that are technically feasible, fit with dominant values, and are workable from a budget perspective, and 4) integrating contextual factors as a strategy for implementation. To explain these mechanisms,

we started with Kingdon's (54) description of the four steps in the policymaking process: setting the agenda, specifying alternatives from which a choice is made, making a choice from those alternatives (e.g. legislative vote or presidential decision), and implementing the decision. Under Kingdon's model, there are three streams that align in order to help get a topic on the government's agenda - the problem, politics and policy streams. The problem stream deals with how a problem comes to attention and how a problem is defined. According to Kingdon, problems are brought to attention by systematic indicators, focusing events such as crises or disasters, or feedback from the operation of current programs. And, people define conditions as problems by comparing current conditions with their values concerning ideal states, comparing their own performance with other countries or jurisdictions, or by framing the problem in a different way. In Kingdon's model, the politics stream includes swings of national mood, administrative or legislative turnover, or interest group pressure campaigns. The politics stream overlaps with the political system contextual factors, especially interests and ideas. Lastly, the policy stream deals with developing policy options that are viable in a given setting. In order for a proposal to be given serious consideration, Kingdon states that it must be technically feasible, fit with dominant values and the current national mood, be workable within the budget and have political support. When these streams are coupled, the topic is more likely to get on the government's agenda and, most importantly, the topic could get on the decision agenda, which means a government is more likely to make a

decision on that topic. (54) Following that the goals of generating an evidence brief are to get the topic on the government's decision agenda (and a policy ultimately developed and implemented), these streams provide a useful framework from which to view the role of contextual factors.

It was found that the factors or themes that played a role in each step in the process of developing evidence briefs in chapter 3 lined up with one of these three streams or with the information presented earlier on integrating contextual factors as a strategy for implementation. First, information on clarifying the problem and its causes aligned with Kindgon's problem stream. In other words, there needed to be relevance for a particular setting to determine that it was worth placing one topic as a priority over many other possible topics, not only in the political arena but also from the perspective of other actors involved in the implementation process (e.g., buy-in from providers for the need to change practice, or to undertake a guidance contextualization process). (24,55) Second, aligning the selected topic with the priorities of the government in which the work was to occur (the venue), was seen as a very important factor when determining the topic in the first place. (35) Again, when the government is involved in the funding or delivery of care, not much will likely change unless there is approval from the government authorities to provide resources or change regulations in order to support the change(s) in practice. Third, selecting appropriate policy options for a given setting is more likely to increase the implementability of the recommendation itself, as seen in the above discussions. Having appropriate

policy options could increase the odds of the topic even getting on the government's agenda, as discussed within the policy stream of Kingdon's agenda-setting framework. (54) In fact, part of the contextualization process is clarifying the problem and finding policy options that align with how the problem is framed within a particular setting. In this light, the process of contextualization is a powerful tool to bring the pieces of the puzzle together in aligning local needs and realities with government priorities. And, fourth, the importance of integrating contextual factors in the process of developing an evidence brief as a strategy for implementation (e.g., involving end-users in guidance development) has already been discussed in this paper but is also highlighted in table 4.

Discussion

Main findings

Sixty one documents were reviewed for this study, including documents from the health systems and policy, clinical guideline, public health, general public policy, environment, economics, and management / administration / organization fields. About half were conceptual and half empirical, with a mix of methods used in the empirical documents. There were many terms used in these documents for describing the processes of shaping guidance to fit within a particular setting, to describe the implementability of recommendations, and to define contextual factors that could influence the implementation of the recommendations. However, there was also much overlap between these terms, which could cause confusion for guidance users. In addition, many commonly

used terms lacked analytic power (e.g., organizational context, political environment).

Implementation was at times defined as the last step, or one of the last steps, in the process of knowledge translation, and at times was defined as a whole process leading to implementation. However, the authors argue that incorporating contextual factors as a strategy in the contextualization process could improve the implementability of the recommendations.

Contextual factors that were found to influence the contextualization process included local evidence, health system arrangements (delivery, financial, and governance arrangements), and political system factors (institutions, interests, ideas, and external factors). These factors could affect the large-scale (e.g., national, regional) implementation of recommendations when the government is involved health system decisions (i.e., funding, regulating, or delivering services), which is the case in many countries.

Understanding what contextual factors play a role in each step of the contextualization process through the development of an evidence brief can help set up this process as a strategy to increase the implementability of the recommendations. Four mechanisms were found that could explain these relationships: 1) determining relevance, 2) aligning with government priorities, 3) selecting policy options that are technically feasible, fit with dominant values, and are workable from a budget perspective, and 4) integrating contextual factors as a

strategy for implementation (e.g., involving end users or other stakeholders as a strategy for advocacy).

Strengths and limitations of the study

There were four main strengths of this study and two limitations. One strength was that the research team had knowledge in a diversity of fields, including clinical, public health, health systems and policy, clinical guideline development and implementation, and political studies. This allowed for a broad perspective in both developing the exclusion criteria and in analyzing/interpreting the data. Second, the ability to include multiple types of data in the critical interpretive synthesis method allowed for the inclusion of empirical as well as conceptual papers, which added depth to the analysis. Third, the search strategy was set up to be inclusive of a diversity of fields to increase the knowledge base and the application of the findings. Fourth, to ensure completeness of the findings, three additional papers from the database searches were reviewed in order to make sure no new themes or contradictory concepts emerged, and peer review was conducted with experts in the health systems and policy and the clinical guideline fields to ensure these concepts resonated with current scholarly work in these fields. The peer review process helped strengthen the presentation of the findings.

One limitation of the study was that terms used in the literature were diverse and at times vague. Therefore, the search strategy may not have captured all of the terms, and therefore concepts, regarding this topic. This could be

especially true outside of the health-related fields, such as in environment or education. The second limitation is that while the principal investigator (EA) was familiar with health-related and political studies topics, there were many stages for interpretation in this study – from selecting search terms, building exclusion criteria, and selecting relevant articles for inclusion, to data collection and analysis. Therefore, if someone were to replicate this study, it is possible that other articles and lenses may have been selected. However, each step was discussed amongst team members to ensure these concepts were as rigorous as possible.

Implications for policy and practice

Three main implications for policy and practice were found. First, guidance is used in many health-related fields. And, governments, researchers and stakeholders must apply these guidance recommendations to their context(s). Clinical and public interventions and changes in practice are applied within health systems, which are, in turn, located within broader political systems. Even a “simple” change in drugs for malaria was found to require a health system response and accrued costs outside of the intervention itself. (56) Considerations of these contextual factors in guidance development and contextualization may help increase the implementability of the recommendations. This study strengthens the argument for the need to contextualize global guidance and the framework presented in prior work (4), but adds local evidence as an important contextual factor. Second, having a structured framework that includes these

contextual factors would be helpful for users at the national/subnational level. Our workbook described elsewhere (16) was developed to accompany a WHO guidance document on increasing access to and use of key interventions to improve maternal and newborn health (52), which has been shown to make the process of developing an evidence brief faster and easier compared with usual processes. (35) This current study has provided information that could be used to improve the workbook. And, having such tools accompany WHO guidance could be helpful for users. Third, this paper, along with findings from chapter 2, highlight the gap that still exists on how to incorporate feedback mechanisms from one part of the process to improve another part of the knowledge translation process. For example, systematic feedback mechanisms could be established between guidance contextualization processes to help inform global guidance development processes.

Implications for research

Three implications for research were found. First, the critical interpretive synthesis method was found to be useful when terms were not well defined and highly variable, especially across various fields. Combining methods from qualitative research analysis (i.e., using a template style of data organization) along with the critical interpretive synthesis method of searching and critically analyzing and interpreting data can be helpful in bringing together this wide variety of data, while allowing for the use of theoretical constructs within particular fields (e.g., 3I's, health system arrangements). The detailed description

given about the use of these methods could help others in applying these approaches in other areas. Second, this work provides frameworks of terms used for the processes for shaping global guidance and for contextual factors used in a variety of fields. These frameworks, which builds on prior work, can be used to guide further research and practice in the field of guidance contextualization and implementation. Third, several mechanisms were offered by which contextual factors may play a role in influencing the implementation of recommendations. Future work could look at testing these mechanisms through case studies or other methods.

Acknowledgements

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Figure 1. PRISMA flow chart for inclusion/exclusion of documents in a systematic review

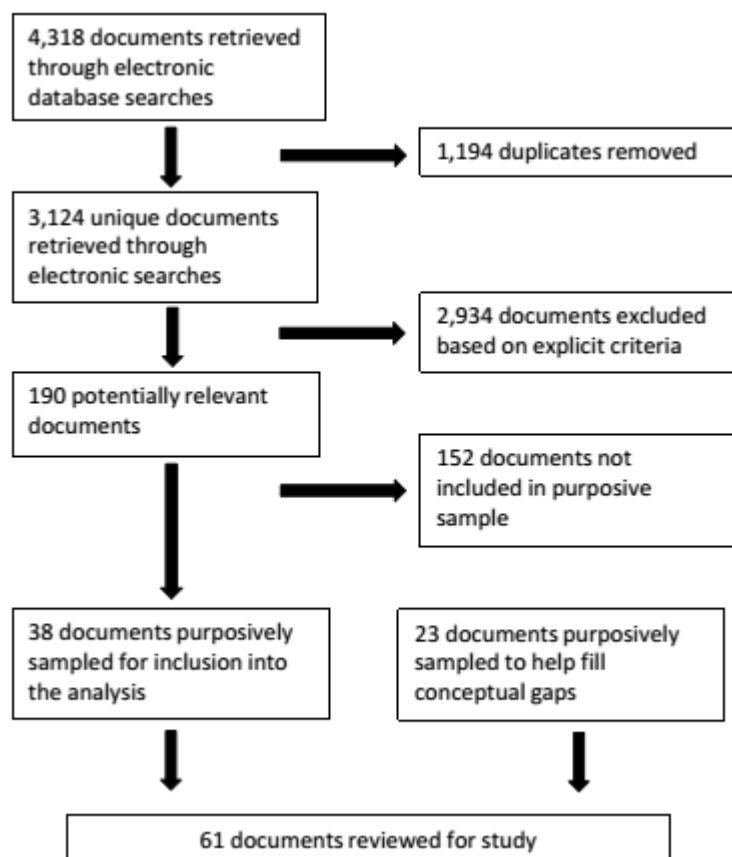


Table 1. Characteristics of documents reviewed for this study

Characteristics		Number	Percent (%) n=61
Peer-reviewed vs. grey literature	Peer-reviewed	50 (+2 in review)	85
	Grey literature	9	15
Main field or discipline (some crossed fields e.g., public health and health systems and policy)	Clinical	23	38
	Public health	2	3
	Health systems and policy	28	46
	General public policy	2	3
	Education	0	0
	Environment	2	3
	Economics	2	3
	Management/administration/ organization	2	3
Year of publication	2015	1	2
	2014	10	16
	2013	10	16
	2012	6	10
	2011	4	7
	2006-2010	14	23
	2001-2005	8	13
	before 2001	4	7
	Not dated	4	7
Conceptual vs. empirical	Conceptual	32	52
	Empirical	29	47
Study design (for empirical papers)	Systematic review	3	10%
	Qualitative (including qualitative literature reviews)	2	7%
	Case study	6	21%
	Mixed methods	13	45%
	Other (cost analysis, unspecified)	5	17%

Table 2. Terms used for shaping guidance for implementation in a particular setting

Term	Definition or description of term and selected sources	Sources discussing these terms
Main goal for clinical interventions, public health interventions, policy interventions or guidance recommendations		
Implement / implementation	<ul style="list-style-type: none"> Implementation as a process e.g., the end of the knowledge translation continuum (20–22) e.g., one step in the process, but not the end (23) e.g., a whole process leading to the use of evidence (could be used synonymously with knowledge translation) (20,24,25) Implementation as a strategy e.g., a strategy for influencing behavior (26,27) e.g., a strategy for improving the quality and effectiveness of healthcare (27,28) Relation to context e.g., selecting an implementation strategy is dependent on context (20,29) e.g., effectiveness of an intervention is dependent on context (30) 	(20–23,25,27,28,30,31,36,37,41,43,45–47,51,53,57–64) (1,3,24,26,29,32,33,36–38,40,42,54,55,64–67)
Potential processes to change guidance for implementation in a specific setting		
Adapt / adaptation(s) / adaptation process / adaption strategy / locally adaptable	<ul style="list-style-type: none"> - “systematic approach to considering the use and/or modification of (a) guideline(s) produced in one cultural and organizational setting for application in a different context.” (28) - Contingent on a guideline(s) needing to exist on the topic already, and needing to be customized to suit the local context. (28) • Adaptation as a process to enhance implementation (23,31) • Adaptation as a product to establish relevance and feasibility – the adapted guideline (28,31,32) • Potential harms of adapting guidelines – too much adaptation for local circumstances could limit the effectiveness of the original findings (28,33) 	(20–24,26,28,30–33,36,42,44–46,48,59,60,62,64–67,69–71)
Adopt / adoption	<ul style="list-style-type: none"> • Adoption as an alternative to adaptation (28) • Adoption as a complement to adaptation (24) 	(4,20,22–24,26–28,32,38,39,41,43–48,51,53,55,60,63,66)
Context / Contextualize / contextualization	<ul style="list-style-type: none"> • Considerations of context in the process of guidance development (1,4,28,30,34,36–38) • Considerations of context in the process of policy development (4,9,16,34,35,39,40) • Context and implementation considerations (4,16,28–30,34,35,40–43) • Context and effectiveness of interventions (28–30,37,40) 	(1,4,16,20,23,24,26,28–32,34–47,51,56–58,60,62–67,70,72,73)
Customize	<ul style="list-style-type: none"> • Requires methods and content experts (31) - Sometimes used as a synonym for adapt (31) 	(28,31,64)
Transfer	<ul style="list-style-type: none"> • Relates to both adaptation and adoption, depending on the contextual factors of the different settings (40,44) 	(20,21,29,30,32,38,39,42,50,58,70)
Translate / translation	<ul style="list-style-type: none"> • Translation into a different format (21,24,45) • Translation into a different language (46) 	(1,4,20,21,24,26–29,31,32,36,41,42,44–47,51,55,59,62,67,71)

Characteristics to enhance implementation of guidance recommendations		
Implementability	<p>“the characteristics of guideline recommendations that may enhance their implementation...” (32)</p> <ul style="list-style-type: none"> • Differentiated from guideline quality (27) • Intrinsic and extrinsic factors of implementability (26–28,32,42) • Guideline implementability tools_(26,27,32,42) 	(21,26–28,31,32,35,40,43,54,58,60)
Acceptability	<p>- “the extent to which the users are likely to adopt a recommendation, based on internal qualities... and on external factors such as the burden imposed on the process and system of care, patient and providers attitudes and beliefs, and patients’ needs, expectations, and preferences”(28)</p> <p>- Related to credibility (33,42)</p>	(4,20,23,28–31,33,42)
Applicability	<p>- “extent to which an intervention process could be implemented in another setting” (30)</p> <p>- In some cases used interchangeably with generalizability and transferability (30)</p> <p>- Sometimes used as a synonym for feasibility (27,28)</p>	(20,26–32,42,43,46,66,71)
Feasibility / feasible	<p>- “Appropriateness reflects whether an intervention is feasible or practical in a specific context (should we do it?)” (29)</p> <p>- Sometimes used as a synonym for applicability (27,28)</p> <p>- Sometimes used as a synonym for cost-effective (58) or as separate entities (47)</p>	(1,20,21,23–33,38,42–48,51,53,58,59,61,62)
Generalizability / generalize	<p>- “the capacity of primary study results to be useful beyond original study populations” (30)</p> <p>- In some cases used interchangeably with applicability and transferability (30)</p>	(21,23,29,30,47,63,71)
Transferability	<p>- “the extent to which the measured effectiveness of an applicable intervention could be achieved in another setting,” focusing on internal and external contextual factors that can impact on the effectiveness of an intervention (30)</p> <p>- In some cases used interchangeably with generalizability and applicability (30)</p>	(22,26,30,71)

Figure 2. Diagram of processes by which guidance can be changed to suit the needs of a specific setting in order to be implemented

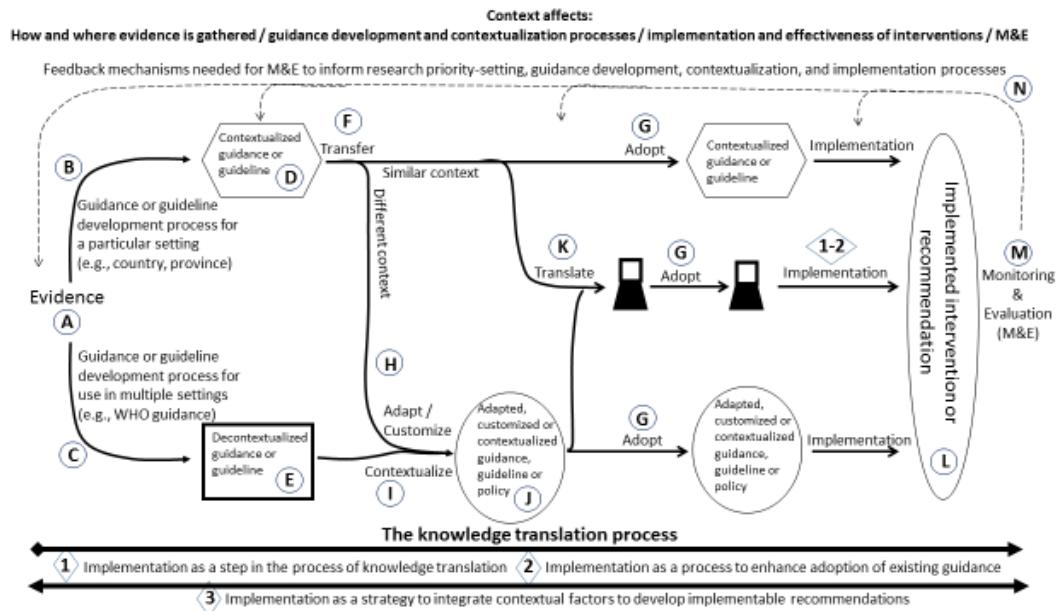
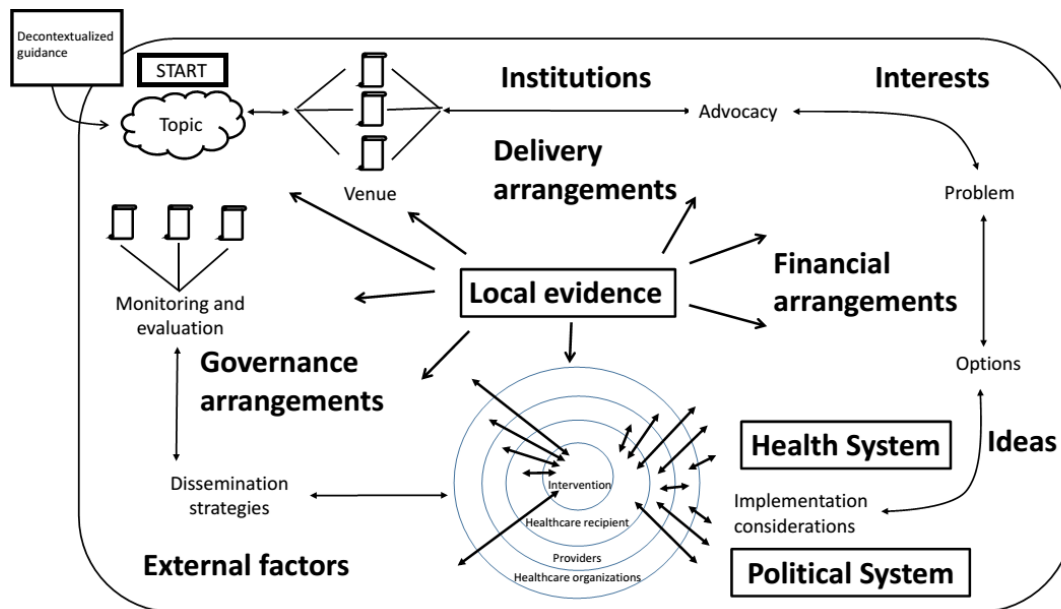


