SUPPORT Tools for evidence-informed health Policymaking (STP)

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Background: Knowing how to find and use research evidence can help policymakers and those who support them to do their jobs better and more efficiently. Each chapter presents a proposed tool that can be used by those involved in finding and using research evidence to support evidence-informed health policymaking. The book addresses four broad areas: **1)** Supporting evidence-informed policymaking, **2)** Identifying needs for research evidence in relation to three steps in policymaking processes, namely problem clarification, options framing, and implementation planning, **3)** Finding and assessing both systematic reviews and other types of evidence to inform these steps, and **4)** Going from research evidence to decisions. • Each chapter begins with between one and three typical scenarios relating to the topic. These scenarios are designed to help readers decide on the level of detail relevant to them when applying the tools described. Most chapters are structured using a set of questions that guide readers through the proposed tools and show how to undertake activities to support evidence-informed policymaking efficiently and effectively.

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(continued from front page) These activities include, for example, using research evidence to clarify problems, assessing the applicability of the findings of a systematic review about the effects of options selected to address problems, organising and using policy dialogues to support evidence informed policymaking, and planning policy monitoring and evaluation. In several chapters, the set of questions presented offers more general guidance on how to support evidence informed policymaking. Additional information resources are listed and described in every chapter. The evaluation of ways to support evidence-informed health policymaking is a developing field and feedback about how to improve the book is welcome.

SUPPORT Tools for evidence informed policymaking (STP)

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The Norwegian Knowledge Centre for the Health Services summarizes and disseminates evidence concerning the effect of treatments, methods, and interventions in health services, in addition to monitoring health service quality. Our goal is to support good decision making in order to provide patients in Norway with the best possible care. The Centre is organised under The Directorate for Health and Social Affairs, but is scientifically and professionally independent.

Table of contents

Preface

This book is based on a series of articles published in *Health Research Policy and Systems*. It is written for people responsible for making decisions about health policies and programmes and for those who support these decision makers. The book is intended to help such people ensure that their decisions are well-informed by the best available research evidence. The SUPPORT tools and the ways in which they can be used are described in more detail in the Introduction. A glossary can be found at the end of the book. Links to Spanish, Portuguese, French and Chinese translations can be found on the SUPPORT website (www.support-collaboration.org). Feedback about how to improve these tools is welcome and should be sent to: STP@nokc.no.

Introduction

John N Lavis, Andrew D Oxman, Simon Lewin, Atle Fretheim

Summary

Knowing how to find and use research evidence can help policymakers and those who support them to do their jobs better and more efficiently. Each chapter presents a proposed tool that can be used by those involved in finding and using research evidence to support evidence-informed health policymaking. The book addresses four broad areas:

1. Supporting evidence-informed policymaking
2. Identifying needs for research evidence in relation to three steps in policymaking processes, namely problem clarification, options framing, and implementation planning
3. Finding and assessing both systematic reviews and other types of evidence to inform these steps, and
4. Going from research evidence to decisions.

Each chapter begins with between one and three typical scenarios relating to the topic. These scenarios are designed to help readers decide on the level of detail relevant to them when applying the tools described. Most chapters are structured using a set of questions that guide readers through the proposed tools and show how to undertake activities to support evidence-informed policymaking efficiently and effectively. These activities include, for example, using research evidence to clarify problems, assessing the applicability of the findings of a systematic review about the effects of options selected to address problems, organising and using policy dialogues to support evidence-informed policymaking, and planning policy monitoring and evaluation. In several chapters, the set of questions presented offers more general guidance on how to support evidence-informed policymaking. Additional information resources are listed and described in every chapter. The evaluation of ways to support evidence-informed health policymaking is a developing field and feedback about how to improve the book is welcome.

Background

Policymakers and those supporting them often find themselves in situations in which better knowledge about ways to find and use research evidence would help them to do their jobs more effectively and efficiently. In this book, we describe how more systematic processes can be used to support evidence-informed policymaking, identify needs for research evidence, find and assess evidence to address these needs, and go from research evidence to decisions. Here in this introduction to the book, we describe the target audiences for the SUPPORT tools, the proposed tools and how they can be used, what the tools do not do, and how we plan to support their further development.

The target audiences for the SUPPORT tools

The SUPPORT tools presented in this book have been developed primarily for policymakers and those who support them.

Policymakers are a diverse group that includes cabinet members (e.g. Ministers of Health or Finance), elected officials (e.g. chairs of legislative committees), senior civil servants (e.g. directors of primary healthcare programmes), and high-level political appointees (e.g. heads of government agencies). Policymakers may differ significantly on the basis of their authority or role in different political systems but what all have in common is the authority to make or influence decisions directly. In some countries, cabinet members may be elected, whereas the senior civil servants who advise them may be neutral advisors with no affiliations to the governing party. In other countries, all positions carrying decision-making authority may be appointed by the governing party. Policymakers may also differ by sector (e.g. health or economy) or operational level (e.g. local or national).

Those who support policymakers are equally diverse and may include individuals within government (e.g. junior civil servants such as policy analysts, or the political staff of an elected official or high-level political appointee), and individuals working in independent units that provide support for the use of research evidence in policymaking. But their role in informing the decisions made by policymakers is common to all. This, despite the fact that they may differ in their degree of independence from policymakers (e.g. a semi-autonomous government agency, or a health systems research unit that is independent of government but supports the use of research evidence in policymaking) and their affiliation with other institutions (e.g. non-governmental organisations, universities).

The SUPPORT tools are also relevant to health system stakeholders. This group may include non-governmental organisations and civil society groups that play diverse roles. They may, for example, seek to influence decisions made by policymakers. Or else they work in areas not normally addressed by policymakers, or in areas where authority has been delegated to them by policymakers themselves. We recognise, though, that some of the language and examples used in this book may resonate more with policymakers and those who support them.

The SUPPORT tools have been written for settings that range from low- and middle-income countries such as Uganda and Chile, to high-income countries such as Canada and Norway. Wherever possible, examples have been drawn from disparate settings. As described below, many of the issues and opportunities encountered in supporting evidence-informed policymaking are remarkably similar across settings.

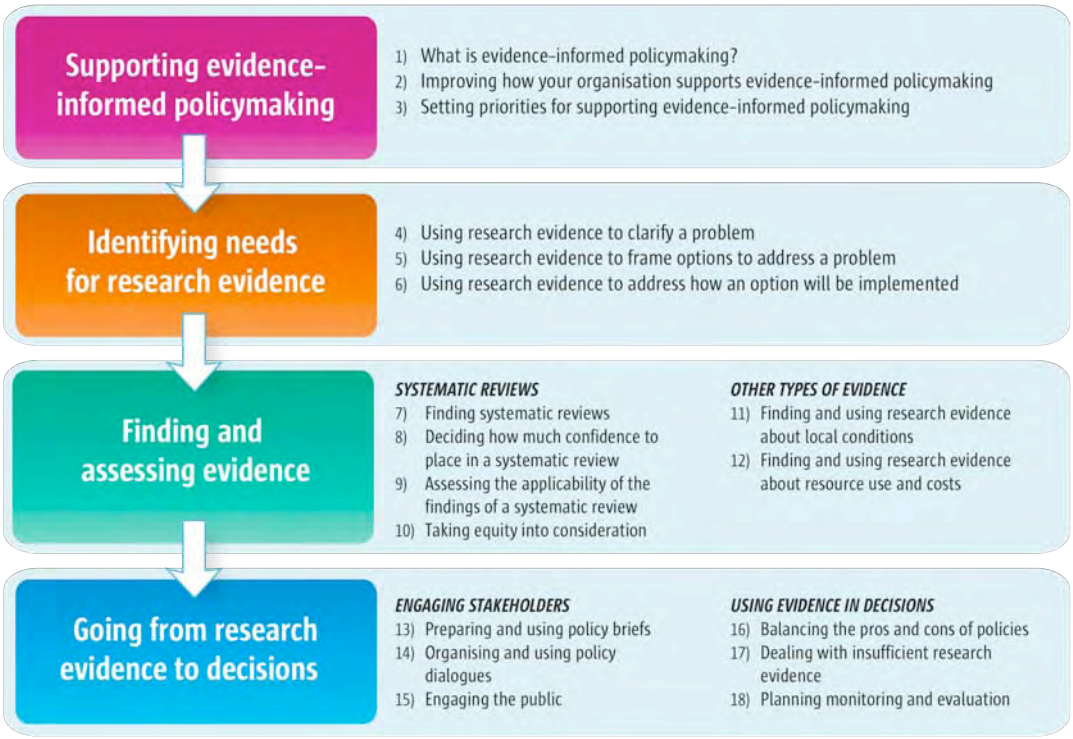
Each chapter begins with between one and three typical scenarios designed to encourage readers to use the tools described and to help them to decide on the relevant level of detail they require. Some scenarios describe senior civil servants who simply need a general sense of the expectations required for their staff – this information can be quickly gained by scanning through the chapter. Other scenarios, for example, relate to junior policy analysts and directors of applied health systems research units. They will require more specific guidance on how to undertake new activities and should therefore read the relevant chapter in more detail when asked to undertake such tasks. The chapter will also be useful to them as a reference.