Figure 3. Diagram of contextual factors influencing the contextualization process through the development of an evidence brief



Appendix 1. Databases and search terms used for electronic database searches

Searched through	Database Name	Description of database	Search string used	Number found and comments
CINAHL	AgeLine	Covers policy topics within aging research	TITLE: (context* OR local* OR adapt* OR appl* OR implement* OR link* OR poli*) AND TITLE: (guideline OR guidance OR recommend*) AND no field selected: (tool OR decision support OR support tool OR framemork OR factor OR countr*)	197
	CINAHL	Health care and allied health literature		
	Social Sciences Abstracts	Social sciences topics		
	Teacher Reference Center	Resources for teachers and administrators		
Global health	Embase	Medical database with more European and International works than Medline	TITLE: (context* OR local* OR adapt* OR appl* OR implement* OR link* OR poli*) AND TITLE: (guideline OR guidance OR recommend*) AND TOPIC: (tool OR decision support OR support tool OR framemork OR factor OR countr*)	1532
	Global Health	International database of journals and grey lit in multiple health-related topics		
	Health and Psychosocial Instruments (HAPI)	Database of measurement instruments		
	HealthSTAR/Ovid Healthstar	Clinical and non-clinical aspects of healthcare delivery		
	Joanna Briggs Institute EBP database	Implementation strategies at various levels of health care system		
	PsycINFO	Journals and grey literature		
Web of Science (All Databases)	Web of Science - SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH	General bibliographic database	TITLE: (context* OR local* OR adapt* OR appl* OR implement* OR link* OR poli*) AND TITLE: (guideline OR guidance OR recommend*) AND TOPIC: (tool OR decision support OR support tool OR framework OR factor OR countr*)	1786
OECD iLibrary – Papers	OECD iLibrary - Papers	Grey literature in multiple subject areas e.g. agriculture & food, development, economics, education, employment, energy, environment, etc.	'context* OR local* OR adapt* OR appl* OR implement* OR link* OR poli*' AND Search Results containing 'guideline OR guidance OR recommend*' AND All Fields containing 'tool OR decision support OR support tool OR framework OR factor OR countr*' Including Multilingual Summaries Published Between 1900 and 2014	80 – 2 searches as not all downloaded into Zotero
Pubmed	Pubmed	Health related topics (includes MEDLINE)	TITLE: (context* OR local* OR adapt* OR appl* OR implement* OR link*) AND TITLE: (guideline OR guidance OR recommend*) AND TOPIC: policy <i>NOT</i> cancer, <i>NOT</i> genetic AND MeSH Term: policy	618
	Medline	Health related topics		
Health Systems Evidence	Health Systems Evidence	Implementation strategies to support change in health systems	'context* OR local* OR adapt* OR appl* OR implement* OR link*' AND 'guideline OR guidance OR recommend'	0 - 1 document was reviewed but was not added to the electronic search count as there was no link found
ProQuest Dissertations & Theses A&I	ProQuest Dissertations & Theses A&I	Multiple topic areas	TITLE: (context* OR local* OR adapt* OR appl* OR implement* OR link* OR poli*) AND TITLE: (guideline OR guidance OR recommend*) AND TOPIC: (tool OR decision support OR support tool OR framework OR factor OR countr*)	105 downloaded, however the search was rerun several times. The programs crashed or the articles did not all download into Zotero after several attempts. The articles that downloaded to Zotero were included.
TOTAL				4,318

Appendix 2. Data extraction sheet

Critical interpretive synthesis of contextual factors used in developing policy from health systems guidance - Data extraction sheet

Date: _____

Field: Health: Clinical Biomedical Public health Health systems and policy HTA
 Education
 Environment
 Finance: Economics Business Management
 Other: _____

Title:

Date:

Authors:

Journal:

Methods used:

<p>a. Primary research</p> <p><input type="checkbox"/> Systematic review (needs to have explicit search and selection criteria)</p> <p><input type="checkbox"/> RCT</p> <p><input type="checkbox"/> Cross-sectional</p> <p><input type="checkbox"/> Cohort study</p> <p><input type="checkbox"/> Interrupted time series</p> <p><input type="checkbox"/> Before-after study</p> <p><input type="checkbox"/> Qualitative study</p> <p><input type="checkbox"/> Case study</p> <p><input type="checkbox"/> Mixed methods (select other methods as applicable)</p> <p><input type="checkbox"/> Other (specify)</p>	<p>b. Non-research</p> <p><input type="checkbox"/> Review (not systematic)</p> <p><input type="checkbox"/> Theory/discussion/policy or position paper</p> <p><input type="checkbox"/> Commentary/editorial</p> <p><input type="checkbox"/> Website content (e.g., Choosing Wisely website)</p> <p>c. Publication status</p> <p><input type="checkbox"/> Peer-reviewed journal</p> <p><input type="checkbox"/> Grey literature</p>
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Focus of document / Tools or factors addressed: (Objective 3 - To characterize other tools available for contextualizing guidance recommendations)

Summary:

Keywords:

Codes:

Themes:

Terminology used in the document, and definition(s) given or description(s) used: (Objective 1 - To better define 'contextualization' as it relates to policy development from health systems guidance)

- 1) Context*
- 2) Adapt*
- 3) Local*
- 4) Appl*
- 5) Implement*
- 6) Country / country-level / country-specific
- 7) Link*
- 8) Other

Information found and how it relates to categories found in workbook for contextualizing health systems (Objective 2 – To catalogue what issue- and context-related factors are currently used for health systems guidance contextualization through the health systems guidance contextualization workbook – categories;

Objective 3 – To characterize other tools available for contextualizing guidance recommendations - data;

Objective 4 - To qualitatively and critically explore what issue- and context-related factors are proposed for the contextualization (or adaptation) of health systems guidance recommendations at the national or subnational level - interpretations)

- 1) Selecting a topic
- 2) Identifying a venue
- 3) Clarifying the problem –
 - a) What is the problem?
 - b) How did the problem come to attention?
 - c) Indicators to establish magnitude and how to measure progress
 - d) Comparisons to establish magnitude
 - e) How can a problem be framed to motivate different groups?
- 4) Framing the options
 - a) Creating an appropriate set of options
 - b) Benefits
 - c) Harms
 - d) Local costs
 - e) Adaptations of options and how would this alter benefits, harms and costs
 - f) Stakeholder's views and how would this influence the acceptability of the option

- 5) Identifying implementation considerations
 - a) Potential barriers at 1) healthcare recipient and citizen level, 2) healthcare professional level, 3) organizational level, 4) system level
 - b) Strategies to address behavioral changes at these levels
- 6) Equity considerations
 - a) Differences in access to or quality of care for disadvantaged groups or communities
 - b) Which groups may be disadvantaged by each option
 - c) Baseline conditions which may change the absolute effectiveness for disadvantaged
- 7) Health system context
 - a) Delivery arrangements
 - b) Financial arrangements
 - c) Governance arrangements
- 8) Political system context
 - a) Institutions: government structures, policy legacies, policy networks
 - b) Interests: interest groups, civil society
 - c) Ideas: values, personal experiences, research evidence
 - d) External factors: political changes, economic changes, major reports, technological changes, new diseases, media coverage
- 9) Monitoring and evaluation
 - a) Is monitoring necessary, what should be measured, should an impact evaluation be conducted and, if so, how should it be conducted
- 10) Making policy recommendations – evidence brief, policy dialogue
- 11) Engaging the public
- 12) Others: Advocacy
- 13) Others: Corruption
- 14) Others:

Further references to search (reference chaining):

Appendix 3. Contextual factors influencing the contextualization process and their relationships with other factors or steps in the process of developing evidence briefs

Contextual factors	Terms found in the literature	Relevant themes (and selected sources)	Relationships with other contextual factors (and selected sources)	Relationships with steps in the process of evidence brief development (and selected sources)	Multi-dimensional relationships (e.g., factors acting together to affect a step in the process) (and selected sources)	Sources discussing these themes
Local evidence	<ul style="list-style-type: none"> - local data - local studies - policy-relevant data - colloquial (non-research) evidence - tacit or experiential knowledge 	<ul style="list-style-type: none"> - Sufficient evidence for action (clinical vs. public health) (43), - Lack of evidence and level of evidence (or setting) (national vs. district, hospital vs. prehospital settings) for a particular context (37), and local data as a way to make better decisions but also to build credibility for universal recommendations (48) 		Local evidence can help in <i>selecting the topic and identifying the venue</i> (e.g., level at which data are gathered in the country/region) (35)	Local evidence relates to all other contextual factors and steps in the process by shaping what is known about the problem and its causes and possible solutions within a given setting. (16,47,48)	(1,3,10,14,16,24,28,35,36,41,42,45,47, 50,56,66,70)
Health system context						
Delivery arrangements	<ul style="list-style-type: none"> - organizational context - organizational opportunities - organizational barriers - organizational structure - institutional circumstances - availability of health services - organization of health services - skills of providers - medical practice patterns - practice variations - clinical characteristics - infrastructure for the delivery of policy options - service/program delivery 		Relates to <i>institutions, interests, and ideas</i> in that these factors shape health delivery systems (51)	<ul style="list-style-type: none"> - Relates to <i>developing advocacy strategies</i> by helping identify leaders and innovators within the health system (24,26) - Helps <i>clarify the problem</i> and <i>frame policy options</i> that are feasible (4,16,39) - Delivery arrangements play a key role in <i>identifying equity considerations</i> in terms of availability of and access to drugs and services (16) - Directly linked to <i>identifying implementation considerations, developing dissemination</i> 		(16,20,22,23,26–28,30,31,33,36–38,42–45,47,51,53,56,58–65,67) (1,4,24,32,39,66,69,71,74)

	<ul style="list-style-type: none"> - health workforce, resources (human resources) - capacity - information, - how care is designed to meet consumer's needs - by whom care is provided - where care is provided - with what supports is care provided 			<p><i>strategies and anticipating M&E needs</i> (e.g., centralization of services in areas where women do not give birth in hospitals thereby decreasing effectiveness of breastfeeding policies) (51)</p>		
Financial arrangements	<ul style="list-style-type: none"> - organizational context - financing systems - (financial) resources/finances - funding organizations - funding mechanisms - donor funding - socioeconomic environment - economic context - economic characteristics - purchasing products and services - drug pricing - remunerating providers - incentivizing consumers 	<p>Breaking down “resources” into its various aspects (e.g., finances, human resources, etc.) can help in planning</p>	<p>- Financial arrangements are influenced by <i>institutions, governance arrangements</i> (e.g., centralized or decentralized responsibility for funding), and <i>external factors</i> (e.g., grants, donor funding) (23)</p> <p>- <i>Interests and ideas</i> also play a role in financial arrangements (e.g., donor funding for vertical programs vs. integrative care) (51)</p>	<p>Financial arrangements influence <i>identifying the venue</i> (e.g., funding guidance/policy development process), <i>developing advocacy strategies</i> (e.g., involving stakeholders), <i>clarifying the problem</i> (e.g., problem coming from a current health system arrangement), <i>framing the options</i> (e.g., costs), <i>identifying implementation considerations</i> (e.g., incentivizing behavior change), <i>developing dissemination strategies</i>, and <i>anticipating M&E needs</i> since funding is needed to support each of these steps (24–26,33,35,66)</p>	<p>Financial arrangements play a key role in <i>equity considerations</i> in terms of availability of and access to drugs and services, and in <i>delivery arrangements</i> since funding is needed in order to provide these drugs and services (60)</p>	<p>(14,20,22,26,27,29,31–33,40,42–44,50,52,54,55,58,59,63–67,73) (1,4,23–25,28,30,35,36,38,40,43,47,62,63,69,71,74)</p>
Governance arrangements	<ul style="list-style-type: none"> - governance - organizational context - organizational structure - organizational authority - organizational opportunities - political environment - political opportunities - health system capacity - professional authority - feasibility - leadership (style) 	<p>While governance arrangements overlap with institutions, the former is about who can make what types of decisions (citizens, professionals, etc.) and the latter is about how institutions at the government level</p>	<p>- Governance arrangements overlap with <i>institutions</i> in the political system. (4,35)</p> <p>- Governance structures have been related to <i>ideas</i> (e.g. good governance needed to change nursing unit culture) (41)</p>	<p>Governance arrangements influence <i>identifying the venue</i> (e.g., authority for policymaking), <i>developing advocacy strategies</i> (e.g., facilitation), <i>clarifying the problem</i> (e.g., problem coming from a current health system arrangement), <i>framing the options</i> (e.g., benefit of building capacity of</p>	<p>Governance structures have been related to <i>financial arrangements, identifying equity considerations</i>, and <i>anticipating M&E needs</i> (e.g., decentralized governance for drinking water regulation and uneven financing for M&E led to inequity in delivering and</p>	<p>(1,3,14,16,20,23–25,28,30–32,34,36,39,42,45,50,52,57,59,61–64,70,72)</p>

	<ul style="list-style-type: none"> - decentralization (which also relates to institutions and government structures) - policy authority - commercial authority - implementation authority - stewardship - consumer and stakeholder involvement 	influence decisions. (4,35)		administrators), and <i>identifying implementation considerations</i> (e.g., procurement of drugs) (16,24,25,35,41,53,64)	monitoring for safe drinking water) (60)	
Political system context						
Institutions	<ul style="list-style-type: none"> - governmental/ government structures - institutional context - institutional circumstances - institutional barriers - political institutions - political environment - political context - political barrier - political opportunities - political arena - politics - veto points - policy networks - political directives - obligations (e.g., formal legislation, international agreements) - national policy - policy legacies - policy environment - legislation and rules - regulatory status of health care technologies - existing policy objectives - legislation - policies - regulatory context - organizational context - organizational structure - organizational barriers 	There is very little mention of institutions outside of documents relating to national-level policy such as health systems, public health, or environmental policy fields	<ul style="list-style-type: none"> - Some concepts of government structures, such as decentralization, overlap with <i>governance arrangements</i> (4,35,56) - Institutions relate to all <i>health system arrangements</i> as institutions shape the health system (51,56) 	<ul style="list-style-type: none"> - Institutional arrangements were directly linked to <i>identifying implementation considerations</i> as barriers in the implementation of guidelines (e.g., malaria or HIV guidelines with regards to maternal and newborn health) (23,25,28,30,38,53) - Institutions relate to <i>selecting the topic</i> (e.g., alignment with government or Ministry of Health priorities), <i>identifying the venue</i> (e.g., government structures), <i>clarifying the problem</i> (e.g., problem as lack of implementation of past programs or policies), <i>framing the options</i> (e.g., costs of implementation at the national vs. regional level), <i>identifying equity considerations</i>, <i>developing dissemination strategies</i>, and <i>anticipating M&E needs</i> (e.g., based on level of implementation) (35,47,51) 	Institutions relate to <i>developing advocacy strategies and interests</i> (e.g., interest groups at play in various levels of government and policy networks) (23,47)	(1,4,16,20,23,25,28–32,35,36,38,40,42–45,47,48,51,53,56–58,60,62–64,66,69,72)

	<ul style="list-style-type: none"> - business structures - administrative capacities - cultural context - local culture - social institutions - societal structures 					
Interests	<ul style="list-style-type: none"> - cultural context - organizational context - political environment of the local society - political climate - political barrier - politics - political arena - policy environment - institutional circumstances - social norm - social context - social acceptability - vested interests - interest groups - stakeholders (e.g., relevant professional groups, patients, target users, target population, practitioners, consumers, policymakers) - relevant parties - national opinion makers - main change agents - trend setters - participants - civil society 	Interests seem to play a role in contextualization of guidance among three groups: 1) those involved in the process of guidance development (to help make the end product more implementable through the development of practical recommendations, (i.e., stakeholder involvement)) (26), 2) those who help with advocacy and/or dissemination (+/- involvement in the process of guidance development) (24), 3) those not involved in guidance development but who may react for or against a policy / intervention (4,16)	Interests relate to <i>ideas</i> as interest groups are formed around and promote particular ideas, to <i>institutions</i> and <i>governance structures</i> (e.g., policy networks), and to <i>external factors</i> and <i>financial arrangements</i> (e.g., global interest groups, donors) (29,44,47,51)	Interests influence <i>selecting the topic</i> and <i>identifying the venue</i> (e.g., aligning with government priorities at a particular level) (35,47)	Interests influence <i>developing advocacy strategies, clarifying the problem, framing the options, identifying implementation considerations, identifying equity considerations, and developing dissemination strategies</i> all based on how the problem is framed to mobilize various groups (i.e., <i>ideas</i>) (24,35,42,47,51)	(16,20,21,23–25,28,30–32,36–39,43,45–48,51,55,56,58,59, 62,64,66,74) (4,26,29,35,40,42, 44,72)
Ideas	<ul style="list-style-type: none"> - cultural context - culture - local culture - political environment - political opportunities - political barrier - organizational opportunities - public opportunities - social norm 	Most of the references are to patient, stakeholder or the population's preferences, but decision makers have their own preferences, values and beliefs, which may not be	Ideas relate to the other contextual factors by shaping the political and health system and to <i>local evidence</i> by determining what, where and how to		Ideas relate to all steps in the process by shaping the priorities of the government and shaping the framing of the problem, all while being influenced by <i>interests</i> (35,41,43,47,51,54,64)	(23–25,27,28, 30,32,34,36, 39–41,44,45,47, 50,56,61–63,65,69, 74) (4,16,20–22,26,29,31,33,35, 37,39,40,44,45,54, 58–60,65,68,71–73,75)

	<ul style="list-style-type: none"> - social circumstances - socioeconomic environment - societal perspective - societal preference - institutional circumstances - policy environment - public support - stakeholder support - information - evidence - research evidence - interpretation - theory - preferences - (social) acceptability/ acceptable - experience - personal experiences - values - beliefs - views - judgment - ethical considerations - practices - ideology - ideological context - ideas - perception - connotations - attitudes - expectations - concerns - traditions 	reflective of the public's views. (4,16)	gather evidence (47,51,66)			
External factors	<ul style="list-style-type: none"> - policy environment - political climate - political changes - external pressures - public support - media support - media coverage - communications 	Few documents discussed the impact or consideration of external factors			External factors can shape how problems are defined and what is receiving attention. In this way, external factors can influence <i>ideas</i> and can shape <i>developing advocacy strategies, clarifying the</i>	(3,10,14,25,34,36, 38,53)

	<ul style="list-style-type: none"> - economic changes - global economic pressures - socioeconomic environment - major reports - technological changes - technological advances - new diseases 				<p><i>problem, framing the options, identifying implementation considerations, and identifying equity considerations (e.g., political changes or major reports framing the problem in a different way or offering new solutions to long-standing problems) (4,54)</i></p>	
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Appendix 4. Steps in the process of guidance contextualization and mechanisms by which contextual factors influence these steps as part of an implementation strategy