The SUPPORT tools and how they can be used

In each chapter, we propose a tool that can be used by those involved in finding and using research evidence to support evidence-informed health policymaking. The book addresses four broad areas of interest related to policymaking: 1. Supporting evidence-informed policymaking (Chapters 1-3 [1-3]) 2. Identifying needs for research evidence in relation to three steps in policymaking processes, namely clarifying problems, framing options and

planning implementation (Chapters 4-6 [4-6]) 3. Finding and assessing evidence to inform each of these steps (Chapters 7-10 [7-10] focus on systematic reviews and Chapters 11-12 [11,12] on other types of evidence) 4. Going from research evidence to decisions (Chapters 13-15 [13-15] focus on engaging stakeholders in evidence-informed policymaking. Chapters 16-18 [16-18] address how to use research evidence in decisions). Figure 1 provides an overview of the book, with the numbers shown referring to the relevant chapter. Additional resources and website links are provided in each chapter.

Overview of the series



In the chapters on supporting evidence-informed policymaking (the first of the four key areas covered in this book), the principal focus of each is a set of questions that can be used to guide ways to support evidence-informed policymaking. Policymakers and those who support them may wish to know more about what evidence-informed policymaking is (Chapter 1) [1], how to improve the ways that their organisation supports evidence-informed policymaking (Chapter 2) [2] or how to set priorities for supporting evidence-informed policymaking (Chapter 3) [3]. These chapters can help to guide those striving to understand and to shape the context for evidence-informed policymaking.

In the other three broad areas (see Figure 1), the main focus of each chapter is a set of questions that can guide how an activity that supports evidence-informed policymaking can be undertaken. Such activities might include using research evidence to clarify a problem (Chapter 4) [4], assessing the applicability of the findings of a systematic review about the effects of a policy or programme option in order to address a problem (Chapter 9) [9], organising and using policy dialogues to support evidence-informed policymaking (Chapter 14) [14], and planning the monitoring and evaluation of policies (Chapter 18) [18].

Those who wish to learn about the different types of research evidence needed in policymaking processes should ideally start with Chapters 4-6 [4-6]. These three chapters correspond to three steps in policymaking processes, namely problem clarification, option framing and implementation planning. These chapters help to identify needs for research evidence in relation to each of these steps. While policymaking processes rarely involve a clear sequence of steps, even highly dynamic processes can benefit from a systematic method

of clarifying a problem, framing options to address it, and defining how an option will be implemented. Chapter 13 [13] describes how to bring these steps together in policy briefs that are used to support the use of research evidence in policymaking.

Those familiar with how to identify needs for research evidence in relation to each step in a policymaking process, as well as those needing to undertake a more focused activity related to finding and assessing evidence, may want to move directly to one or more of Chapters 7-12 [7-12]. Within these chapters, there are two sub-sets of chapters. The first addresses the following issues related to systematic reviews:

- How to find systematic reviews (Chapter 7) [7]. Policymakers and those who support them will need to understand the rationale for seeing systematic reviews as a 'first place to look' and how to find them efficiently
- How much confidence can be placed in a systematic review (Chapter 8) [8]. Like any type of research, a systematic review can be conducted and reported well or poorly. Policymakers will want to know the reliability of a review that supports an option that they will be endorsing
- How to assess the applicability of the findings of a systematic review (Chapter 9) [9]. Those who support policymakers will need to assess whether the findings of a review of studies conducted in very different settings, do actually apply in their own setting
- How to take equity into consideration when assessing the findings of a systematic review (Chapter 10) [10]. Many policymakers will wish to consider the potential impacts of an option on disadvantaged groups or settings

Chapter 7 [7] emphasises the merits of systematic reviews, while the three chapters that follow, grapple with the challenges of using reviews in policymaking. Chapters 11 and 12 together complete a second sub-set about finding and using research evidence about local conditions (Chapter 11) [11] and resource use and costs (Chapter 12) [12].

Once research evidence has been found and assessed, a variety of opportunities and issues may arise when going from research evidence to a decision. This issue is the focus of Chapters 13-18 [13-18]. These chapters contain two additional sub-sets of three chapters each. The first examines ways to engage stakeholders to support evidence-informed policymaking. Two introduce new innovations:

- Policy briefs that package research evidence so as to inform deliberations among policymakers and stakeholders (Chapter 13) [13]
- Policy dialogues that allow research evidence to be considered together with the views, experiences and tacit knowledge of those who will be involved in, or affected by, future decisions about a high-priority issue (Chapter 14) [14]

Research evidence is only one factor that can influence the policymaking process. Policy dialogues provide an opportunity to discuss research evidence as well as the many other factors that can exert influence. The third chapter focuses on how to engage the public in evidence-informed policymaking (Chapter 15) [15].

The second and final sub-set addresses issues related to using research evidence in decisions. These are:

- Using research evidence in balancing the pros and cons of policies (Chapter 16) [16]
- Dealing with insufficient research evidence (Chapter 17) [17], and
- Planning the monitoring and evaluation of policies (Chapter 18) [18]

The last chapter could also be read in conjunction with the chapters about problem clarification (Chapter 4) [4], options framing (Chapter 5) [5] and implementation planning

(Chapter 6) [6]. Planning monitoring and evaluation is arguably a fourth step in policymaking processes.

Some issues, such as equity, are a recurring theme in many of the chapters even if they are the primary focus of only one chapter (Chapter 10) [10].

What the SUPPORT tools do not do

The SUPPORT tools have been developed giving due consideration to other features of the policymaking process. For example, the chapter about using research evidence to clarify a problem (Chapter 4) [4] notes the importance of watching for windows of opportunity that may arise due to political events, such as a shifts or changes in the balance of organised political forces or the appointment of a new health minister. Chapter 9 [9] examines how to assess the applicability of the findings of a systematic review and notes the importance of evaluating whether the studies included in a systematic review were conducted in settings with largely similar perspectives and political influence amongst health system stakeholders, compared to the settings to which policy decisions may be applied.

The SUPPORT tools do not, however, address efforts to support health policymaking in general. As the titles indicate, the focus of each tool is on supporting *the use of research evidence* in health policymaking. This does not mean that other forms of support could not complement these tools. Policymakers, for example, also need to know how to assess and influence stakeholder dynamics (independent of the implications of such dynamics for the applicability of the findings of a systematic review). Such dynamics, including power relations among stakeholders and the interests of these different groups, are a key factor influencing the policymaking process. Values are another domain where tools to support their systematic and explicit consideration in health policymaking could be useful for policymakers and those who support them.

By focusing on how to support the use of research evidence in health policymaking, the SUPPORT tools are meant to aid the use of the best research evidence available at the time that it is needed and in the time available to compile such evidence. Research evidence may be lacking, incomplete, imperfect and even contradictory. But policymakers still need to make decisions. Proceeding on the basis of available research evidence, with an awareness of its strengths and limitations, would be seen by many stakeholders as an indication that the work of policymakers was appropriate and constructive. Monitoring how options are implemented, evaluating their impacts, and later making adjustments as better research evidence becomes available, would further this impression.

Further development of the SUPPORT tools

Some of the activities and broader efforts to support evidence-informed policymaking that are addressed in the SUPPORT tools have received considerable attention in research. For example, the SUPPORT tool that is used for finding and using research evidence about resource use and costs (Chapter 12) [12] draws on relevant aspects of the economic evaluation literature. Further, some of the SUPPORT tools have already been used extensively in the field and adapted iteratively based on these experiences. For example, successive iterations of the SUPPORT tool for using research evidence to frame options to address a problem (Chapter 5) [5] have been used in workshops for policymakers, stakeholders and researchers from more than ten countries in Africa, four countries in Asia, and seven countries in the Americas. For us, this field testing has reinforced the fact that

many of the issues and opportunities encountered in supporting evidence-informed policymaking are remarkably similar across settings.

Other activities and support efforts have received less attention. For example, SUPPORT tools such as those that address how to improve the ways that an organisation supports evidence-informed policymaking (Chapter 2) [2], how an organisation sets priorities for supporting evidence-informed policymaking (Chapter 3) [3], how to prepare and use policy briefs (Chapter 13) [13], and how to organise and use policy dialogues (Chapter 14) [14] would all benefit from the development of a more rigorous evidence base. These tools have also been subjected to less field-testing thus far. We are disseminating the full set of tools in anticipation that wider use and application will inform further adaptation. Feedback on how to improve the tools is welcome. We would also welcome feedback about what tools need to be added to the book.