Steps in the process of guidance contextualization	Relevant themes (context-related factors associated with theme) (selected sources)	Mechanisms (Kingdon (54)+ implementability)	Sources
Selecting the topic	<ul style="list-style-type: none"> - Relevance of the topic (problem stream) (local evidence, interests, ideas) (16,28,35,54,55) - Ties into <i>clarifying the problem</i> through criteria that help establish relevance: prevalence of the condition, burden associated with the condition, potential for improving quality of care or patient outcomes, etc. (35,47,55)- Alignment with priorities of Ministry or government and finding the right time (window of opportunity) (politics stream) (institutions, interests, ideas, external factors) (35,47,54) - Consideration of priority regions/ populations (institutions, interests, ideas, local evidence) (35,47) - Alignment with guidance (policy stream) (external factor) (4,35,54) 	<ol style="list-style-type: none"> 1) Determining relevance 2) Aligning with government priorities 3) Selecting policy options that are technically feasible, fit with dominant values, and are workable from a budget perspective 4) Integrating contextual factors as a strategy for implementation 	(4,16,20,22, 28,31,35, 39,40,47, 54,55,77)
Identifying the venue	<ul style="list-style-type: none"> - Level of government responsible, which is needed to identify the target audience, product, language and format (institutions, financial arrangements, governance arrangements) (16,35) - Government commitment to evidence-informed policy making (ideas) (35) - Professional connections (institutions, interests) (4,35,72) - Type of research available in the country (e.g., district or national evidence) (local evidence) (35) - Prior laws or level of authority for regulations (e.g., training) (institutions, governance arrangements) (4,16,35,72) 	As above	(4,16,23,28, 35,42,55, 71,72)
Developing advocacy strategies	<p>Examples of advocacy strategies:</p> <ul style="list-style-type: none"> - targeting a specific audience, mainly policymakers, researchers and administrators within institutions - national technical working groups, collaboration between programs in developing guidance (institutions, interests, ideas, governance arrangements, financial arrangements) (23,51,53), - targeting specific communities or providers - community engagement, community participation, stakeholder involvement, champions / facilitators, (interests, ideas, delivery, financial and governance arrangements, implementation considerations) (24,41,48,51), - targeting a broader audience of policymakers, providers, stakeholders, and health care recipients - social marketing, electronic media, publishing in journals, conferences and workshops, evidence briefs (all contextual factors) (24,30,48) 	As above	(16,20,22– 24,29,30, 38–42,44, 47,48,51, 53,54,56, 62,64,69, 78)
<p>Clarifying the problem</p> <p>Other terms used: health questions,</p>	<ul style="list-style-type: none"> - Defining the problem as: <ul style="list-style-type: none"> - a risk factor, disease or condition (institutions, local evidence) (16,28,30,47) - the programmes, services or drugs currently being used to address a risk factor, disease or condition (implementation considerations, local evidence) (16,28) 	As above	(4,16,20,25, 28–32,36, 39,42,46, 47,51,53,55 ,60,62,66, 67,69,72)

health goals, policy goals	<ul style="list-style-type: none"> - the current health system arrangements (financial, delivery, and governance arrangements, local evidence) (16,28) - the current degree of implementation of an agreed upon course of action (implementation problems) (implementation considerations, financial, delivery, and governance arrangements, institutions, interests, ideas, external factors) (16) - Problems are brought to the attention of participants by: (16,54) <ul style="list-style-type: none"> - Systematic indicators (e.g. wait times) (local evidence) - Focusing events like crises and disasters (external factors) - Feedback from the operation of current programs (financial, delivery, and governance arrangements, local evidence) - People define conditions as problems by: (16,54) <ul style="list-style-type: none"> - Comparing current conditions with their values concerning ideal states (ideas, local evidence) - Comparing own performance with other countries (ideas, local evidence) - Moving the subject into a different category (ideas) - Relates to <i>interests/advocacy</i> in that “The way in which expertise is defined and SAB [scientific advisory boards] are structured determines how a problem is framed, which in turn influences the decision around the inclusion or exclusion of particular perspectives and the way in which facts are selected and interpreted and conclusions are drawn...The framing of the problem by the significant opinion leaders such as the media, think tanks, or major NGOs is taken into account.” (47) 		
Framing the options	- “Policy or programme options may be more appropriate when they are technically feasible, fit with dominant values, and are workable within the budget” (16,54)	3) Selecting policy options that are technically feasible, fit with dominant values, and are workable from a budget perspective 4) Integrating contextual factors as a strategy for implementation	(4,16,20,23, 30,36,39, 47,49,50,54 ,56,72,79, 80)
Other terms used: recommendations, policy goals, policy options	<ul style="list-style-type: none"> - Includes consideration of benefits, harms and costs (all contextual factors) (16,79) - Includes consideration around communication of scientific uncertainty in policymaking (47,50) 		
<i>Benefits</i>	- Benefits must be considered for each recommendation in a particular setting and must outweigh harms / costs, which includes judgements (4,16,28,47,57,59)		(4,16,22,23, 26-28,30, 31,33,36, 45-47,55, 57,59,60, 63,68,70)
Other terms used: desirable outcomes / societal impact	- Benefits extend beyond the recommendations to the process of guideline development by involving stakeholders, bringing awareness to the topic and for advocacy (26,57)		
<i>Harms</i>	- Important to consider potential harms, who could be affected, and how to mitigate harms (23,47)		(4,16,20-23,26,28, 46,47,51, 55,59,70)
Other terms used: side effects / risks / unintended consequences / undesirable outcomes / societal impact	<ul style="list-style-type: none"> - Need to consider individual level as well as societal and health systems effects (16,23) - Important to consider effects of intervention (e.g., risks and benefits of treatment), effects of foregoing alternative options / focusing on the selected options (e.g., framing of problem, single-disease focus vs. integrating care), short-term and long-term effects (e.g., risk of drug resistance) (23,47,51) 		
<i>Costs</i>	- Mainly concerned with cost or resource implications of implementing a recommendation (costs of the intervention itself and costs associated with policy change / implementing		(16,20,22-27,29,32, 33,36,41, 42,44,46-

Other terms used: resources, cost implications, resource implications, financial resources	the intervention). However, also need to consider cost or resource implications of process of developing guidance (23,28,66) - Other considerations for determining costs: appropriate economic evaluation method, broader public sector costs (i.e., outside of health sector), time horizon and activities used in evaluation (e.g., future pay-offs for public health interventions) (16,56,58) - Consider tools such as developing a template of an ideal implementation process, with associated costs, to help plan policy changes (45,56)		48,51,56, 58,61–64, 66–68,71, 73) (21,28,30,3 1,37,43,54, 58,59, 69)
Identifying implementation considerations	- Many examples are given of barriers and / or facilitators at multiple levels of implementation. Most of these are specific to the intervention / setting. However, most documents clump all facilitators and barriers together, yet it is important to assess barriers and facilitators at all levels involved in the implementation process (healthcare recipient and citizen level, healthcare professional level, organization level, system level) in order to better analyze the process and outcomes of implementation. (all contextual factors) (16,23,56)	1) Determining relevance, 3) Selecting policy options that are technically feasible, fit with dominant values, and are workable from a budget perspective 4) Integrating contextual factors as a strategy for implementation	(4,16,21– 24,27,28, 30,32,33, 38–42,46– 48,51,53, 55–57,61, 62,64,66– 68,70,72, 76,78)
Identifying equity considerations Other terms used: equality / equitable	- Increased vulnerability of a population due to characteristics of that population through biological differences or lack of access to (or poor quality) interventions or services (i.e., determinants of health) (all contextual factors) (16,47,51,60) - Linked to <i>ideas</i> as a value in policymaking and to acceptance of an intervention by actors at multiple levels (4,16,47) - Can be influential in <i>clarifying the problem</i> and in <i>identifying implementation considerations</i> , including <i>health systems arrangements</i> and <i>political systems factors</i> (35,47) - <i>Anticipating monitoring and evaluation needs</i> includes consideration for differences in baseline conditions and effects of interventions (16,30,47,60)	1) Determining relevance 2) Aligning with government priorities 3) Selecting policy options that are technically feasible, fit with dominant values, and are workable from a budget perspective 4) Integrating contextual factors as a strategy for implementation	(1,3,14,16, 20,22,23, 30,40,45, 50,57–59, 61)
Developing dissemination strategies	- Reflects back to <i>developing advocacy strategies</i> , except the dissemination strategies are more targeted once the problem has been clarified and the options have been developed (all contextual factors) (24)	4) Integrating contextual factors as a strategy for implementation	(1,16,20, 22–24,29, 30,38,39, 42,44,47, 48,56,62, 64,69,78)
Anticipating monitoring and evaluation needs Other terms used: audit, quality indicators, feedback, measurement, outcomes, metric	- Levels proposed: process (e.g., guideline implementation), behavioral (e.g., adherence to recommendations), and impact or outcome (e.g., clinical or health outcomes) (16,20,41) - Relates to <i>identifying equity considerations</i> and <i>financial arrangements</i> in that differential access to resources for M&E may exacerbate inequities (47,60) - Relates to <i>identifying implementation considerations</i> and <i>ideas</i> (e.g., feedback and audit as a strategy for behavioral change) (33,38,41)	3) Selecting policy options that are technically feasible, fit with dominant values, and are workable from a budget perspective 4) Integrating contextual factors as a strategy for implementation	(20,23,24, 32,33,36, 38,39,46, 47,55,58,60 ,64,66,67) (4,16,21,22, 25–31,41, 42,45,53, 56,59,62, 70)

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Chapter 5 – Conclusions

It has been recognized that in order for global guidance to strengthen health systems, the issue addressed by the global guidance first needs to get on the government's agenda, the guidance needs to inform policy development, and the policy needs to be approved and implemented. (1,2) Furthermore, the guidance recommendations need to be contextualized or adapted to a particular setting, whether national or subnational. (1) Together, the three studies presented in this dissertation offer a way to examine the development and use of a workbook as a tool for contextualizing health systems guidance. The workbook offers a user-friendly, systematic and transparent method for preparing evidence briefs at the national or subnational level, while incorporating critical contextual factors that can impact on the implementability of the recommendations. Evidence briefs have been used extensively in both high-income and LMICs to enhance knowledge translation efforts. (1,3–6) Using qualitative methods, in which both the phenomenon being studied and the context surrounding the phenomenon can be evaluated has provided rich insights into factors affecting the development of the workbook (chapter 2), the use of the workbook (chapter 3), and further defining contextualization and what and how contextual factors influence this process through the development of evidence briefs (chapter 4). This chapter first provides a summary of findings from each study and then presents recommendations for improving the workbook gathered through the three studies. The substantive, methodological and disciplinary contributions of each study and

the dissertation as a whole are provided. Finally, the strengths and limitations of the dissertation and the implications for future research are discussed.

Principal findings

The three studies each look at a part of the process of developing and evaluating the use of a workbook for contextualizing health systems guidance. Chapter 2 used a case study approach to explore the process of developing the workbook. It was important to understand how the process unfolded, but also who was involved and what barriers and facilitators arose throughout the process in order to inform future plans for developing knowledge translation tools at the international level (i.e., WHO). Thirteen interviews, 52 documents, and a reflexive journal, which was kept throughout the process to provide insights into the process and context as well as decisions that were made, were used as data for this study. Three main steps, and various sub-steps, were identified in the process of developing the workbook for health systems guidance contextualization: 1) determining the need for the workbook and gaining approval to develop the workbook, 2) developing the workbook (taking on the work of developing the workbook, creating the structure of the workbook, operationalizing the workbook, undergoing approval processes, and editing the workbook), and 3) implementing the workbook both at the WHO level and at the national / subnational level. At each of these steps, five critical factors emerged from the data as barriers and/or facilitators: 1) having well-placed and credible champions, 2) creating and capitalizing on opportunities, 3) finding the right language to engage various

actors and obtain buy-in, 4) obtaining and maintaining meaningful buy-in, and 5) ensuring access to human, financial and other resources. It was found that an assessment of the presence or absence of these factors could help explain why the work moved forward or not for each step. Specifically, approval was gained to develop the workbook (step 1), and the workbook was developed and published online in December 2012 (step 2). However, implementation of the workbook at the WHO and national/subnational levels has not yet occurred because of the absence of several of these critical factors. Briefly, at the WHO level, there are champions who have been trying to institutionalize the idea of having workbooks developed as part of the guidance development process, but they have not been able to obtain meaningful buy-in from other actors involved in the guidance development process. At the country level, it may be difficult to find champions who can take on this work, and limited capacity and resources for developing locally relevant research or for local guidance development have provided few opportunities to move this work forward. In addition, there are some regions or countries where evidence is not valued as an input into the policy process, so not gaining buy-in could also present a barrier. Two exceptions are Peru and Uganda, where these five factors were in place as part of the study described in chapter 3. Specifically, champions within those countries already bought into the importance of evidence-informed policymaking, and there were resources to support the opportunities to evaluate the use of the workbook in these countries. Several

recommendations were provided by the participants for improving the workbook, and these were incorporated into the recommendations below.

Chapter 3 examined the process of using the workbook to develop evidence briefs in two quite different settings, Peru and Uganda. An embedded case study was used to explore the process of using the workbook but also highlighted the importance of context in developing policy to suit the needs of a particular setting. Nineteen participant-observation sessions, 8 interviews, 50 documents, and a reflexive journal were used as data for this study. Even though both countries started with the same guidance recommendations and the same method to develop an evidence brief (i.e., the workbook), and even the same facilitators (both myself and my supervisor, John Lavis), each country team, because of unique contextual factors, ended up focusing on very different topics, venues for decision-making, ways to define the problem and its causes, potential policy options, and considerations for implementation. Overall, the workbook was seen as helpful by the participants when compared with usual processes for developing evidence briefs. And, in fact, participants in both countries stated they were using or would use the workbook again for other topics. However, it was noted that the process of contextualizing guidance is time and resource intensive and cannot replace the work of methods and content experts from the specific country. Benefits and challenges of using the workbook were provided, and recommendations found through this work are provided later in this chapter.

Chapter 4 uses a critical interpretive synthesis method of literature review combined with qualitative methods for data analysis (e.g., template-organizing style, and constant comparative method) to review a wide range of literature from various fields in order to better define contextualization and to identify contextual factors which could be used in adapting global guidance at the national or subnational level. Based on 61 relevant documents identified through electronic database searches (n=38) and additional purposive sampling to fill conceptual gaps (n=23), models were developed of: 1) the processes by which guidance can be changed to suit the needs of a specific setting in order to be implemented, and how context relates to these processes, and 2) contextual factors influencing the guidance contextualization process. The chapter describes how integrating contextual factors as part of the development of evidence briefs can be used as a strategy to maximize the implementability of guidance recommendations at the national / subnational level. Furthermore, contextual factors to be considered include: local evidence (evidence specific to the jurisdiction of focus), health system arrangements (delivery, financial, and governance arrangements), and political system factors (institutions, interests, ideas, and external factors), along with other implementation considerations for a particular intervention. In addition, four mechanisms are suggested for how these contextual factors may increase the implementability of the recommendations by: 1) determining relevance, 2) aligning with government priorities, 3) selecting policy options that are technically feasible, fit with dominant values, and are workable from a budget

perspective, and 4) integrating contextual factors as a strategy for implementation (e.g., involving end users or other stakeholders as a strategy for advocacy). Lastly, recommendations for improving the workbook were gleaned from this work, and are presented next.

Recommendations for improving the workbook

Altogether, each of these studies has provided information about how to improve the workbook for contextualizing health systems guidance. The recommendations are drawn from the perspectives of global guidance developers (chapter 2), users of guidance at the national/subnational level (chapter 3), and a multidisciplinary literature search of guidance or guideline contextualization or implementation (chapter 4). This section is broken down into components that could be added or highlighted in the workbook and potential modifications to the workbook. There was an explicit attempt in chapters 2 and 3 to identify components that could be removed from the workbook, especially since participants in both studies stated the workbook was too long, but no specific components were identified by the participants for removal. Instead, a couple of participants remarked specifically that each component was useful.

Components that could be added or highlighted in the workbook

Selecting the topic

The workbook does not currently address ‘selecting a topic’ as an explicit step, given it was assumed that the guidance document itself would serve as the basis for the topic. However, it was found in chapter 3 that selecting the topic was

very much a step in the process, even with an available guidance document. The reason was that the issue had to align with the priorities of the government or Ministry of Health. In Peru, the topic was changed from delivering (birthing) at a health facility, to increasing access to and use of contraception in one specific region, Loreto, Peru, because of considerations of the Ministry's priorities (which changed due to a change in leadership). In Uganda, the topic remained broad and all of the recommendations in the OptimizeMNH guidance were reviewed, but this was after much discussion around other factors which could have influenced selecting a topic. Uganda's EVIPNet team usually worked through a rigorous process of selecting a topic that was relevant to policymakers in Uganda (including surveys and Delphi techniques to select topics). Having the workbook, and focusing on the guidance, however, made this process much shorter than it otherwise would have been because the OptimizeMNH guidance already described the problem of lack of access to key interventions to improve maternal and newborn health from a global perspective, and because it was determined that the process would include working through the relevant recommendations for Uganda. Several documents were found in chapter 4 that addressed the importance of selecting a topic, especially as differentiated from clarifying the problem. (7) These findings resonated with the findings from chapter 3. Therefore, it is recommended that the workbook include a step in its framework to address the importance of 'selecting the topic and identifying the venue' (next section), and that the factors found to be relevant in chapters 3 and 4 be included.

Identifying the venue

The workbook currently mentions that a venue for decision-making should first be identified, which helps determine the audience, format, and language for presenting the information found through the process of developing an evidence brief. As was found in chapter 3, this step was discrete, yet iterative, in relation to selecting the topic and other aspects of developing the evidence brief. For example, deciding whether the target venue was at the national or a subnational level was discussed for both countries, following the suggestions of the workbook. The venue turned out to be different based on the contextual factors of each country (see chapter 3). Determining the venue was important for deciding who to involve in the process, as different jurisdictions follow varying processes and can involve different people, such as a working group in Uganda at the national level. The venue also determined the context used for clarifying the problem, framing the options and identifying implementation considerations, including consideration of health system and political system contextual factors. These points strengthen the recommendation to add a step for ‘selecting the topic and identifying the venue.’

Developing advocacy strategies

A couple of participants in chapter 2 first identified the need to highlight advocacy strategies. The workbook, in its current form, discusses engaging the public, including stakeholders, in the process of developing evidence briefs.

However, this is part of step 8 on making national or subnational policy recommendations or decisions. Chapter 3 also reinforced the need to highlight advocacy strategies, but none of the participants offered specific strategies to include. The work for chapter 4 did discover several specific advocacy strategies, such as involving end-users in the guidance development or contextualization processes or finding influential early adopters who could then promote the changes (e.g., health workers changing practice) (8,9). However, these strategies were setting- and intervention-specific, so a full listing of these was not pursued. Instead, it is recommended that a specific step be added to the workbook on identifying advocacy strategies, which could include examples for users based on the topic of the guidance. This could also include thinking about stakeholder and public engagement in the process of developing the evidence brief, which will have to align with country processes and the topic. The benefits highlighted for including stakeholders in the contextualization / adaptation process included improving dissemination and advocacy and bringing forth ideas about how to clarify the problem, frame the options and identify implementation considerations. (8–10)

Resource implications for framing policy options

Even though costs and resource implications are mentioned in the workbook currently, it was noted in both chapters 3 and 4 that policymakers pay a great deal of attention to costs, yet this area is not well elaborated in many evidence briefs. Tools such as developing a template for an ideal implementation

process, with associated costs, to help plan policy changes, could be considered.

(11)

Developing dissemination strategies

Dissemination strategies were mainly brought forth through the documents in chapter 4, and they were often linked with advocacy strategies. (9) However, it is recommended that advocacy strategies be considered up front as a way of thinking about who to involve in the process of developing an evidence brief, while dissemination strategies and further advocacy strategies also be considered as each option is being developed in order to target these strategies for each recommendation. So, a separate step could be added to the workbook, but in an effort to try to keep the workbook condensed, this issue could also be addressed in the advocacy section or as part of implementation considerations.