Conclusion

The SUPPORT tools in this book have been designed to help policymakers and those who support them to do one aspect of their job better or more efficiently – namely to find and use research evidence to support health policymaking. The tools are also relevant to health system stakeholders, such as non-governmental organisations and civil society groups. Different readers will use the tools in different ways. Policymakers may skim the chapters to get ideas on how they should be adjusting the expectations they set for their staff. Those who support policymakers may choose to read a particular chapter to help them with undertaking a new activity, and then use the chapter later as a reference guide or as a way of refining their skills. We hope that policymakers and those who support them will help us to develop and improve what is presented here.

Resources

Useful documents and further reading

- Lavis JN, Oxman AD, Moynihan R, Paulsen E. Evidence-informed health policy: 1. Synthesis of findings from a multi-method study of organizations that support the use of research evidence. Implementation Science 2008, 3:53: www.implementationscience.com/content/3/1/53 – Source of insights from organisations actively engaged in supporting the use of research evidence in policymaking, particularly policymaking in low- and middle-income countries

- Sutcliffe S, Court J. A Toolkit for Progressive Policymakers in Developing Countries. London, UK: Overseas Development Institute, 2006: www.odi.org.uk/resources/download/154.pdf – Source of additional tools that can be used by those supporting policymaking, particularly policymaking in low- and middle-income countries

- Ciliska D, Thomas H, Buffett C. Introduction to Evidence-Informed Public Health and a Compendium of Critical Appraisal Tools for Public Health Practice. Hamilton, Canada: National Collaborating Centre for Methods and Tools, 2008: http://www.nccmt.ca/pubs/2008_07_IntroEIPH_compendiumENG.pdf – Source of additional tools that can be used by those supporting the use of research evidence in policymaking, particularly related to public health

- Guyatt G, Rennie D, Meade MO, Cook DJ (Editors). Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice. Second Edition. New York, USA: McGraw Hill Medical, 2008 – Source of additional tools that can be used by those supporting the use of research evidence in policymaking, particularly in policymaking related to clinical care

- Research Matters. Knowledge Translation: A 'Research Matters' Toolkit. Ottawa, Canada: International Development Research Centre: www.idrc.ca/research-matters/ev-128908-201-1-DO_TOPIC.html – Source of additional tools that can be used by those supporting the use of research evidence in policymaking, particularly by researchers

Links to websites

- *SUPporting POlicy relevant Reviews and Trials (SUPPORT) Collaboration:* www.support-collaboration.org/ – Source of translations of this book into Spanish, Portuguese, French and Chinese

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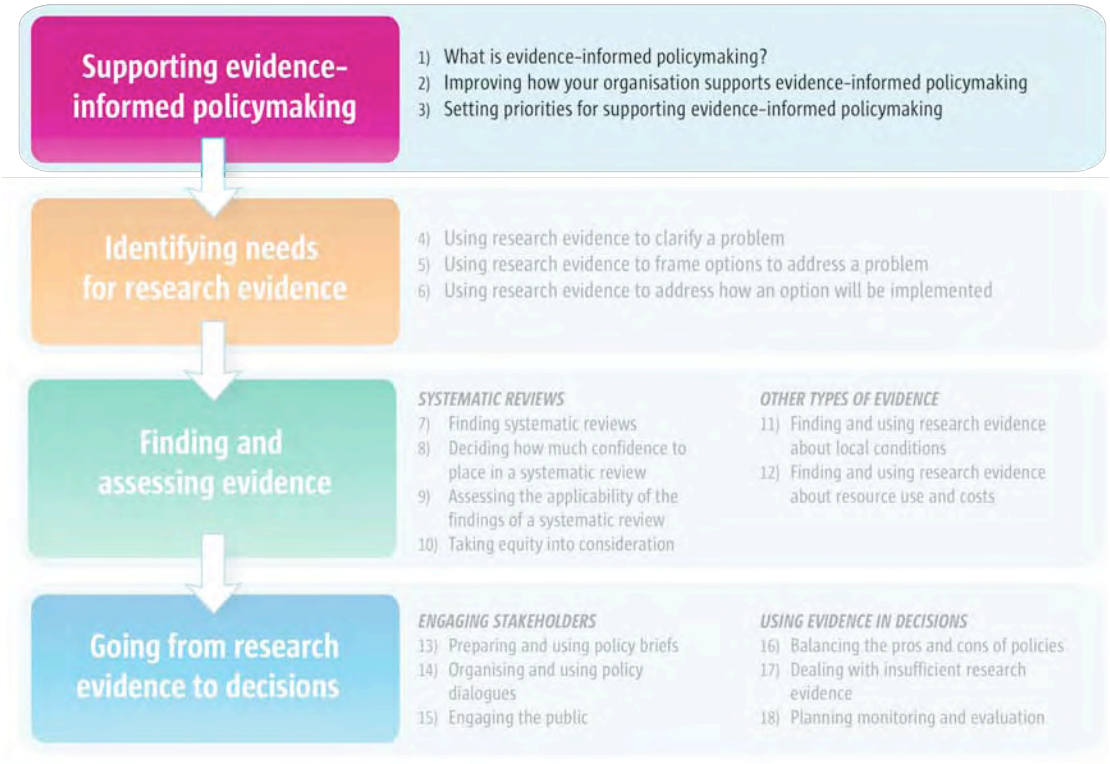
Chapters 1, 2 and 3: Supporting evidence-informed policymaking