Considerations of corruption

Considering corruption as a factor in contextualization was first conceived in discussions with peers at McMaster University and documented in the reflexive journal. Corruption was again mentioned as a consideration for selecting specific jurisdictions in which to evaluate the use of the workbook in a country that was eventually not included in the study described in chapter 3. However, this consideration was kept in mind throughout the latter studies. In chapter 3, participants in both Peru and Uganda were explicitly asked about including considerations of corruption as part of the workbook. This elicited a strong reaction against doing so based on the understanding that corruption was very

prominent in parts of Latin and South America and Africa (and other parts of the world), and mentioning it as a factor could create problems, especially with policymakers or stakeholders who might believe this was directed at them. Only one document in chapter 4 was found that mentioned corruption (12). While there may be much more research in this area, it was felt that, at this point in time, encouraging the use of a transparent process (such as the workbook) could be used to hold those involved in the implementation process accountable and therefore it was best not to address this topic explicitly.

Glossary of medical terms

In chapter 3, a couple of participants noted that a glossary of medical terms could be useful for those policymakers and stakeholders who did not have a health background. Being able to put the implementation of an intervention in perspective required an understanding of what the intervention involved (e.g., who could carry out the intervention, how invasive was the intervention, what type of facility was required, what supplies and supports would be needed, etc.). This issue only came up in Uganda, where a couple of participants did not have health backgrounds. Everyone involved in the development of the evidence brief in Peru had health backgrounds, so this was not raised as an issue, but the participants did state that this could be helpful for other users. The question was then whether the glossary of medical terms should be provided as part of the guidance document itself or as part of the workbook to contextualize the guidance. It was determined that either way would suffice, but this highlighted the

fact that there needed to be feedback loops to inform guidance development processes from what was learned by using the guidance at the national / subnational levels.

Potential modifications to the workbook

Format

As was mentioned previously, the workbook was considered to be too long, even though no suggestions were made to remove any specific parts of the workbook. However, participants in both chapters 2 and 3 suggested that the workbook could be more visually appealing given there is so much text currently, particularly in the introduction section. This will need to be looked at further to see how these changes could be made.

Language

Another suggestion made by participants in chapter 2 was that the workbook (and the OptimizeMNH guidance) sounded very academic and that it would be helpful to use more lay language in order for policymakers and stakeholders to understand the terms and concepts better. In chapter 3, several participants stated that the language could be made simpler but also mainly suggested that using more examples could be helpful. Other participants felt the language was easy to understand and that plenty of examples were provided. It is recommended that complementary products be developed for use by various audiences (e.g., executive summary, workshop presentation, etc.) alongside the workbook.

Study contributions

The workbook for contextualizing health systems guidance is the first tool to provide a systematic method to combine global recommendations with national / subnational assessments of local problems and their causes, as well as of existing health system arrangements that may need to be changed, and political system considerations that need to be taken into account. Substantively, this dissertation overall provides a better understanding of the processes involved in developing and evaluating the use of this workbook and the contextual factors which affected various parts of these processes. In addition, the three studies offered a unique methodological approach to evaluating the workbook using qualitative research methods. Another unique methodological aspect was that information gathered in one study was compared and contrasted to findings within the other studies, which strengthened concepts within each study and the recommendations made to changing the workbook as described above. This dissertation contributes to the field by suggesting ways in which to improve the workbook but also by suggesting considerations for the processes involved in developing and using the workbook. Substantive, methodological and disciplinary contributions of each study are discussed next.

Substantive contributions

Chapter 2 highlights that developing the workbook was not a singular process, but was instead made up of discrete steps and substeps. In addition, a model was created of the critical factors, and their relationships, that contribute to

the success or non-success of each step in the process of developing the workbook. Together, these insights could help those looking to develop tools at the international level plan for possible barriers and facilitators in order to improve the chances that their work will be successful.

Substantively, chapter 3 provides first-hand insights into what and how contextual factors played a role in developing an evidence brief and shaping policy recommendations in Peru and Uganda. There has been a call for greater understanding of these factors and their roles, as the contextualization process is key to creating implementable policies for particular settings. (1,3) Building on these findings, and through a systematic literature review, two new theoretical models are presented in chapter 4. The first model is on the processes by which guidance can be shaped to fit a particular setting and how context relates to this process and to the implementation of recommendations. The second model shows what factors influence the guidance contextualization process. In addition, mechanisms by which contextual factors may affect the chances of policy being implemented are described. This work adds substantial efforts in furthering the knowledge in what and how contextual factors play a role in guidance contextualization and policy development processes.

Methodological contributions

Chapters 2 and 3 used qualitative case studies (13,14), which provided the opportunity to not only explore in an in-depth way the processes of developing and using the workbook, but also allowed for the contexts to be examined. Often,

contexts are described as a means to develop a rich description of the phenomena.

(14) However, exploring the contexts and relating contextual factors to the processes were also central to the creation of the models in this dissertation. In addition, both of these case studies included prospective components (chapter 2) or were fully prospective (chapter 3) in nature. This allowed for prospective data collection methods such as participant-observations, which while not new methods, did provide an immense amount of first-hand experience with the processes and factors affecting the processes under study.

Chapter 4 presents a critical interpretive synthesis method of literature review, which was found to be well-suited to the purpose of finding a wide variety of literature from various fields while searching for terms that were quite vague and overlapping at times. In addition, several related concepts were searched within the same search strategy, which allowed for individual concepts to be examined (e.g., terms used to describe how guidance is shaped in order to be implemented, and contextual factors used in contextualizing guidance), but it also allowed for relationships to be built between the concepts (e.g., how do contextual factors affect the contextualization of guidance). Combining a critical interpretive synthesis method for systematically reviewing the literature with qualitative techniques for data collection and analysis has been described within the field of health systems and policy in the past. (3) Chapter 4 also presents a detailed description of how these methods can be combined, along with a template-style of data organization and a constant comparative method, which helped facilitate the

collection and analysis of information. Lastly, by incorporating theories from various fields, such as the health systems and policy framework for components of health systems (delivery, financial, and governance arrangements) (1), the political studies “3I” framework for components of political systems (institutions, interests, ideas, and external factors) (1,3), Kingdon’s agenda setting model (problem, politics and policy streams) (2), and multiple frameworks from the clinical guideline and public health fields on guideline implementation (8,10,15–21), allowed for the development of models that could be applicable to a variety of fields that incorporate guidance or guidelines in the use of research evidence for informing policy decision making.

While it is more usual to conduct a literature search as a first study in a dissertation, due to the opportunity that arose to study the process of developing the workbook and the short timeframe given to completing the workbook, the critical interpretive synthesis was conducted after the other two studies had been initiated. Because of the experience gained through the case studies and given that the majority of the literature that could have been included in the critical interpretive synthesis came from the clinical guideline field, it is very likely that the analyses in chapter 4 would have yielded more clinically oriented frameworks than the ones that were developed, if the order of these studies had been reversed.

Another unique methodological aspect of this dissertation overall was that these studies were conducted in a concurrent manner, and information gathered in one study was compared and contrasted to findings within the other studies to

strengthen the concepts found in each chapter and to strengthen the recommendations made to changing the workbook (e.g., the need to highlight advocacy strategies).

Disciplinary contributions

Chapter 2 highlights that understanding the challenges involved in developing and implementing new tools can help identify potential points of tension and find ways to overcome them. For example, understanding the critical factors involved in the process of developing the workbook could help in the planning of the development of other tools (e.g., the need for a well-placed and credible champion) or in evaluating why a process may not be advancing as expected and potential solutions (e.g., trying to find the right language to build understanding and obtain buy-in). Similar findings (i.e., factors) were reported by Gagliardi et al (22) for the implementation of integrated knowledge translation (IKT), or collaboration between researchers and policymakers. Challenges and enablers affecting the success of IKT were similar to those found in this study and included champions, opportunities, organizational endorsement, resistance to change, resources, motivation, and time.

This chapter also highlights the need for having a plan for dissemination and implementation considered during the preparation of these tools. The same message is reinforced throughout every study in this dissertation. Whether it is in planning the development of a clinical guideline, health systems guidance, country-level policy, or a new tool, not having a plan for implementation can

severely limit the use and therefore the usefulness of these resource-intensive product-development processes.

Chapter 3 provides several contributions for the field of health systems and policy. First, the workbook was seen as helpful for contextualizing global guidance in two, quite different, settings, and the participants in both countries felt the workbook made the process of developing evidence briefs easier. Therefore, organizations which produce global guidance, such as WHO, need to consider institutionalizing the development of workbooks (or other tools) into their guidance development processes to help users at the national / subnational level contextualize each guidance document. The workbook, along with the recommendations suggested in this dissertation, could provide a template for other workbooks to accompany guidance / guidelines on other topics developed by WHO. Second, having a team of country experts who understood the health system and the priorities of the government or Ministry of Health was helpful at multiple steps in the process of developing an evidence brief. This is an important consideration for countries that are looking to establish an EVIPNet or that have not already incorporated such networks into their current processes. However, as can also be seen from the findings, contextualizing health systems guidance is a resource-intensive process. There are multiple steps in the process and many elements need to be considered. While the workbook may simplify this process by supporting a user-friendly, systematic and transparent process, it cannot replace the work required by a team of methods and content experts. Third, many low-and

middle-income countries have little capacity for local health- and political-system analysis, for linking research to problems, options and implementation considerations, and for embedding this work into their policymaking processes. WHO and partner organizations may have a role to play in helping countries build this capacity.

Chapter 4 offers three main contributions. First, the importance of considering context throughout the knowledge translation cycle is reinforced. Even in designing primary studies, it is important to report the context within which an intervention is studied. This can help address issues of implementability into a new context. (17,20,23,24) Second, a structured framework that includes relevant contextual factors is described including local evidence, health system arrangements (delivery, financial and governance arrangements), and political system factors (institutions, interests, ideas, and external factors). This framework could be helpful for users of guidance at the national / subnational level and for informing future research and practice in the area of guidance contextualization. If a broader look is not taken at the problem and its causes in a particular area, the health system arrangements, and the political system factors, there will continue to be better and better quality guidelines and health systems guidance that are developed but that ultimately go unutilized. Third and last, mechanisms are presented of how contextual factors could influence the implementability of guidance recommendations. These findings could support users of guidance at the

national / subnational level plan for the integration of contextual factors as a strategy to increase the implementability of their recommendations.

Strengths and limitations

There are four main strengths and two limitations to this dissertation as a whole. The first strength is that all three studies addressed the development and evaluation of the workbook for contextualizing health systems guidance. Having this focus allowed for an evaluation of the processes involved as well as how the findings contributed to recommendations for improving the workbook. In addition, findings from one study were looked at within other studies to understand their overall significance (e.g., corruption, advocacy strategies) and to strengthen the recommendations made for improving the workbook.

Second, the use of qualitative research methods was shown to be very powerful for the types of research questions asked in each study. The case studies for chapters 2 and 3, allowed for an in-depth examination of the processes under study (e.g., developing and evaluating the use of the workbook) as well as the contexts under which these processes took place. Even the critical interpretive synthesis (chapter 4) allowed for the examination of more than one dimension (e.g., terms used to describe processes of guidance adaptation / contextualization and contextual factors influencing these processes). In this dissertation, the study of these contexts and multiple dimensions added a rich understanding of the interplay between contextual factors and various parts of the processes. In addition, methods for ensuring rigor were incorporated into each study. Both case

studies included member-checking and peer review processes, and the critical interpretive synthesis included a review of additional documents to ensure completeness of the findings along with peer review for ensuring the face validity of the concepts.

Third, the information generated by these studies have practical applications, both as stand-alone studies and overall. The individual contributions to the field for each study have already been described above. But, as a whole, this dissertation also provides recommendations for improving the workbook. Having a structured workbook to help users at the national / subnational level combine global recommendations with local evidence and analyses of the local health system and political system is an important step in advancing the use of evidence to inform policy. This dissertation adds a significant contribution with practical recommendations for improving the workbook based on the perspectives of international guidance developers, national users of guidance, and a wide variety of literature from various fields. Even though many of the findings focus on the workbook, which is meant to support the development of evidence briefs, the findings also have practical implications for other fields in which guidance / guidelines are used.

Fourth, the entire dissertation followed a multi-disciplinary approach to each study and to the overall improvement of the workbook. Disciplines which were drawn upon in the collection and analysis of data for all three studies included knowledge translation, health systems and policy, political studies,

guidance / guideline development, health, and public health. Specifically, using theoretical constructs from these fields gave a broader range of tools for explaining the mechanisms by which contextual factors interacted with other elements under study. This allowed for a very rich and practical understanding of the topics and for the application of the findings.

One limitation of this dissertation is that the workbook is used for a defined purpose and time in the development of draft evidence briefs which means that the rest of the process of developing an evidence brief, convening policy dialogues, developing policy that is informed by the evidence brief and policy dialogue summary, implementing the policy, and evaluating the impact of the policy on the population's health is outside of the scope of this dissertation. Therefore, how the contextual factors and components of the processes found in these studies affect the ultimate policy decisions and their implementation is not known. For example, is it better for a country to have an EVIPNet with direct organizational ties to the Ministry of Health, such as in Peru, or is it better to have a broader participatory process, such as in Uganda? The second limitation in this dissertation has to do with the methods used in the case studies. Findings from case studies, while potentially transferable, may not be generalizable to all other cases. So, readers using these methods for developing a different knowledge translation tool would need to consider their own contexts (e.g., is the tool developed at the international level) before applying these findings to their work.

There are three additional limitations to point out for individual studies. First, chapter 2 had the potential for recall bias with retrospective interviews recounting events that were as distant as 4 years and as recent as 6 months. However, having multiple interviewees and triangulating information with documents likely helped decrease the impact of any potential recall bias. Second, the terms searched in chapter 4 for the critical interpretive synthesis were quite diverse and at times vague. Therefore, the search strategy may not have captured all of the terms, and therefore concepts, regarding this topic, especially outside of the health-related fields, such as in environment or education. However, an effort was made to include databases that covered other fields in order to maximize the knowledge base covered in the study. Third, there were many stages where interpretation was needed in chapter 4 – from selecting search terms, building exclusion criteria, selecting relevant articles for inclusion, to data collection and analysis. Therefore, if someone were to replicate the study, it is possible that other articles and lenses may have been selected. However, each step was discussed amongst team members to ensure these concepts were as rigorous as possible.

Future research

Three considerations for future research emerge from this dissertation. First, the workbook was shown to be useful in two settings where the researchers were already familiar with developing evidence briefs. It is recommended that WHO, and other international organizations developing guidance, consider the institutionalization of workbooks into guidance development processes. This

dissertation has contributed to improving the workbook for contextualizing health systems guidance and to furthering knowledge about what and how contextual factors play a role in developing implementable guidance recommendations for a particular setting. Evaluations of a revised workbook should be considered in order to maximize the usefulness of this tool for a variety of topics across multiple settings. This will also help evaluate the framework of contextual factors and the mechanisms which are provided as to how contextual factors may influence the implementability of guidance recommendations. In addition, monitoring and evaluation will help identify impacts and unanticipated consequences of this approach.

One key issue that is highlighted throughout the dissertation is that developing global guidance and contextualizing guidance are both resource- and time-intensive processes and require content and methods experts. Moving forward, it will be important to identify how to best achieve efficiencies given WHO's constitutional mandate for setting normative standards (i.e., producing guidance) and the reality that countries need significant support for contextualizing global recommendations. One potential solution may be greater engagement of WHO regional or country offices in these processes, but further work is needed in this area.

Second, the methods used in this dissertation could be applied for developing other knowledge translation tools. Using qualitative research methods has been shown to be flexible and provide a rich understanding of the processes

and their contexts. This can help shape the understanding of what and how particular factors play a role in developing other knowledge translation tools.

Lastly, as was already mentioned, how the contextual factors and components of the processes found in these studies affect the ultimate policy decisions and their implementation is not known. Analyzing the various stages of policy development and implementation will be helpful for understanding the implications of the factors in terms of policy and health outcomes. Setting up an international inventory of evidence briefs and policies arising from global guidance could be useful in this endeavor. An added benefit of placing these products in the public domain, such as EVIPNet currently does with evidence briefs and policy dialogues, is that it enables others to assess the quality of the contextualization process.

Conclusion

Overall, this dissertation has provided insights into the processes involved in developing and evaluating a workbook for contextualizing health systems guidance. In addition, contextual factors and possible mechanisms for how these factors influence each other and various steps in the processes have helped contribute knowledge to a variety of fields where guidance / guidelines may be used. The workbook itself has been evaluated in two, diverse, real-life settings and has been found to be useful in the process of developing evidence briefs. In addition, recommendations have been provided to improve the workbook. Having a user-friendly, systematic and transparent process for combining global guidance

recommendations with local evidence and local analyses of the health system and political system is hoped to improve the chances of translating research evidence into implementable knowledge in order to strengthen health systems and thereby deliver life-saving interventions to those who need them most.

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APPENDIX A. Introduction of workbook for contextualizing health systems guidance

OPTIMIZE**MNH**

WHO recommendations

**Optimizing health worker roles to improve access to key
maternal and newborn health interventions through task shifting**

Annex 8

Contextualizing the guidelines – workbook

Contextualizing the guidance to optimize health worker roles to improve access to key maternal and newborn health interventions through task shifting

Health systems strengthening by using evidence-informed guidance is a developing area of interest internationally.(1) Using global-level guidance based on evidence can help support policy development at the global and national levels as well as guidance at the national level.(2) However, to date, health systems guidance has not included information to help users at the national (or sub-national) level combine global guidance with national assessments of the situation, including health system arrangements and political system considerations.(2) Developing health systems policy is a complex process by which characteristics of the problem (as well as options for addressing it and implementation considerations), health system arrangements, and political system factors influence policy agenda-setting, development and implementation.(2) If these contextual factors can be addressed during the policy development process, then the policy recommendations or policy decisions should be designed to fit the specific needs of policymakers and stakeholders grappling with these issues within their countries, which should facilitate the decision-making and implementation steps.

This annex is intended to help policymakers and stakeholders contextualize the recommendations with national evidence and other considerations, to help develop policy recommendations or policy decisions around the issue of optimizing health workers' roles (through training, regulation and support) to improve maternal and newborn health in low- and middle-income countries (LMICs). Some people call this task shifting or task-sharing; however, this term is unfortunately taken by some to mean simply the transferring of tasks from one cadre of health worker to another cadre, which, in reality, has complex legal and professional implications. In addition, a workbook based on this material has been created in order to make the information as user-friendly as possible. This annex and included workbook are based primarily on the second article of the 'guidance for evidence-informed policies about health systems' series (1-3) which in turn draws from the content of the 'SUPPORT tools for evidence-informed health policymaking' articles [clarifying evidence needs in policymaking,(4-6) taking equity into consideration,(7) preparing policy briefs and policy dialogues,(8;9) engaging the public,(10) and planning monitoring and evaluation of policies(11)]. In addition, insights from the OptimizeMNH Guidance panel discussions were incorporated into this chapter. The WHO health systems building blocks show how interventions can only be implemented successfully if health workers are supported by the other interrelated parts of health systems (i.e., governance, financing, health workforce, medicines and technologies, information, service delivery). Even though the building blocks are not addressed as categories in this chapter, per se, all the topics within the building blocks are covered in a format which fits with current political science and health systems research concepts.

This annex will guide users through the 8 steps of the evidence-based health systems guidance for policymaking framework (see Figure 1) which include: 1) clarify the problem; 2) frame the options; 3) identify implementation considerations; 4) consider the broader health system context; 5) consider the broader political system context; 6) refine the statement of the problem, options and

implementation considerations in light of health system and political system factors; 7) anticipate monitoring and evaluation needs; and 8) make national policy recommendations or decisions. A workbook summarizing this information will help the users navigate each section. It is recommended to follow each step of the workbook while reading this section in order to understand the full picture. Generally, each step utilizes broad health systems (or political systems) questions, integrates specific maternal and newborn health considerations, prompts for use of research evidence (where applicable), and ends with a summary of findings to highlight key messages from that section. The prompts are labeled as coming from a systematic review (more rigorous evidence); systematic analysis of programmes; or simply as a prompt, which is meant to serve as an example. Citations are included for each systematic review or systematic analysis of programmes used throughout the workbook.

Users should start by identifying their specific national processes for policymaking in order to determine the proper venue (e.g. national guidance panel, ministry of health, etc.) to address this guidance. This is important for determining the proper product, audience, format, and language to be used in making recommendations or policy decisions. Step 8 (make national policy recommendations or decisions) guides users in engaging the public in the policymaking process, developing an evidence brief, and planning a policy dialogue; however, these may not be appropriate measures for all venues. An evidence brief uses systematically developed statements created at the national or sub-national level to assist making decisions about appropriate options for addressing a health system problem in that specific setting. A brief also assists with implementation, monitoring and evaluation and can be used in national guidance development processes or in policy development processes. The policy dialogue uses systematically planned processes organized at the national or sub-national level to solicit the views, experiences and tacit knowledge of those who will be involved in or affected by decisions about appropriate options for addressing a health system problem in that specific setting. A summary of the policy dialogue may also be used in guidance and policy development processes. In addition to finding the right venue, it is also important to determine if now is the time to bring this issue forward. Waiting for an open policy window (e.g. the issue was discussed during an election and citizens want change) can increase the likelihood that one or more of the policy options can be pursued.

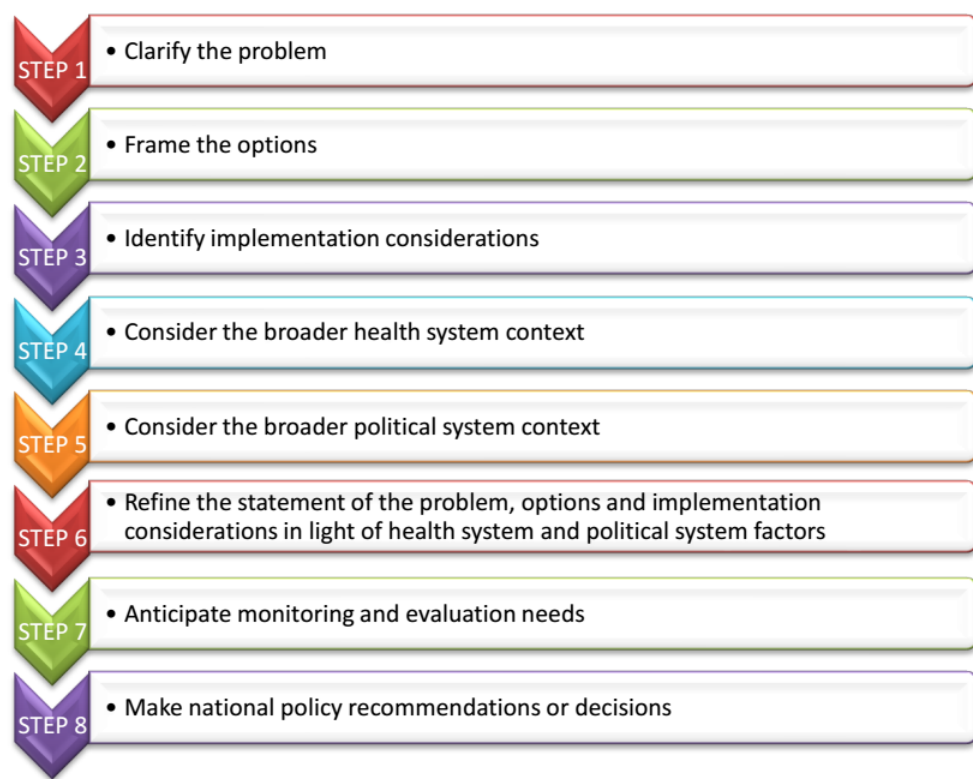


Figure 1. Evidence-based health systems guidance for policymaking framework

STEP 1 – Clarify the problem

Clarifying a problem is a critical part of the policymaking process, and can influence whether and how policymakers take action to address a problem.⁽⁵⁾ In this step, a series of general questions (first column of the workbook) from the SUPPORT tools for evidence-informed health policymaking, article 4,⁽⁵⁾ is used to guide policymakers and stakeholders through clarifying the problem addressed by the OptimizeMNH guidance documents as it is being experienced in their country. These questions are followed by specific maternal and newborn health considerations in the second column, which should help determine if the OptimizeMNH guidance documents would be applicable in a given country. Following these considerations, two columns prompt users to think about important systematic reviews or other systematically collected global data, and national data and research evidence, where applicable, to ensure global and local evidence are included in the policy decision-making process. Examples of types of national data and research evidence are given in the last column.

Questions include: 1) What is the problem? (which can relate to one or more of four areas – a) a risk factor, disease or condition; b) the programmes, services or drugs currently being used to address a risk factor, disease, or condition; c) current health system arrangements, including delivery, financial and governance arrangements; or d) the current degree of implementation of an agreed upon course of action); 2) How did the problem come to attention, and has this process influenced the

prospect of it being addressed, in addition to the guidance?; 3) What indicators can be used or collected to establish the magnitude of the problem and to measure progress in addressing it?; 4) What comparisons can be made to establish the magnitude of the problem and to measure progress in addressing it?; and 5) How can the problem be framed (or described) in a way that will motivate different groups?

- Questions specific to the OptimizeMNH guidance which should help users determine if the OptimizeMNH guidance recommendations would be helpful for their country include: 1) Is there a significant problem with a lack of provision of key interventions needed to attain MDGs 4 & 5 in particular communities/regions which affect the access to / utilization of these interventions?; 2) Is the availability of skilled health workers a significant contributor to the problem, and if so, which cadres of health workers are in short supply and in which communities (rural/urban; poor/wealthy neighbourhoods)? ; 3) What cadres covered by the OptimizeMNH guidance recommendations might be candidates for expanded training, regulation and support to enhance access to / utilization of key interventions needed to attain MDGs 4 & 5, and for which interventions might they take responsibility?; and 4) Are health system supports (e.g. training and supervision) for existing and needed cadres lacking? OptimizeMNH

1) What is the problem?

- a) A risk factor, disease or condition - the OptimizeMNH guidance addresses preventable maternal and newborn morbidity and mortality. As an example to be followed throughout this step, the sources of national data and research evidence which could be used here include community surveys and vital registries. The remaining examples will not be listed in the chapter, but are listed in the workbook.
 - b) The programmes, services or drugs currently being used to address a risk factor, disease or condition.
- **Is there a significant problem with a lack of provision of key interventions needed to attain MDGs 4 & 5 in particular communities/regions which affect the access to / utilization of these interventions?** Key interventions addressed in the OptimizeMNH guidance include:
 - Promotional interventions for maternal and newborn health
 - Distribution of oral supplements
 - Initiation and maintenance of antiretroviral treatment or antiretroviral prophylaxis for pregnant women and for prevention of HIV infection in infants
 - Continuous support during labour
 - Prevention and treatment of postpartum haemorrhage
 - Delivery of neonatal resuscitation
 - Management of puerperal sepsis using parenteral antibiotics before referral

- Initiation and maintenance of kangaroo mother care
 - Delivery of antibiotics for neonatal sepsis
 - Delivery of injectable antibiotics for preterm pre-labour rupture of membranes (PROM)
 - Undertaking of external cephalic version (ECV)
 - Delivery of therapeutic interventions in pregnancy and childbirth
- c) The current health system (delivery, financial and governance) arrangements within which programmes, services and drugs are provided – health system arrangements can contribute to a problem, and the specific areas of each are addressed in more detail in Step 4 (Consider health system factors). Briefly, **delivery arrangements** include: how care is designed to meet consumer’s needs, by whom care is provided, where care is provided, and with what supports is care provided; **financial arrangements** include: financing systems, funding organizations, remunerating providers, purchasing products and services, and incentivizing consumers; **governance arrangements** include: policy authority, organizational authority, commercial authority, professional authority, and consumer and stakeholder involvement.
- **Is the availability of skilled health workers a significant contributor to the problem and if so, which cadres of health workers are in short supply and in which communities (rural/urban; poor/wealthy neighbourhoods)?** The health worker cadres addressed in the OptimizeMNH guidance documents include:
 - Lay health workers (LHW)
 - Auxiliary nurses
 - Auxiliary nurse midwives
 - Nurses
 - Midwives
 - Associate clinicians (non-physician clinicians)
 - Advanced level associate clinicians (non-physician clinicians)
 - Non-specialist doctors
 - **What cadres covered by the OptimizeMNH guidance recommendations might be candidates for expanded training, regulation and support to enhance access to / utilization of key interventions needed to attain MDGs 4 & 5, and for which interventions might they take responsibility?**
 - **Are health system supports (e.g. training and supervision) for existing and needed cadres lacking?**

- See the full guidance document and annex 1 to find the definitions of cadres and determine which cadres could be doing different (or additional) tasks. Key interventions addressed in the OptimizeMNH guidance are listed down the left column. Each cadre is listed across the top row. Various colors are used to denote whether an intervention was recommended prior to the guidance work, is recommended by the OptimizeMNH guidance panel, is to be considered with targeted monitoring and evaluation, is to be considered only in the context of rigorous research, is not recommended by the guidance panel, or was not recommended prior to the guidance development (i.e. would not be considered safe). It is recommended to note which cadre of workers are currently performing which key interventions (e.g. with tick marks), and, based on the OptimizeMNH guidance, which cadres could be performing other key interventions (e.g. with question marks). The areas with question marks can then be the focus for the rest of the workbook in developing policy options. For full details of the research evidence used in the OptimizeMNH guidance, and to find which targeted monitoring and evaluation or rigorous research methods are suggested, please refer to other chapters in this book.
- d) The current degree of implementation of an agreed upon course of action (e.g. policy or guideline), which can include implementation problems at four levels – healthcare recipient and citizen level (e.g. unaware of available programmes), healthcare provider level (e.g. lack of adherence to national guidelines), organizational level (e.g. poor management of staff), and system level (e.g. policies not enforced).

2) How did the problem come to attention, and has this process influenced the prospect of it being addressed, in addition to the guidance?

Three factors usually bring attention to a problem. These include a focusing event, such as the national release of the WHO OptimizeMNH guidance (which is an event that can be capitalized upon in a given country); a change in indicator, such as maternal mortality increasing; and feedback from the operation of current policies and programmes, such as managers noting that few women are seeking available services.

3) What indicators can be used or collected to establish the magnitude of the problem and to measure progress in addressing it?

Indicators are factors used to measure achievements or to reflect changes from an intervention.⁽¹¹⁾ Examples of indicators to measure outcomes or changes for maternal and newborn health are provided in worksheet 1, but could include maternal and newborn mortality data or human resources for health distribution (HRH) measures, such as a maldistribution of high-level providers across communities.

4) What comparisons can be made to establish the magnitude of the problem and to measure progress in addressing it?

Four types of comparisons can be used to establish the magnitude of the problem: comparisons over time within a country, such as maternal and newborn mortality increasing or decreasing over time; comparisons between countries and other appropriate comparators, such as

contrasting with similar countries; comparisons against plans, such as the MDGs or national targets; and comparisons against what policymakers and / or stakeholders predicted or wanted, which could include decreasing maternal and newborn mortality.

5) How can the problem be framed (or described) in a way that will motivate different groups?

How a problem is stated can motivate different groups to act. For example, some groups may be motivated by the need to see change happen (e.g. “We have the highest rate of infant mortality in the region”) whereas others may be more motivated to keep to goals (e.g. “We will achieve the national goals for infant mortality within 5 years by improving access to and utilization of key interventions.”) Targeted goals may also motivate some groups to act (e.g. support routine care in underserved communities / regions, but not everywhere).

As stated earlier, areas for incorporating important systematic reviews or other systematic data (e.g. systematic analysis of programmes) and examples of sources for national data and research evidence are listed in the last two columns of worksheet 1. The table ends with a ***summary of findings on clarifying the problem section***, in which important concepts around describing the nature and scope of the problem can be consolidated from the work done throughout this step.

In addition, the cross-cutting theme of equity considerations will be listed for steps 1-3 at the end of each table. However, these considerations should be part of the discussion for each question. For clarifying the problem, an equity consideration includes: **Are there differences in access to or quality of care for disadvantaged groups or communities?**

Step 2 – Frame the options

Policy or programme options may be more appropriate when they are technically feasible (e.g. have appropriate resources), fit with dominant values (e.g. national mood; political support), and are workable within the budget.⁽¹²⁾ In this step, policy options should be developed based on the findings of the work from Step 1. For example, option 1 could be to focus on the cadres with the most number of interventions that they could safely and effectively deliver but are not now delivering; option 2 could be to focus on the interventions with the most number of cadres who could safely and effectively deliver them but are not now delivering them; and option 3 could be to focus on all of the combinations of cadres who could safely and effectively deliver key interventions but are not now delivering them. There are three columns in worksheet 2 which allow for these options to be developed. The policy options need not be mutually exclusive and can, in fact, be complementary, but they should help foster discussion about the costs and consequences (benefits and harms) of each proposed option.^(6;7;13) In addition, information on what types of evidence can be used to help answer these questions can be found in the table of worksheet 2. The questions for this step are from the SUPPORT tool series, article 5,⁽⁶⁾ which will walk the user through the process of framing the policy options.

The questions used to guide this step include: 1) Has an appropriate set of options been identified to address the problem?; 2) What benefits are important to those who will be affected and which benefits are likely to be achieved with each option?; 3) What harms are important to those who will be affected, which harms are likely to arise with each option and how can these harms be mitigated? 4) What are the local costs of each option, and is there local evidence about their cost-

effectiveness?; 5) What adaptations might be made to any given option and how might they alter its benefits, harms and costs?; and 6) Which stakeholder's views and experiences might influence the acceptability of each option and its benefits, harms and costs?

1) Has an appropriate set of options been identified to address the problem?

Options can include:

- a) The provision of a cost-effective programme, service or drug, and
- b) Health system arrangement issues (to be developed further in step 4, but listed in step 1)

For the purposes of the OptimizeMNH guidance work, the combination of interventions and cadres, plus or minus additional supportive health system arrangements (to be developed further in step 4) would be used to develop the options. Once these elements are chosen, it can be decided if they can stand alone or if they are part of a larger framework (e.g. health human resources planning).

2) What benefits are important to those who will be affected and which benefits are likely to be achieved with each option?

3) What harms are important to those who will be affected, which harms are likely to arise with each option, and how can these harms be mitigated?

4) What are the local costs of each option, and is there local evidence about their cost-effectiveness?

For this question it is important to consider all the potential impacts of resource use (e.g. costs of transportation, etc.).

5) What adaptations might be made to any given option and might they alter its benefits, harms and costs?

6) Which stakeholder's views and experiences might influence the acceptability of each option and its benefits, harms and costs?

- Healthcare recipients and citizens
- Health workers
- Managers in organizations (e.g. districts and facilities)
- Policymakers and stakeholders at national or sub-national levels
- Others

Worksheet 2 ends with a **summary of costs, benefits, and harms of each option** section in which important concepts can be considered from the work done throughout this step.

Equity considerations to be included throughout the framing of the options are:

1) Which groups or communities are likely to be disadvantaged by each option?

Prompt: Is there an association between the mechanism of the options and particular characteristics, such as economic status, employment or occupation, education, place of residence, gender or ethnicity?

2) Is there evidence of differences in baseline conditions of groups which would change the absolute effectiveness of each option for disadvantaged groups or communities?

Prompt: Baseline risks are typically greater in disadvantaged populations, and therefore, a larger absolute effect might be expected. If improving the delivery of artemisinin combination therapy (ACT) has the same relative effect on mortality from malaria in disadvantaged children as for other children, then the absolute effect might be greater in disadvantaged populations with higher mortality rates.

Step 3 – Identify implementation considerations

Implementation of a policy can be complex and cause the policy to fail if adequate considerations are not taken.(4) Identifying barriers to implementation and finding strategies to deal with these issues will facilitate the work of translating policy into practice.(4) Building on what was learned from step 2, carry over the modified options from worksheet 2 to worksheet 3. Continue to tailor the policy or programme options by planning for implementation issues in order to maximize the likely benefits of proposed changes in the health system. In worksheet 3, the option columns across the page allow for each option to be assessed with each question found on the rows in the left column. Again, types and /or sources of evidence which could be used to answer these questions are given throughout worksheet 3. The questions for this step are from the SUPPORT tool series, article 6,(4) which will walk the user through the process of planning for the implementation of the options.

Questions for step 3 include: 1) What are the potential barriers to the successful implementation of each option?; 2) What strategies should be considered in order to facilitate the necessary behavioural changes among healthcare recipients/citizens?; 3) What strategies should be considered in order to facilitate the necessary behavioural changes among healthcare professionals?; 4) What strategies should be considered in order to facilitate the necessary organizational changes?; and 5) What strategies should be considered in order to facilitate the necessary system changes?

1) What are the potential barriers to the successful implementation of each option?

Consider barriers at four levels:

- a) At the healthcare recipient and citizen level
- b) At the healthcare professional level
- c) At the organizational level
- d) At the system level

Examples of considerations for each of these levels, which are taken from systematic reviews, are given in worksheet 3.

- 2) **What strategies should be considered in order to facilitate the necessary behavioural changes among healthcare recipients/citizens?**
- 3) **What strategies should be considered in order to facilitate the necessary behavioural changes among healthcare professionals? (e.g. reconciliation of ‘competing’ guidelines and accountabilities for different cadres in relation to this guidance; training and supervision which is focused on confidentiality)**
- 4) **What strategies should be considered in order to facilitate the necessary organizational changes?**
- 5) **What strategies should be considered in order to facilitate the necessary system changes? (e.g. rationalization of the referral system; coordination with other health workforce initiatives)**

A **summary of implementation considerations for each option** section is found at the end of worksheet 3 in which important concepts from this step can be condensed.

A cross-cutting equity consideration throughout the implementation planning step includes: **With these issues in mind, what can be done during implementation to reduce inequities, if possible, or to make sure they are not increased?**

In addition, the OptimizeMNH guidance document mentions general implementation considerations for all cadres which cut across all of the above categories:

Role distribution

- Clear scopes of practice are needed, and these need to be implemented at all levels of the health system. Linked to this, the distribution of roles and responsibilities between the health worker taking on the intervention and other health workers needs to be made clear, including through regulations and job descriptions

Regulatory issues

- Changes in regulations may be necessary to support any changes in the health worker’s scope of practice

Stakeholder involvement

- Health worker representatives and relevant professional bodies should be involved in the planning and implementation of the intervention to ensure acceptability among affected health workers
- Recipients of the intervention should also be involved in planning and implementation
- Local beliefs and practical circumstances related to the health conditions in question should be addressed within the programme design

Training and supervision

- Health workers and their supervisors need to receive appropriate initial and ongoing training in the intervention
- Responsibility for supervision needs to be clear and supervision needs to be regular and supportive

Systems for referral

- Where necessary, referral systems need to function well, i.e. financial, logistical (e.g. transport) and relational barriers need to be addressed. Specifically, local health systems need to be strengthened to improve quality of care at the first referral facility

Supplies

- Supplies of drugs and other commodities need to be secure

Incentives

- Optimizing health worker's roles needs to be in the context of a comprehensive remuneration scheme, in which salaries and incentives reflect any changes in scope of practice. Giving incentives for certain tasks but not for others may negatively affect the work that is carried out.

Step 4 – Consider the broader health system context

After working through the problem, options and implementation considerations from steps 1-3, it is important to think about how key features of the health system are likely to influence decision-making about whether and how to act on the guideline recommendations regarding these cadres.(2) Step 4 walks the user through these health system factors, with consideration given to delivery (e.g. training and supervision supports and referral processes), financial (e.g. incentives), and governance (e.g. regulations governing scopes of practice) arrangements. Each option (columns across worksheet 4) should be brought forward from worksheet 3 and deliberated in turn in relation to the health system factors, which are found down the rows in the left column on worksheet 4. Either findings from a systematic review, findings from a systematic analysis of programmes, or prompts are given for each health system factor in the worksheet as an example(s).