1. What is evidence-informed policymaking?

Andrew D Oxman, John N Lavis, Simon Lewin, Atle Fretheim

Summary

In this chapter, we discuss the following three questions:
1. What is evidence?
2. What is the role of research evidence in informing health policy decisions?
3. What is evidence-informed policymaking?

Evidence-informed health policymaking is an approach to policy decisions that aims to ensure that decision making is well-informed by the best available research evidence. It is characterised by the systematic and transparent access to, and appraisal of, evidence as an input into the policymaking process. The overall process of policymaking is not assumed to be systematic and transparent. However, within the overall process of policymaking, systematic processes are used to ensure that relevant research is identified, appraised and used appropriately. These processes are transparent in order to ensure that others can examine what research evidence was used to inform policy decisions, as well as the judgements made about the evidence and its implications. Evidence-informed policymaking helps policymakers gain an understanding of these processes.

Scenario

You work in the Ministry of Health and the Minister of Health has asked you to present options for improving the extent to which children are covered by health insurance. You want to ensure that decisions about how to address this important problem are well-informed. You decide to commission a unit that supports the Ministry of Health in using evidence in policymaking to prepare a policy brief summarising both the best available evidence characterising the problem and the options for addressing it

Background

For senior policymakers and others involved in scenarios such as the one outlined above, this chapter provides a basis for a common understanding of what constitutes 'evidence', the role of evidence in health policymaking, what constitutes 'evidence-informed health policymaking', and why it is important.

The achievement of universal and equitable access to healthcare, of health-related Millennium Development Goals (MDGs), and of other health goals is more likely to be realised through well-informed health policies and actions [1-4]. Unfortunately, the reality is that health policies are often not well-informed by research evidence [4-7]. Poorly-informed decision making is one of the reasons why services sometimes fail to reach those most in need, why health indicators may be off-track and why many countries are unlikely to be able to meet the health MDGs [8]. Poorly-informed decision making may also contribute to problems related to the effectiveness, efficiency (i.e. value for money), and equity of health systems.

Sub-Saharan Africa spends, on average, approximately €80 per person on healthcare. In comparison, Asia spends €190 and OECD high-income countries spend €2,700 per person [9]. With limited resources and a substantial healthcare burden, it is vital that low- and middle-income countries spend their healthcare budgets wisely. High-income countries also face resource constraints due to growing healthcare demands and costs.

Access to health services is often not equitable and this may be exacerbated by inefficient health systems [10]. Once individuals do gain access, care may be substandard or expensive. Effective and cheap interventions, such as magnesium sulphate for eclampsia and pre-eclampsia, are sometimes not used, or are simply unavailable [11]. Ineffective or unnecessarily expensive interventions (such as routine episiotomies, and the provision of intravenous fluids rather than oral rehydration solutions for diarrhoea in children) are sometimes still used. Better use of research evidence for selecting and promoting interventions, and for deciding on the delivery, financial and governance arrangements to support the use of these interventions can help to reduce these problems, as illustrated by the examples shown in Table 1.1.

Table 1.1
Examples of the use of research evidence in policymaking

Magnesium sulphate for the treatment of eclampsia and pre-eclampsia An example of inadequate health system arrangements to support an inexpensive and effective intervention	There is high-quality evidence showing that magnesium sulphate, a low-cost drug, is effective for the treatment of eclampsia and pre-eclampsia [12,13]. However, the drug, like many other effective treatments in low- and middle-income countries, is still not yet widely available [11,14]. Failures in the registration, procurement, and distribution mechanisms for magnesium sulphate have contributed to its poor availability in countries such as Mozambique and Zimbabwe [11]. In other countries, problems include a lack of guidelines mandating the use of magnesium sulphate, the failure to include it on lists of essential drugs, a failure to implement existing guidelines, and restrictions on which facilities and health workers are authorised to administer it [14]. Although eclampsia and severe pre-eclampsia affect few women relative to the number of people affected by other healthcare problems, approximately 63,000 women worldwide die from these conditions every year. These conditions are also associated with neonatal deaths