Questions to work through in step 4 include: 1) How do delivery arrangements influence the possibility of each option being adopted and implemented successfully?; 2) How do financial arrangements influence the possibility of each option being adopted and implemented successfully?; and 3) How do governance arrangements influence the possibility of each option being adopted and implemented successfully?

1) How do delivery arrangements influence the possibility of each option being adopted and implemented successfully?

- How care is designed to meet consumer's needs
- By whom care is provided
- Where care is provided
- With what supports is care provided

2) How do financial arrangements influence the possibility of each option being adopted and implemented successfully?

- Financing systems
- Funding organizations
- Remunerating providers
- Purchasing products and services
- Incentivizing consumers

3) How do governance arrangements influence the possibility of each option being adopted and implemented successfully?

- Policy authority
- Organizational authority

- Commercial authority
- Professional authority
- Consumer and stakeholder involvement

Worksheet 4 wraps up with a **summary of health system considerations for each option** section to revisit the main health system factors gathered through this step.

Step 5 – Consider the broader political system context

Understanding how key features of the political system (institutions, interests, ideas, and external factors) influence these policy options will help account for further potential barriers or facilitators during policy development and implementation.(2) Start by transferring viable policy options from worksheet 4 to the top of the columns across worksheet 5. Then, for each of the three options, work through the political system considerations. Questions regarding political system factors, including institutions (e.g. what decision-making venues and processes could be faced), interests (e.g. which cadres are likely to face concentrated benefits or costs), ideas (e.g. values about equity of access / utilization), and external factors (e.g. new health minister) are posed down the rows on the left column. Prompts are given for each political system factor in the worksheet as an example. You may wish to work through each section, and place an X in a corner of the box if this would be a barrier, or a check mark (✓) if the policy option does not meet any significant barriers in that category (e.g., interest groups).

Questions for step 5 include: 1) Would current political institutions allow for or hinder each policy change?; 2) Which politically active group(s) might have an interest in (face concentrated or diffuse costs or benefits) and mobilize for or against each option?; and 3) Does each option resonate with the beliefs and values of the government and the public? Is there any local research evidence on stakeholder's views and experiences?; and 4) Are there external factors which may press the issue forward or draw attention away from each option?

1) Would current political institutions allow for or hinder each policy change?

- Government structures – how many levels of government would be involved in making healthcare decisions about the options (e.g. national, provincial, district, etc.)
- Policy legacies – how have past policies shaped the competencies of current administrative bodies that would be involved in deciding upon or implementing the option
- Policy networks – how do specific groups relate to or are incorporated into government structures (e.g. a government-appointed guidance panel may engage stakeholders in their policy-making process for specific issues)

2) Which politically active group(s) might have an interest in (face concentrated or diffuse costs or benefits) and mobilize for or against each option?

- Interest groups (e.g. patient groups, professional groups)
- Civil society

**3) Does each option resonate with the beliefs and values of the government and the public?
Is there any local research evidence on stakeholder's views and experiences?**

- Values
- Personal experiences
- Research evidence

4) Are there external factors which may press the issue forward or draw attention away from each option?

- Political changes (e.g. election brings in new political party)
- Economic changes (e.g. global economic crisis)
- Major reports (e.g. OptimizeMNH guidance documents released)
- Technological changes (e.g. expanded use of mobile phones)
- New diseases (e.g. influenza epidemic)
- Media coverage (e.g. spotlight on corruption within the health system)

A **summary of political system considerations for each option** section is included at the end of worksheet 5 to consolidate the key points gathered through this step.

Step 6 – Refine the statement of the problem, options and implementation considerations in light of health system and political system factors

Worksheet 6 is meant as a tool for users to reflect upon the process of contextualizing the problem, options and implementation considerations in light of national health system and political system factors, which can influence the likelihood of a policy option being adopted and implemented successfully. Each option should be transcribed in the column headers of worksheet 6.

The **summary of findings on clarifying the problem** from the end of worksheet 1 should be transcribed in the appropriate section of worksheet 6. A section is provided for reflection on how considerations related to key health system and political system factors can change how the problem is being clarified. The same process should be followed with the **summary of costs, benefits, and harms of each option** from the end of worksheet 2 and the **summary of implementation considerations for each option** from the end of worksheet 3. Finally, space is provided for a **contextualized re-iteration of clarifying the problem, framing the options, and planning for implementation in light of health system and political system considerations**. This re-iteration can be used to determine whether the existing options could be viable or if it would be better to consider new or modified policy options.

Step 7 – Anticipate monitoring and evaluation needs

Monitoring and evaluation (M&E) are used in order to know if a policy or programme has been implemented as expected and is working.(11) Monitoring involves systematically collecting evidence to answer questions about the nature and extent of implementation, and evaluation is similar but tends to focus more on the achievement of results.(11) Indicators are factors used to measure achievement or reflect changes from an intervention, while an impact evaluation helps determine if observed changes in outcomes (impacts) are caused from a policy or programme.(11) Throughout the first 6 steps, viable options should have been determined. Place these policy options at the top of the columns across worksheet 7. Then, answer the questions in the left column of the worksheet. Questions in this section are from the SUPPORT tools, article 18.(11)

Questions in step 7 include: 1) Is monitoring necessary?; 2) What should be measured?; 3) Should an impact evaluation be conducted?; and 4) How should the impact evaluation be done?

1) Is monitoring necessary?

- Is monitoring already in place or are new systems necessary?
- What are the costs of establishing a new system?
- Are findings going to be useful for change? What actions would occur if monitoring reveals things are not going as planned?

What indicators should be monitored and does the capacity exist to monitor and to make changes based on the data (and which, if any, cadres require targeted monitoring related to the delivery of specific interventions?

For options from the Cadre Worksheet in which the recommendation was in the context of monitoring and evaluation (M&E), follow the directions for M&E given for each area in the full OptimizeMNH guidance document. If not, then the M&E activities should look at the interventions and on the cadres' engagement in specific interventions.

2) What should be measured?

- What parts of the results chain should be / could be measured?

A modified results chain,(11) includes:

- Inputs – financial, human and material resources used for the intervention
- Activities – Actions taken or work performed through which inputs, such as funds, technical assistance and other types of resources are mobilized to produce specific outputs
- Outputs – The products, capital goods, and services which result from an intervention; may also include changes resulting from the intervention which are relevant to the achievement of outcomes,

- Outcomes – The likely or achieved short-term and medium-term effects of an intervention's outputs
- Impacts - Positive and negative, primary and secondary long-term effects produced by an intervention, directly or indirectly, intended or unintended
- What properties of an indicator make it useful?

Factors to consider when selecting indicators:(11)

- Validity – extent to which the indicator accurately measures what it is supposed to measure
- Acceptability – extent to which the indicator is acceptable to those being assessed and those recording the data
- Feasibility – extent to which valid, reliable and consistent data are available for collection
- Reliability – extent to which there is minimal measurement error, or the extent to which findings are reproducible if collected by another party
- Sensitivity to change – ability to detect changes in the unit of measurement
- Predictive validity – ability to accurately predict relevant outcomes
- Consider also – cost, time, and motivation to collect or manipulate the data

3) Should an impact evaluation be conducted?

It is important to compare the costs of conducting an impact evaluation with the costs of not conducting one, in case the programme does not work or causes harm. Would a programme be stopped or changed if poor outcomes were found? Does the capacity exist to conduct the evaluation (and which, if any, cadres require evaluation related to the delivery of specific interventions)? In addition, can the impact evaluation be done at the early stages of implementation (e.g. a pilot study) to improve or stop the rest of the implementation, if necessary?

4) How should the impact evaluation be done?

The choice of evaluation involves many factors (e.g. time, costs, ethical considerations, etc.). Worksheet 7 lists some potential types of evaluation used in impact evaluations. However, all types of evaluation methods should be planned for and included in the earliest stages of planning to ensure valid, reliable and useable data.

A *summary of monitoring and evaluation needs for each option* section at the end of worksheet 7 helps wrap up the concepts gained through this step.

Step 8 – Make national policy recommendations or decisions

Users should identify their specific processes for policymaking to determine the proper venue (e.g. national guidance panel, ministry of health, etc.) to address the contextualization and implementation of the guidance. The recognition of this process is important for determining the proper product, audience, format, and language to be used in developing the policy recommendations or policy decisions. If policy recommendations are made based on the above work, then summarizing the pros and cons of each option with special considerations for implementation, health system factors, political system factors, equity issues and monitoring and evaluation needs will give policymakers a good sense of what options are feasible, acceptable and useful. Looking for the right time to bring this forward (open policy window, e.g. election where the issue has been discussed) can also help advance the policy options. If a decision is made to consider acting on one or more of the guidance recommendations regarding the cadres in light of the health and political system assessments, then local data and evidence (e.g. mortality data; studies about contributors to access/utilization problems) and local tacit knowledge, views and experiences can be combined with global evidence (both from the OptimizeMNH guidance and from other sources, such as Health Systems Evidence) to prepare an evidence brief for policy. A structured, evidence brief for policy (or a policy proposal) can help decision-makers have a focused discussion (e.g. policy dialogue) based on sound global and local evidence,(2) if these are appropriate for the venue used in each country in developing policy recommendations or making policy decisions. The boxes in worksheet 8 address issues of engaging the public in the policymaking process, developing a policy brief, and planning a policy dialogue, which are based on the SUPPORT tools series, articles 13-15.(8-10) For a full description, please see the original articles.

1. If applicable, has the public been engaged in the policymaking process?(10)

- What strategies can be used to engage the mass media in informing the public about policy development and implementation?

Structured press releases, fact boxes, press conferences, providing stories, avoiding jargon, providing access to experts, tip sheets, training for journalists, web-based or social media considerations

- What strategies can be used to engage civil society groups?

Patient organizations, community groups, coalitions, advocacy groups, faith-based organizations, charities or voluntary organisations, professional associations, trade unions, business associations, etc. can be involved in multiple steps of the policymaking process.

- How can consumers become involved in policy development and implementation?

Consultation, collaboration, or consumer control (e.g. consumers develop and advocate or implement health policies themselves)

- How will the above information be used in shaping the policymaking process?

Are there plans / time to add the information learned through these processes? Explain these processes to those involved, as it may otherwise be seen as tokenism if advice is not taken.

2. Is a policy brief being developed to collate all of the analyses captured in the workbook?(8)

- Does the policy brief address a high-priority issue and describe the relevant context of the issue being addressed?
- Does the policy brief describe the problem, costs and consequences of options to address the problem, and the key implementation considerations?
- Does the policy brief employ systematic and transparent methods to identify, select and assess synthesized research evidence?
- Does the policy brief take quality, local applicability, and equity considerations into account when discussing the synthesized research evidence?
- Does the policy brief employ a graded-entry format?

Allows busy policymakers to quickly scan for relevance to topic and context (e.g. 1:3:25 format - one page with take home messages: 3-page executive summary: 25-page report with reference list for more information)

- Was the policy brief reviewed for both scientific quality and system relevance?

Merit review involving one of each: policymaker, other stakeholder, researcher

3. Is a policy dialogue being planned to support evidence-informed policymaking?(9)

- Does the dialogue address a high priority issue?
- Does the dialogue provide opportunities to discuss the problem, options to address the problems, and key implementation considerations?
- Is the dialogue informed by a pre-circulated policy brief and by a discussion about the full range of factors that can influence the policymaking process?
- Does the dialogue ensure fair representation among those who will be involved in, or affected by, future decisions related to the issue?

Policymakers, managers, staff or members in civil society groups, health professional associations, researchers, etc.

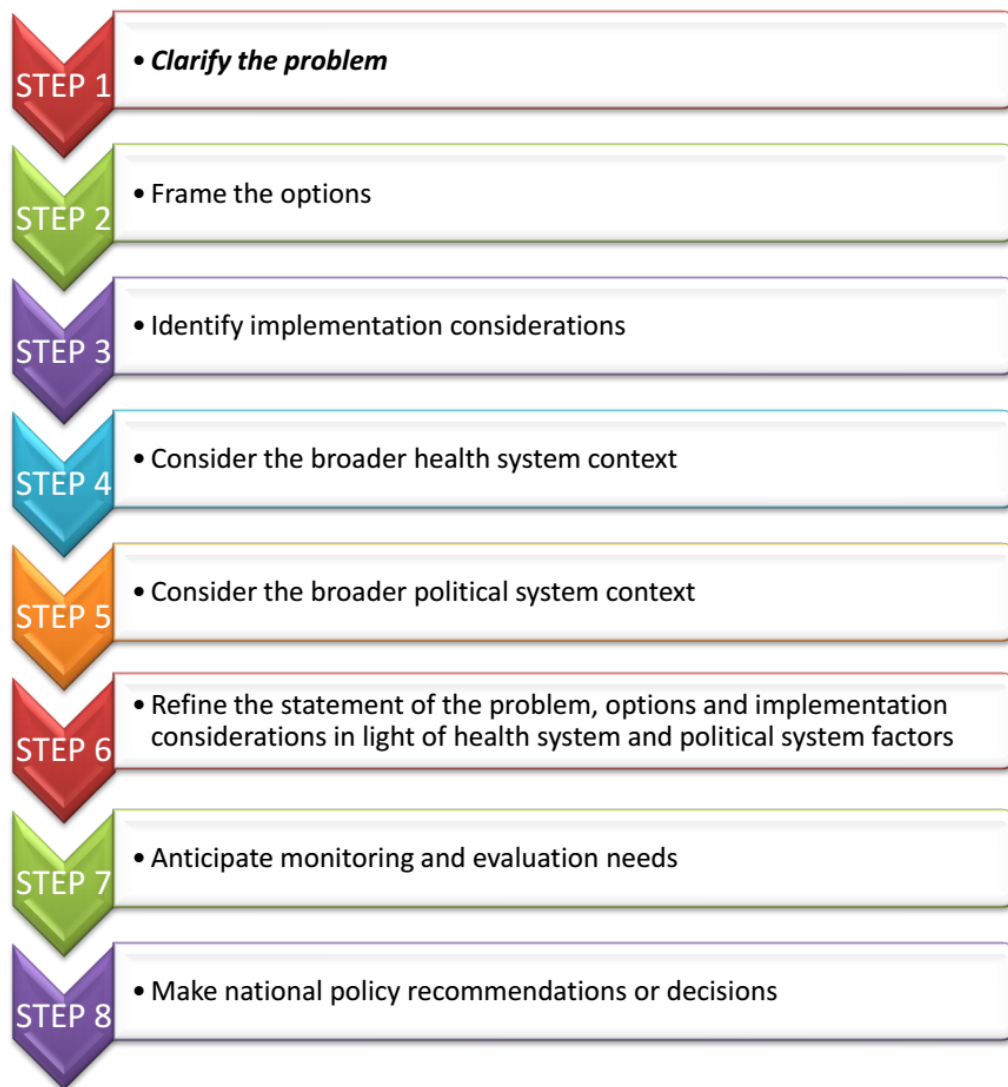
Usually 15-20 or more people, depending on the issue and the area affected by the issue.

- Does the dialogue engage a skilled, knowledgeable and neutral facilitator, follow a rule about not attributing comments to individuals, and not aim for consensus?
- Are outputs produced and follow-up activities undertaken to support action?

The Workbook

Follow the directions in each step of the prior section to navigate through the corresponding worksheets in the workbook. The evidence-based health systems guidance for policymaking framework diagram will help you locate the step from the above section which corresponds to each worksheet in this workbook.

Evidence-based health systems guidance for policymaking framework



Worksheet 1 – Clarify the problem

General considerations	Specific maternal and newborn health considerations (OptimizeMNH)	Important systematic reviews or other systematic data	National data and research evidence
1. What is the problem? Does the problem relate to (could be more than one):			
a) a risk factor, disease or condition	Preventable maternal and newborn morbidity and mortality		community surveys and vital registries
b) the programmes, services or drugs currently being used to address a risk factor, disease or condition	<p>Is there a significant problem with a lack of provision of key interventions needed to attain MDGs 4 & 5 in particular communities/regions which affect the access to / utilization of these interventions?</p> <p>Key interventions from the OptimizeMNH guidance:</p> <ul style="list-style-type: none"> - Promotional interventions for maternal and newborn health - Distribution of oral supplements - Initiation and maintenance of antiretroviral treatment or antiretroviral prophylaxis for pregnant women and for prevention of HIV infection in infants - Continuous support during labour - Prevention and treatment of postpartum haemorrhage - Delivery of neonatal resuscitation - Management of puerperal sepsis using parenteral antibiotics before referral - Initiation and maintenance of kangaroo mother care - Delivery of antibiotics for neonatal sepsis - Delivery of injectable antibiotics for preterm pre-labour rupture of membranes (PROM) - Undertaking of external cephalic version (ECV) - Delivery of therapeutic interventions in pregnancy and childbirth 	Look for systematic reviews on the specific programme, service or drug	healthcare administrative data/ health management information systems, monitoring and evaluation data, community or healthcare provider surveys
c) the current health system (delivery, financial and governance) arrangements within which programmes, services and drugs are provided Delivery Arrangements - How care is designed to meet consumer's needs - By whom care is provided	<p>Is the availability of skilled health workers a significant contributor to the problem, and, if so, which cadres of health workers are in short supply and in which communities (rural/urban; poor/wealthy neighborhoods)?</p> <p>OptimizeMNH</p> <ul style="list-style-type: none"> • Lay health workers (LHW) 		<p>healthcare administrative data</p> <p>Proceed to which key interventions provided by which cadres are</p>

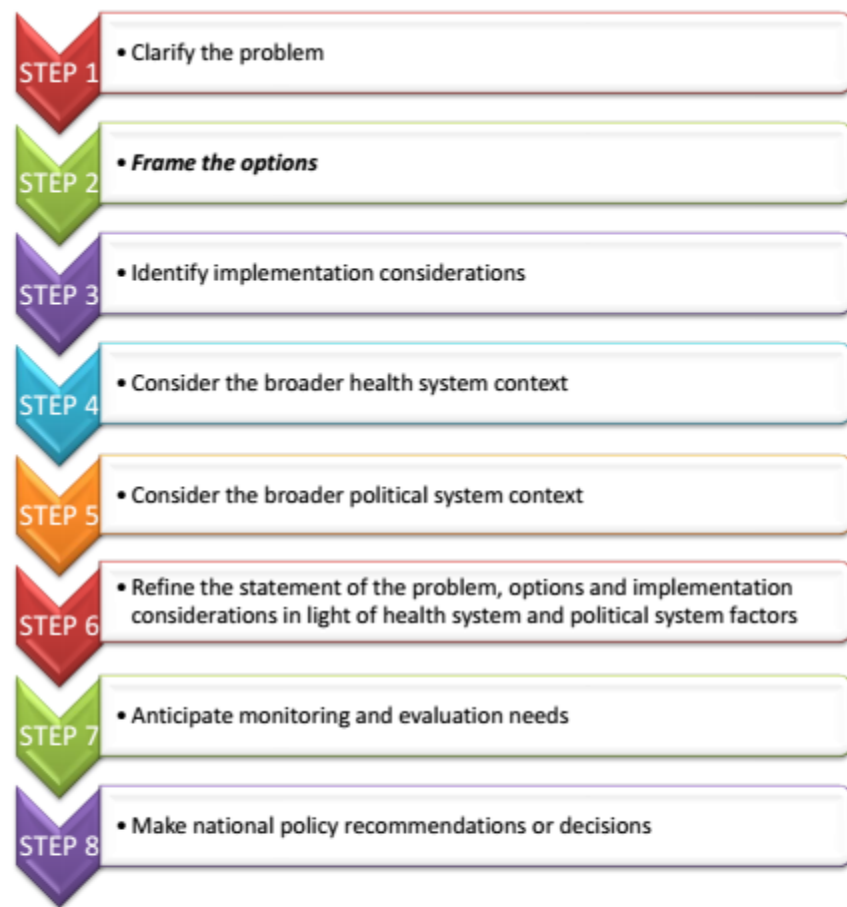
<p>- Where care is provided - With what supports is care provided</p> <p>Financial Arrangements</p> <ul style="list-style-type: none"> - Financing systems - Funding organizations - Remunerating providers - Purchasing products and services - Incentivizing consumers <p>Governance Arrangements</p> <ul style="list-style-type: none"> - Policy authority - Organizational authority - Commercial authority - Professional authority - Consumer and stakeholder involvement 	<ul style="list-style-type: none"> • Auxiliary nurses • Auxiliary nurse midwives • Nurses • Midwives • Associate clinicians (non-physician clinicians) • Advanced level associate clinicians (non-physician clinicians) • Non-specialist doctors <p>What cadres covered by the OptimizeMNH guidance recommendations might be candidates for expanded training, regulation and support to enhance access to / utilization of key interventions needed to attain MDGs 4 & 5, and for which interventions might they take responsibility?</p> <p>Are health system supports (e.g. training and supervision) for existing and needed cadres lacking?</p>		<p>currently being performed with check marks, and which key interventions could be performed by specific cadres but are not currently carried out by those cadres with question marks. Use the areas with question marks to formulate the options for the following tables.</p> <p>health expenditure surveys, healthcare provider surveys,</p> <p>legislation, regulation, policies, drug formularies and policymaker surveys</p>
<p>d) the current degree of implementation of an agreed upon course of action (e.g. policy or guideline) Consider implementation problems at four levels:</p> <p>1) healthcare recipient and citizen level (e.g. unaware of available programmes)</p> <p>2) healthcare provider level (e.g. adherence to national guidelines)</p> <p>3) organizational level (e.g. poor management of staff)</p> <p>4) system level (e.g. policies not enforced)</p>			<p>community or healthcare provider surveys, healthcare administrative data</p>
<p>2. How did the problem come to attention, and has this process influenced the prospect of it being</p>			

addressed, in addition to the guidance?			
<ul style="list-style-type: none"> - a focusing event - change in an indicator - feedback from the operation of current policies and programmes 	<p><i>Release of OptimizeMNH WHO guidance</i></p> <p><i>Maternal mortality increasing</i></p> <p><i>Managers note that very few women are seeking available services</i></p>		
3. What indicators can be used or collected to establish the magnitude of the problem and to measure progress in addressing it?			
	<p><i>Maternal and newborn mortality</i></p> <p><i>Unmet need for family planning</i></p> <p><i>Human resources for health distribution , such as a maldistribution of high-level providers across communities</i></p> <p><i>Disaggregated data, such as data by ethnicity/culture, gender, or socioeconomic status can help clarify whether the problem is widespread or pronounced in some communities, which is important for equity considerations</i></p>		<ul style="list-style-type: none"> - available indicators - community surveys and vital registries - healthcare administrative data - legislation, regulation, policies, drug formularies and policymaker surveys - health expenditure surveys, healthcare provider surveys
4. What comparisons can be made to establish the magnitude of the problem and to measure progress in addressing it?			
<ul style="list-style-type: none"> - comparisons over time within a country - comparisons between countries and other appropriate comparators - comparisons against plans - comparisons against what policymakers and/or stakeholders predicted or wanted 	<p><i>Maternal and newborn mortality increasing/decreasing over time</i></p> <p><i>Contrast with similar countries</i></p> <p><i>MDGs, national targets</i></p> <p><i>Decrease in maternal and newborn mortality; increased access to family planning</i></p>		
5. How can the problem be framed (or described) in a way that will motivate different groups?			
	<i>"We have the highest rate of infant mortality in the region" vs. "We will achieve the national</i>		Qualitative research for socially-meaningful

	goals for infant mortality within 5 years"		terms
<p>Summary of findings on clarifying the problem – describe the scope and nature of the problem based on the above findings</p> <p>(e.g. Prompt: With the dawning of the MDGs in 2015, the problem of maternal deaths due to postpartum hemorrhage (PPH), especially in rural areas, has been brought forth by a national nursing group. Their spokesperson stated that it is imperative for our government to uphold the promise of safeguarding the health of its high-risk, rural, women, and recent guidance from the WHO for improving maternal and newborn health (OptimizeMNH recommendations) could help steer the work in this area. Compared with surrounding nations, our maternal mortality rate is worse. Currently, doctors are not available most of the time in the rural areas, but there are lay health workers who are located in the highest-risk areas. According to the OptimizeMNH recommendations, lay health workers (LHW) could administer misoprostol to prevent PPH, but this is not currently done in practice in our country.)</p>			

Cross-cutting factors: Equity considerations

Are there differences in access to or quality of care for disadvantaged groups or communities?



Worksheet 2 – Frame the options

	Option 1: <i>could be to act on the cadre with the most question marks</i>	Option 2: <i>could be to act on the key interventions with the most question marks</i>	Option 3: <i>could be to act on all of the question marks</i>
1. Has an appropriate set of options been identified to address the problem?			
<p>a) the provision of a cost-effective programme, service or drug,</p> <p>b) health system arrangement issues as described in step 1 of this workbook</p> <p><i>Prompt: the combination of interventions and cadres, plus or minus additional supportive health system arrangements (to be examined in more detail in step 4) would be used to develop the options from the OptimizeMNH guidance</i></p> <p><i>Then, decide if these elements can stand alone or if they are part of a larger framework</i></p>			
2. What benefits are important to those who will be affected and which benefits are likely to be achieved with each option?			
<p>Use systematic reviews for global evidence</p> <p>Use randomised controlled trials (RCTs), interrupted time series, controlled before/after studies or systematic evidence for local evidence</p>			
3. What harms are important to those who will be			

affected, which harms are likely to arise with each option, and how can these harms be mitigated?			
Use systematic reviews for global evidence Search for effectiveness studies or observational studies for local evidence			
4. What are the local costs of each option, and is there local evidence about their cost-effectiveness?			
Consider all important potential impacts of resource use (policy delivery, transportation costs, etc.) (13) Use systematic reviews, RCTs, observational studies, and cost-effectiveness studies, if available, and consider if the settings are similar Find local data from national or local databases or non-health outcome related sources, such as invoices or records of travel (4, 13)			
5. What adaptations might be made to any given option and might they alter its benefits, harms and costs?			
Look at options applied elsewhere and determine if adapting this option is viable. Use systematic reviews for global evidence and process evaluations to help determine which components of elements are critical and which are not important			
6. Which stakeholder's views and experiences might influence the acceptability of each option and its benefits,			

harms and costs?			
<ul style="list-style-type: none"> Healthcare recipients and citizens Health workers Managers in organizations (e.g. districts and facilities) Policymakers and stakeholders at national or sub-national levels Others <p>Use systematic reviews for global evidence</p> <p>Use qualitative or observational studies to determine local evidence</p>			
<p>Summary of costs, benefits, and harms of each option (e.g. Prompt: training one LHW to provide misoprostol will cost X days of training and being away from the job during that time, \$Y for training materials, and the pay for a replacement for X days. The additional training will help provide care for Z# of women/yr which could save the lives of these women and their children and decrease the morbidities of PPH. The training time may affect the care of the patients for X days, although they will have coverage. The majority of the women served will be in a high-risk poor rural area.)</p>			

Cross-cutting factors: Equity considerations

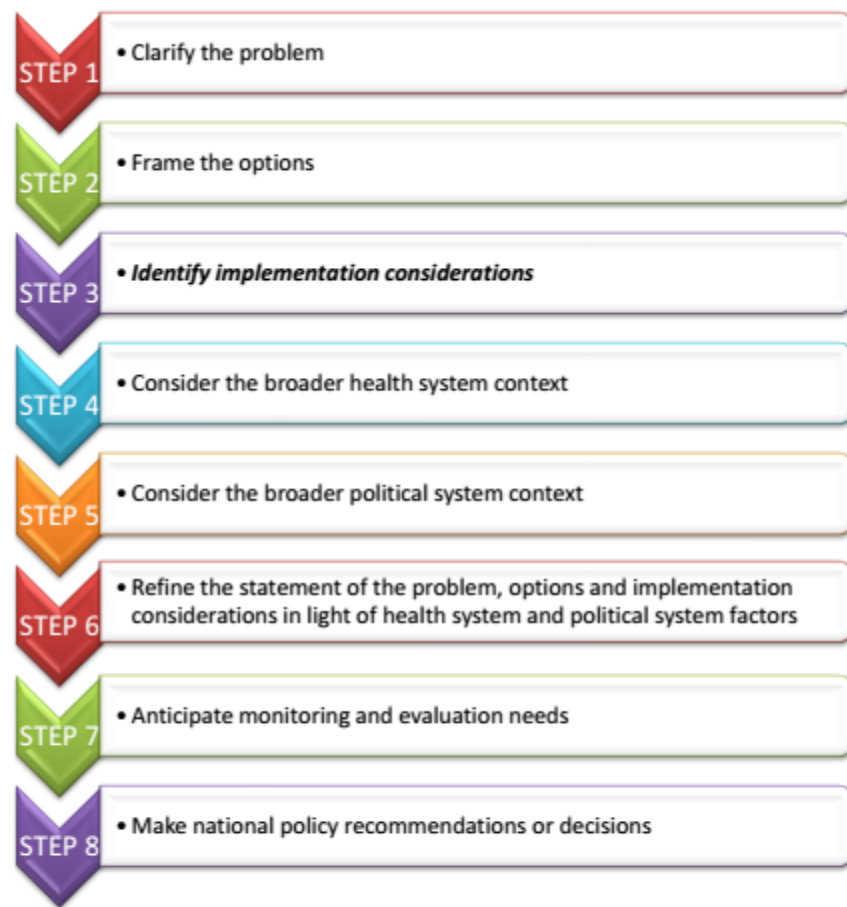
Which groups or communities are likely to be disadvantaged by each option?

Prompt: Is there an association between the mechanism of the options and particular characteristics, such as economic status, employment or occupation, education, place of residence, gender or ethnicity?

Is there evidence of differences in baseline conditions of groups which would change the absolute effectiveness of each option for disadvantaged groups or communities?

Prompt: Baseline risks are typically greater in disadvantaged populations, and therefore, a larger absolute effect might be expected. If improving the delivery of artemisinin combination therapy (ACT) has the same relative effect on mortality from malaria in disadvantaged children as for other children, then the absolute effect might be greater in disadvantaged populations with higher mortality rates.

Evidence-based health systems guidance for policymaking framework



Worksheet 3 – Identify implementation considerations

	Option 1: <i>could be to act on the cadre with the most question marks</i>	Option 2: <i>could be to act on the key interventions with the most question marks</i>	Option 3: <i>could be to act on all of the question marks</i>
1. What are the potential barriers to the successful implementation of each option? Consider barriers at four levels:			
Among healthcare recipients and citizens <i>Systematic review: Recipients were unaware of the range of services provided by nurses, reducing demand for those services (14)</i>			
Among healthcare professionals <i>Systematic review: Roles of different providers may be unclear (15)</i>			
At the organizational level <i>Systematic review: Technical and relational changes in referral systems are important to consider (15)</i>			
At the system level <i>Systematic review: Poor planning and integration of new skills for midwives can be a barrier to undertaking new tasks (16)</i> Use systematic reviews for global evidence Use qualitative or mixed methods studies to determine stakeholder's views on barriers and /or facilitators Use cost-effectiveness data or stakeholder's views for potential implementation strategies			
2. What strategies should be considered in order to			

facilitate the necessary behavioural changes among healthcare recipients/citizens?			
Use systematic reviews or qualitative studies to provide insights into healthcare recipient behaviours Health Systems Evidence provides syntheses of research evidence about implementation strategies that can support change in health systems			
3. What strategies should be considered in order to facilitate the necessary behavioural changes among healthcare professionals?			
Use systematic reviews or qualitative studies to provide insights into health workers' behaviours Health Systems Evidence provides syntheses of research evidence about implementation strategies that can support change in health systems			
4. What strategies should be considered in order to facilitate the necessary organizational changes?			
Few systematic reviews available; consider change management strategies Health Systems Evidence provides syntheses of research evidence on governance, financial and delivery arrangements within health systems, and about implementation strategies that can support change in health systems			
5. What strategies should be considered in order to facilitate the necessary system changes?			

<p>Use systematic reviews for specific policy implementation issues (e.g. costs of training, regulation, and supports)</p> <p>Health Systems Evidence provides syntheses of research evidence about governance, financial and delivery arrangements within health systems, and about implementation strategies that can support change in health systems</p>			
<p>Summary of implementation considerations for each option</p> <p>(e.g. Prompt: Recipients in rural, high risk, areas are not aware of the services LHWs provide and are therefore not seeking their care. A qualitative study using focus groups regarding service utilization from LHWs showed that town hall meetings were an appropriate way to spread awareness of these services, increasing their utilization)</p>			

Cross-cutting factors: Equity considerations

With these issues in mind, what can be done during implementation to reduce inequities, if possible, or to make sure they are not increased?

General implementation considerations for all cadres (OptimizeMNH guidance documents)

Role distribution

- Clear scopes of practice are needed, and these need to be implemented at all levels of the health system. Linked to this, the distribution of roles and responsibilities between the

health worker taking on the intervention and other health workers needs to be made clear, including through regulations and job descriptions

Regulatory issues

- Changes in regulations may be necessary to support any changes in the health worker's scope of practice

Stakeholder involvement

- Health worker representatives and relevant professional bodies should be involved in the planning and implementation of the intervention to ensure acceptability among affected health workers
- Recipients of the intervention should also be involved in planning and implementation
- Local beliefs and practical circumstances related to the health conditions in question should be addressed within the programme design

Training and supervision

- Health workers and their supervisors need to receive appropriate initial and ongoing training in the intervention
- Responsibility for supervision needs to be clear and supervision needs to be regular and supportive

Systems for referral

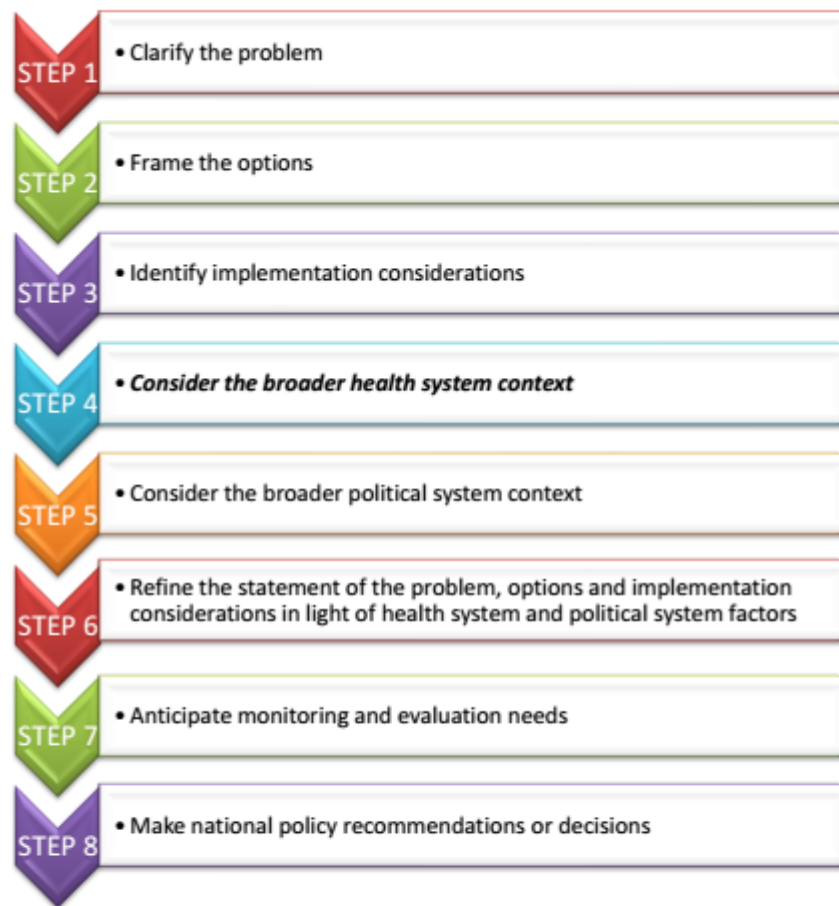
- Where necessary, referral systems need to function well, i.e. financial, logistical (e.g. transport) and relational barriers need to be addressed. Specifically, local health systems need to be strengthened to improve quality of care at the first referral facility

Supplies

- Supplies of drugs and other commodities need to be secure

Incentives

- Optimizing health worker's roles needs to be in the context of a comprehensive remuneration scheme, in which salaries and incentives reflect any changes in scope of practice. Giving incentives for certain tasks but not for others may negatively affect the work that is carried out



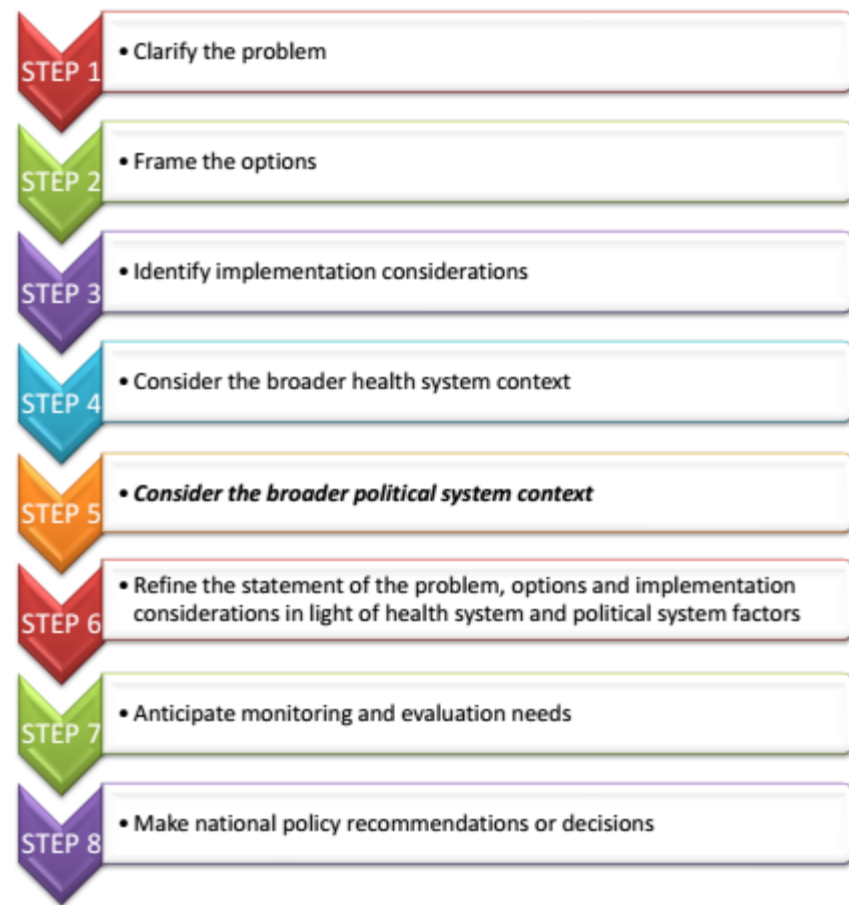
Worksheet 4 – Consider the broader health system context