Paying for performance An example of the widespread use of a health system arrangement with uncertain effects and inadequate impact evaluation	Paying for performance (P4P) refers to the transference of money or material goods conditional on people taking a measurable action or achieving a predetermined performance target. P4P is widely advocated and used with the aim of improving healthcare quality and utilisation, and achieving other health goals, including the MDGs. An overview of the effects of any type of P4P in the health sector targeted at patients, providers, organisations or governments found 12 systematic reviews [15]. The results indicated that financial incentives targeting recipients of healthcare and individual healthcare professionals appear to be effective in the short run for simple and distinct, well-defined behavioural goals. However, there is limited evidence that financial incentives can sustain long-term changes. There is also limited evidence of the effects of P4P targeted at organisations, or of the effects of P4P in LMICs. In LMICs, P4P schemes have generally included ancillary components, such as increased resources, training and technical support. Evaluations of these schemes have rarely assessed the effects of conditionality per se. There is almost no evidence of the cost-effectiveness of P4P. Moreover, P4P can have undesirable effects, including motivating unintended behaviours, distortions (ignoring important tasks that are not rewarded with incentives), gaming (improving or cheating on reporting rather than improving performance), cherry picking (selecting or avoiding patients based on how easy it is to achieve performance targets), the widening of the resource gap between rich and poor, and greater dependence on financial incentives
Reference pricing in British Columbia An example of an evidence-informed approach to more efficient drug policies	Since 1995, the province of British Columbia (BC) in Canada has operated a Reference Drug Program (RDP) and several related policies have attracted both praise and criticism as strategies for cost containment [16]. The policies were introduced by Pharmacare, the publicly-funded drug insurance programme operated by the provincial Ministry of Health. Pharmacare had been struggling for years with double-digit growth in annual drug costs and the aim of the RDP was to provide similar insurance coverage for similar drugs without increasing other health service costs or incurring adverse health events. The RDP was challenged by the pharmaceutical industry who argued that it was hazardous to patients. But the RDP was defended by the Ministry of Health as being evidence-based. The degree to which the RDP had achieved its goals was evaluated by independent researchers, and this provided the basis for the Ministry of Health to defend and sustain the programme. Researchers needed to adapt to the policymakers' context, which included competing definitions of medical necessity and a policy cycle that accelerated and decelerated rapidly [17-20]. The sustained involvement of researchers in an advisory committee on policy implementation built mutual respect and understanding between researchers and policymakers, and the smooth implementation of a randomised policy trial. However, the personal collaborative relationships established between the policymakers and researchers were not easily transferable to new staff who did not share the history
Seguro Popular in Mexico An example of an evidence-informed approach to	In 2004, Mexico's national government rolled out a new system of health insurance called the Seguro Popular, or the Popular Health Insurance scheme, with the aim of extending coverage to the approximately 50 million Mexicans not covered by existing programmes [21-23]. The scheme was progressively introduced across Mexico, starting with the poorest

extending health insurance coverage and evaluating its impacts	communities first, and offered a defined package of health services. According to Julio Frenk, Mexico's Secretary of Health during this time: "This is almost a textbook case of how evidence really first of all changed public perceptions, then informed the debate, and then got translated into legislation" [21]. One of the key pieces of initial evidence that sparked widespread debate about the need for reform was the finding that Mexico's old health system, contrary to popular belief, was funded largely regressively through private out-of-pocket contributions. Having informed the debate and the development of the scheme, evidence has also played a role in evaluation. Taking advantage of the timetable of the progressive rollout, the government set up a controlled trial that compared the outcomes for those communities receiving the scheme, and those still waiting for it. In Mexico, evidence that flows from evaluative research, such as the controlled study of the Seguro Popular, is seen as central to the nation's reinvigorated democracy. In 2004, recognising its political and ethical obligation to evaluate the impact of policy decisions, the government of Mexico passed legislation requiring that impact evaluations be conducted for a variety of public programmes, explicitly recognising the value of learning what works – and why – as a guide for future budget decisions [24,25]

An evidence-informed approach better enables policymakers to manage their own use of research evidence. It also enables them to manage better the misuse of research evidence by lobbyists, including researchers when they act as advocates for particular policy positions. Evidence-informed approaches allow policymakers to:

- Ask critical questions about the research evidence available to support advocated policies
- Demonstrate that they are using good information on which to base their decisions, and
- Ensure that evaluations of their initiatives are appropriate and that the outcomes being measured are realistic and agreed in advance

An evidence-informed approach to policymaking also allows policymakers to acknowledge that policies may be informed by imperfect information. This recognition reduces political risk because it sets in motion ways to alter course if policies do not work as expected. There is a far greater political risk when policies are advocated without acknowledging the limitations of the available evidence and when policies are then adhered to regardless of the results. This renders policymakers subject to criticism for failures related and unrelated to the policy itself.