	Option 1: <i>could be to act on the cadre with the most question marks</i>	Option 2: <i>could be to act on the key interventions with the most question marks</i>	Option 3: <i>could be to act on all of the question marks</i>
1. How do delivery arrangements influence the possibility of each option being adopted and implemented successfully?			
How care is designed to meet consumer's needs <i>Systematic review: Taskshifting may change provider-recipient relationships (15)</i> <i>Systematic review: Views varied, but far more 'medical' tasks, recipients preferred doctors over nurses, but for more sensitive (e.g. pelvic exams) tasks, patients at times preferred (female) nurses (14)</i>			
By whom care is provided <i>Systematic review: In some settings, gender norms meant female LHWs could not move easily within their communities to fulfill their responsibilities (17)</i>			
Where care is provided <i>Systematic analysis of programmes: Some health workers in underserved areas have to cover large distances and this can change the nature of their work (18)</i>			
With what supports is care provided <i>Systematic review: Poor planning and integration of new skills for midwives can be a barrier to undertaking new tasks (16)</i>			
2. How do financial arrangements influence the			

possibility of each option being adopted and implemented successfully?			
Financing systems <i>Systematic analysis of programmes: The ability of the government to allocate necessary financial resources influenced programme implementation (18)</i>			
Funding organizations <i>Systematic analysis of programmes: The ability of the government to clarify roles and financial responsibilities with sub-national health authorities influenced programme implementation (18)</i>			
Remunerating providers <i>Systematic analysis of programmes: Providing incentives for some tasks, but not for others, negatively affected the scope of the work performed (18)</i>			
Purchasing products and services <i>Systematic review: In low income countries, nurses' limited access to medicines and equipment may have contributed to recipients' dissatisfaction with care delivered by nurses (14)</i>			
Incentivizing consumers <i>Prompt: Decreasing or removing user fees for services provided by nurses could increase the use of these services</i>			
3. How do governance arrangements influence the possibility of each option			

being adopted and implemented successfully?			
Policy authority <i>Systematic analysis of programmes: Statutory support for changes in tasks may be important for most cadres (e.g. prescribing) (19)</i>			
Organizational authority <i>Systematic analysis of programmes: Managers did not always have authority over certain administrative decisions regarding corrective actions for workers (18)</i>			
Commercial authority <i>Prompt: Patents and prices of family planning methods may make some methods inaccessible to consumers</i>			
Professional authority <i>Systematic review: Roles of different providers may be unclear (15)</i>			
Consumer and stakeholder involvement <i>Systematic analysis of programmes: Acceptability of a programme may be influenced by the extent to which stakeholders were consulted in the development of the programme (14, 19)</i>			
Summary of health system considerations for each option <i>[e.g. Prompt: LHWs do not have a</i>			

<p> <i>formal association (governance arrangement) and therefore often work independently. Remuneration for services is not consistent (financial arrangement) and the working conditions can be difficult (delivery arrangement). Patients may have concerns over confidentiality with LHWs as they are local workers (delivery arrangement). A review on strategies used in other high-risk rural settings with similar problems would be useful to further understanding the problem and possible solutions. Local information would help understand (if this concern with confidentiality exists in particular high-risk communities)</i> </p>			
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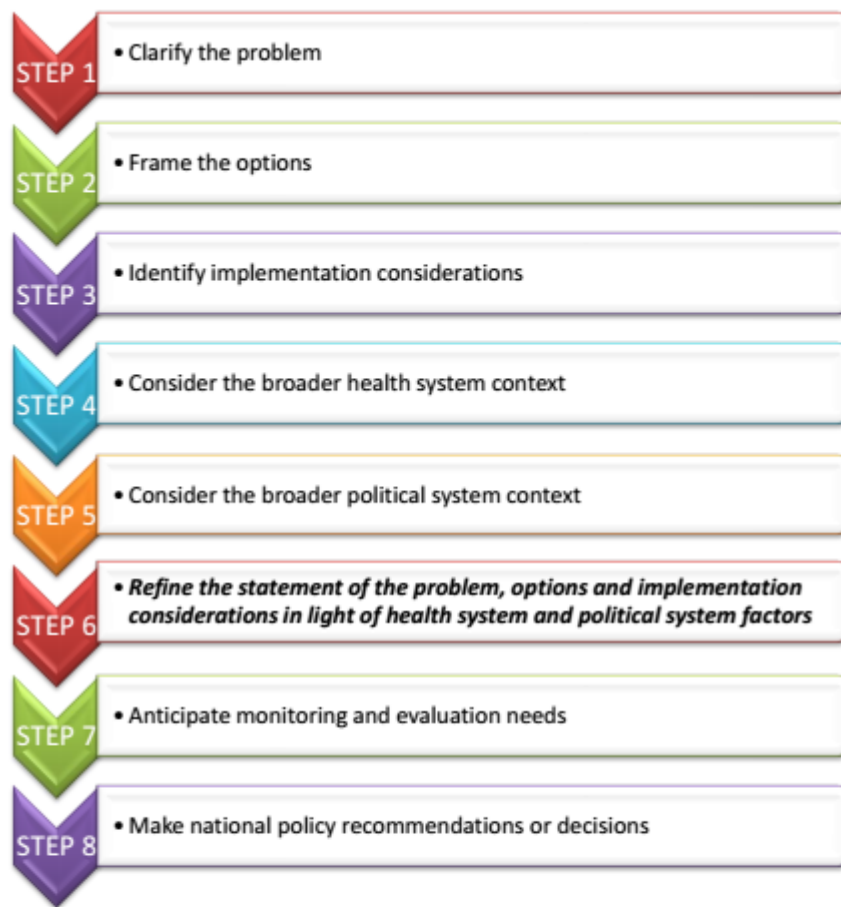


Worksheet 5 – Consider the broader political system context

	Option 1: <i>could be to act on the cadre with the most question marks</i>	Option 2: <i>could be to act on the key interventions with the most question marks</i>	Option 3: <i>could be to act on all of the question marks</i>
1. Would current political institutions allow for or hinder each policy change?			
Government structures <i>Prompt: Constitution states that health care is a sub-national responsibility, so provincial finance, health and development ministries are where most key decisions are made</i>			
Policy legacies <i>Prompt: Legislation created only a limited role for the ministry of health so civil servants never developed the administrative capacities required to pursue certain approaches</i>			
Policy networks <i>Prompt: A government-appointed guidance panel engages key stakeholders in the process of informing policymaking on various issues</i>			
2. Which politically active group(s) might have an interest in (face concentrated or diffuse costs or benefits) and mobilize for or against each option?			
Interest groups <i>Prompt: Physician and nursing associations have the technical and communications staff needed to influence the policy making process but midwifery and lay health worker associations do not</i>			
Civil society <i>Prompt: Citizens are poorly</i>			

organized and groups representing them have difficulty reaching consensus on their preferred option			
3. Does each option resonate with the beliefs and values of the government and the public? Is there any local research evidence on stakeholder's views and experiences?			
Values Prompt: Widely held values support a focus on equity in the health system			
Personal experiences Prompt: Personal experiences of the minister influence much of her decision-making			
Research evidence Prompt: Significant attention is given by civil servants to systematic reviews of effects and to economic evaluations but little attention is given to qualitative syntheses about stakeholder's views and experiences			
4. Are there external factors which may press the issue forward or draw attention away from each option?			
Political changes Prompt: A recent election has brought a new president or legislative coalition to power			
Economic changes Prompt: A global economic crisis has reduced donors' capacities to support national programmes			
Major reports Prompt: OptimizeMNIH guidance documents released			

Technological changes <i>Prompt: Mobile phone technology introduced new possibilities for performance management</i>			
New diseases <i>Prompt: An influenza outbreak has led to calls for improved reporting at the district level</i>			
Media coverage <i>Prompt: A series of investigative news articles in the national newspaper has revealed the weak enforcement of contracts in the health system</i>			
Summary of political system considerations for each option <i>(e.g. Prompt: many LHWs support expanding their roles to provide more services for the prevention of post-partum hemorrhage in high-risk rural areas. However, doctor's associations have concerns regarding the safety of these proposed changes. Doctors have more resources and influence over government officials. A recent report from the WHO shows that maternal mortality has not decreased enough to meet the MDGs by 2015, which is increasing the pressure by prominent national newspapers to pay attention to this issue.)</i>			



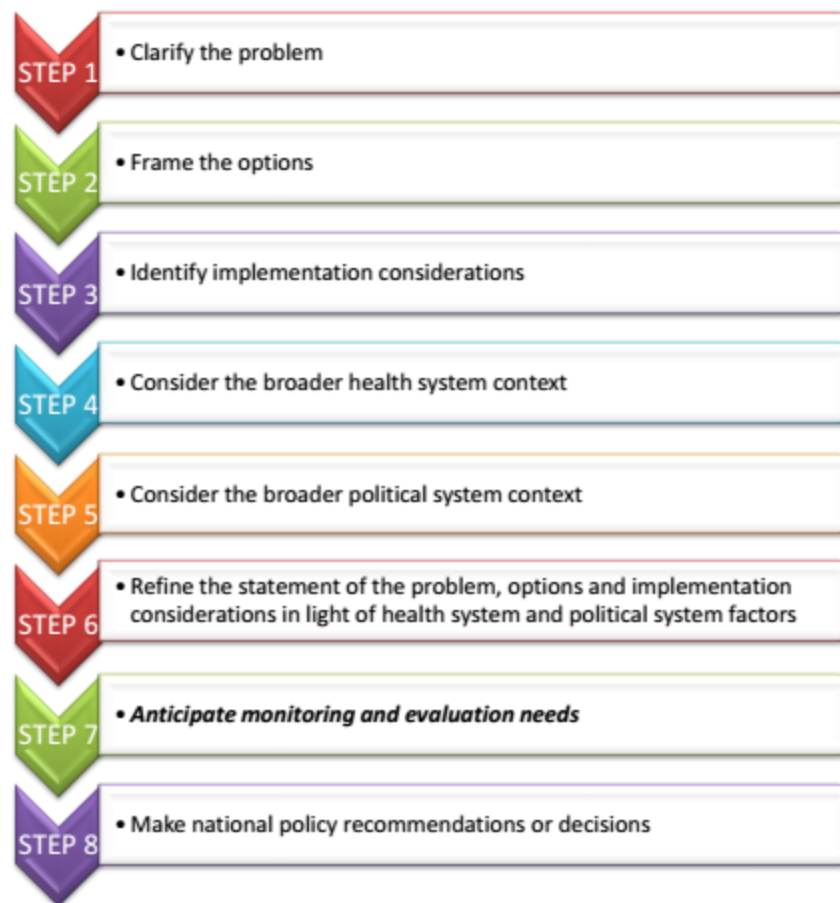
Worksheet 6 – Refine the statement of the problem, options and implementation considerations in light of health system and political system factors

	Option 1: <i>could be to act on the cadre with the most question marks</i>	Option 2: <i>could be to act on the key interventions with the most question marks</i>	Option 3: <i>could be to act on all of the question marks</i>
<i>Summary of findings on clarifying the problem (from worksheet 1)</i>			
How would consideration to the health system and political system factors change the options with regards to clarifying the problem?			
<i>Summary of costs, benefits, and harms of</i>			

<i>each option</i> (from worksheet 2)			
How would consideration to the health system and political system factors change the options with regards to framing the options?			
<i>Summary of implementation considerations for each option</i>			

(from worksheet 3)			
How would consideration to the health system and political system factors change the options with regards to planning for implementation?			
Contextualized re-iteration of clarifying the problem, framing the options, and planning for implementation in light of health system and political			

<p>system considerations.</p> <p>Consider whether any of the options would be unlikely to be adopted as they are, and whether a new or modified option would be more likely to be brought forward.</p>			
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Worksheet 7 – Anticipate monitoring and evaluation needs

	Option 1: <i>could be to act on the cadre with the most question marks</i>	Option 2: <i>could be to act on the key interventions with the most question marks</i>	Option 3: <i>could be to act on all of the question marks</i>
1. Is monitoring necessary?			
Is monitoring already in place or are new systems necessary?			
What are the costs of establishing a new system?			
Are findings going to be useful for change? What actions would occur if monitoring reveals things are not going as planned? For options in which the recommendation was in the context of M&E, follow the directions for M&E given for each area in the full guidance document. If not, then the M&E activities should look at the interventions and on the cadres' engagement in specific interventions.			
2. What should be measured?			
What parts of the results chain should be / could be measured?*			
What properties of an indicator make it useful?***			
3. Should an impact evaluation be conducted?			

Compare the costs of conducting an impact evaluation with the costs of not conducting one, in case the programme does not work or causes harms – would a programme be stopped or changed if poor outcomes were found?			
Can the impact evaluation be done at the early stages of implementation (e.g. pilot study) to improve or stop the rest of the implementation, if necessary?			
4. How should the impact evaluation be done?			
<p>Randomised controlled trial (RCT) when appropriate to compare with/without intervention groups</p> <p>Controlled before-after evaluation or interrupted time-series to look at multiple times, when RCTs are not feasible</p> <p>Economic evaluation or cost-effectiveness analysis</p> <p>Process evaluation to examine whether the programme or policy was delivered as intended</p> <p>All types of evaluation methods should be planned for and included in the earliest stages of planning to ensure valid, reliable and useable data</p>			
<p>Summary of monitoring and evaluation needs for each option</p> <p>(e.g. Prompt: 8 districts are eligible for the given intervention of training, supporting and</p>			

<p><i>regulating LHWs in providing misoprostol for the prevention of post-partum hemorrhage. A RCT is planned to compare outcomes in 4 of the districts to receive the intervention starting in 4 months and the other 4 districts will be started with the intervention in 12 months. The districts for each group will be chosen randomly, and multiple indicators looking at the implementation (patient satisfaction, numbers of LHWs involved) and outcomes (mortality rate, use of misoprostol) will be measured.)</i></p>			
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* Modified results chain (10)

Inputs – financial, human and material resources used for the intervention

Activities – Actions taken or work performed through which inputs, such as funds, technical assistance and other types of resources are mobilized to produce specific outputs

Outputs – The products, capital goods and services which result from an intervention; may also include changes resulting from the intervention which are relevant to the achievement of outcomes,

Outcomes – The likely or achieved short-term and medium-term effects of an intervention's outputs

Impacts – Positive and negative, primary and secondary long-term effects produced by an intervention, directly or indirectly, intended or unintended

** Factors to consider when selecting indicators (10)

Validity – extent to which the indicator accurately measures what it is supposed to measure

Acceptability – extent to which the indicator is acceptable to those being assessed and those recording the data

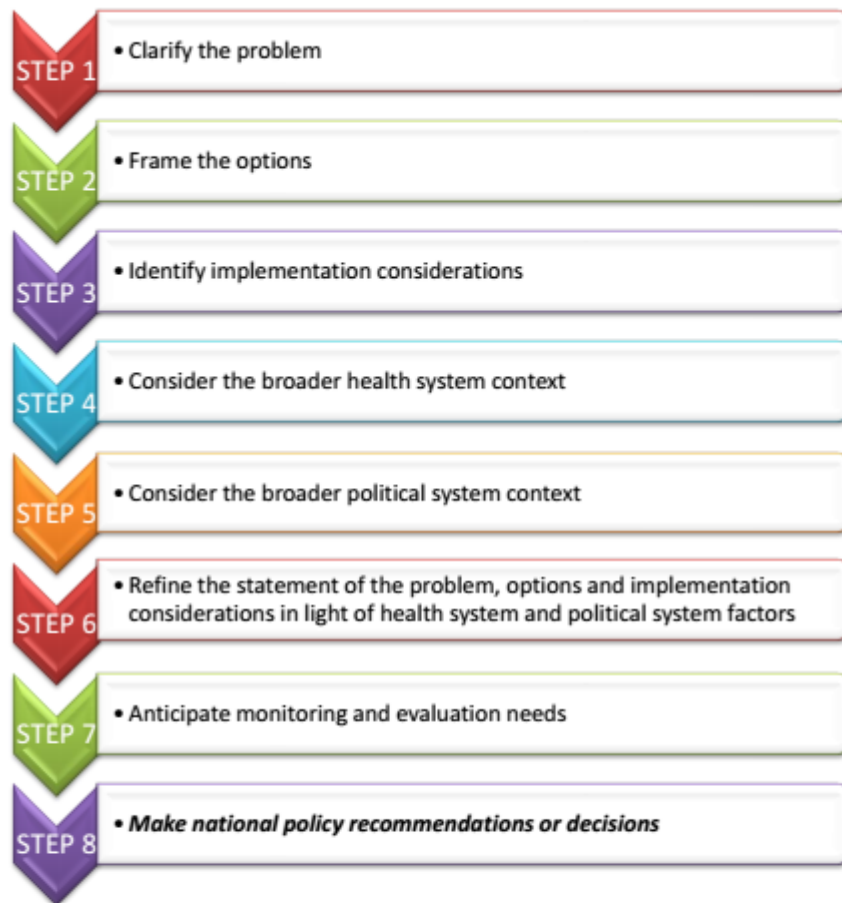
Feasibility – extent to which valid, reliable and consistent data are available for collection

Reliability – extent to which there is minimal measurement error, or the extent to which findings are reproducible if collected by another party

Sensitivity to change – ability to detect changes in the unit of measurement

Predictive validity – ability to accurately predict relevant outcomes

Consider also – cost, time, and motivation to collect or manipulate the data



Worksheet 8 – Make national policy recommendations or decisions

Users should identify their specific processes for policymaking to determine the proper venue (e.g. national guidance panel, ministry of health, etc.) to address this work. The recognition of this process is important for determining the proper product, audience, format, and language to be used in developing the recommendations or policy decisions. The next three boxes address issues of engaging the public in the policymaking process, developing a policy brief, and planning a policy dialogue, if these are appropriate measures for the context-specific venue.

1. If applicable, has the public been engaged in the policymaking process? (9)

- What strategies can be used to engage the mass media in informing the public about policy development and implementation?
Structured press releases, fact boxes, press conferences, providing stories, avoiding jargon, providing access to experts, tip sheets, training for journalists, web-based or social media considerations
- What strategies can be used to engage civil society groups?
Patient organizations, community groups, coalitions, advocacy groups, faith-based organizations, charities or voluntary organisations, professional associations, trade unions, business associations, etc. can be involved in multiple steps of the policymaking process.
- How can consumers become involved in policy development and implementation?
Consultation, collaboration, or consumer control (e.g. consumers develop and advocate or implement health policies themselves)
- How will the above information be used in shaping the policymaking process?
Are there plans / time to add the information learned through these processes? Explain these processes to those involved, as it may otherwise be seen as tokenism if advice is not taken.

2. Is a policy brief being developed to collate all of the analyses captured in the workbook? (7)

- Does the policy brief address a high-priority issue and describe the relevant context of the issue being

<p>addressed?</p> <ul style="list-style-type: none"> • Does the policy brief describe the problem, costs and consequences of options to address the problem, and the key implementation considerations? • Does the policy brief employ systematic and transparent methods to identify, select and assess synthesized research evidence? • Does the policy brief take quality, local applicability, and equity considerations into account when discussing the synthesized research evidence? • Does the policy brief employ a graded-entry format? Allows busy policymakers to quickly scan for relevance to topic and context (e.g. 1:3:25 format = one page with take home messages: 3-page executive summary: 25-page report with reference list for more information) • Was the policy brief reviewed for both scientific quality and system relevance? Merit review involving one of each: policymaker, other stakeholder, researcher
<p>3. Is a policy dialogue being planned to support evidence-informed policymaking? (8)</p> <ul style="list-style-type: none"> • Does the dialogue address a high priority issue? • Does the dialogue provide opportunities to discuss the problem, options to address the problems, and key implementation considerations? • Is the dialogue informed by a pre-circulated policy brief and by a discussion about the full range of factors that can influence the policymaking process? • Does the dialogue ensure fair representation among those who will be involved in, or affected by, future decisions related to the issue? Policymakers, managers, staff or members in civil society groups, health professional associations, researchers, etc. Usually 15-20 or more people, depending on the issue and the area affected by the issue. • Does the dialogue engage a skilled, knowledgeable and neutral facilitator, follow a rule about not attributing comments to individuals, and not aim for consensus? • Are outputs produced and follow-up activities undertaken to support action?

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