In this book, our aim is to improve the effectiveness, efficiency and equity of health policies through the better use of research evidence to inform decisions. Our focus is on decisions about how best to organise health systems, including arrangements for delivering, financing and governing health services, and strategies for bringing about change [1,26]. In this book, we use these types of decisions as examples to illustrate the ways in which decision making can be better informed by research evidence. Similar approaches can be used to inform decisions about which programmes, services or drugs are provided [27].

1. What is evidence?

Discussions of evidence-based practice and evidence-informed policymaking can generate debate about what exactly constitutes 'evidence'. A common understanding is that "evidence concerns facts (actual or asserted) intended for use in support of a conclusion" [28]. A fact,

in turn, is something known through experience or observation. An important implication of this understanding is that evidence can be used to support a conclusion, but it is not the same as a conclusion. Evidence alone does not make decisions.

This understanding of what evidence is has a number of implications. Firstly, expert opinion is more than just evidence. It is the combination of facts, the interpretation of those facts, and conclusions. Evidence always informs expert opinions. And appropriate use of that evidence requires the identification of those facts (experience or observations) that form the basis of the opinions, as well as an appraisal of the extent to which the facts support the conclusions [29].

Secondly, not all evidence is equally convincing. How convincing evidence is depends on what sorts of observations were made and how well they were made. Research evidence is generally more convincing than haphazard observations because it uses systematic methods to collect and analyse observations. Similarly, well designed and executed research is more convincing than poorly designed and executed research.

Thirdly, judgements about how much confidence can be placed in different types of evidence (in other words, the 'quality' of the evidence) are made either implicitly or explicitly. It is better to make these judgements systematically and explicitly in order to prevent errors, resolve disagreements, facilitate critical appraisal, and communicate information. This, in turn, requires explicit decisions about the actual types of evidence that need to be considered.

Fourthly, all evidence is context-sensitive, given that all observations are necessarily context-specific. Judgements therefore always need to be made about the applicability of evidence beyond its original context or setting. It is best to make judgements about the applicability of this evidence systematically and explicitly, for the same reasons that it is best to make judgements about the quality of the evidence in a systematic and explicit way.

Fifthly, 'global evidence' – i.e. the best evidence available from around the world – is the best starting point for judgements about the impacts of policies and programmes. Although all evidence is context-sensitive, decisions based on a subset of observations that are presumed to be more directly relevant to a specific context (such as those undertaken in a particular country or population group), can be misleading [30]. Judgements about whether to base a conclusion on a subset of observations are better informed if made in the context of all relevant evidence [31].

Finally, it is necessary that local evidence (from the specific setting in which decisions and actions will be taken) informs most other judgements about problems, options for addressing problems, and implementation strategies. This includes evidence of the presence of modifying factors in specific settings, the degree of need (e.g. the prevalence of disease or risk factors or problems with delivery, financial or governance arrangements), values, costs and the availability of resources.

2. What is the role of research evidence in informing health policy decisions?

To make well-informed decisions about issues such as how best to provide universal and equitable access to healthcare, policymakers need access to robust evidence. Evidence is needed to clarify what services and programmes to offer or cover, how to deliver those services, financial arrangements, governance arrangements, and how to implement change

[1]. Systematic reviews can be used to inform decisions for key questions within each of these domains [3-5]. An explanation and examples of systematic reviews are provided in Table 1.2. Figure 1.1 illustrates the role of evidence from systematic reviews together with local evidence in informing the judgements that need to be made about health policy decisions.

Policy decisions are always influenced by factors other than evidence. These include institutional constraints, interests, ideas (including values), and external factors like recessions. Research evidence is also not the only type of information needed to inform the judgements necessary for policy decision making. Nonetheless, strengthening the use of research evidence, and the ability of policymakers to make appropriate judgements about its relevance and quality, is a critical challenge that holds the promise of helping to achieve significant health gains and better use of resources.

Figure 1.1
An example of the role of evidence in health policymaking

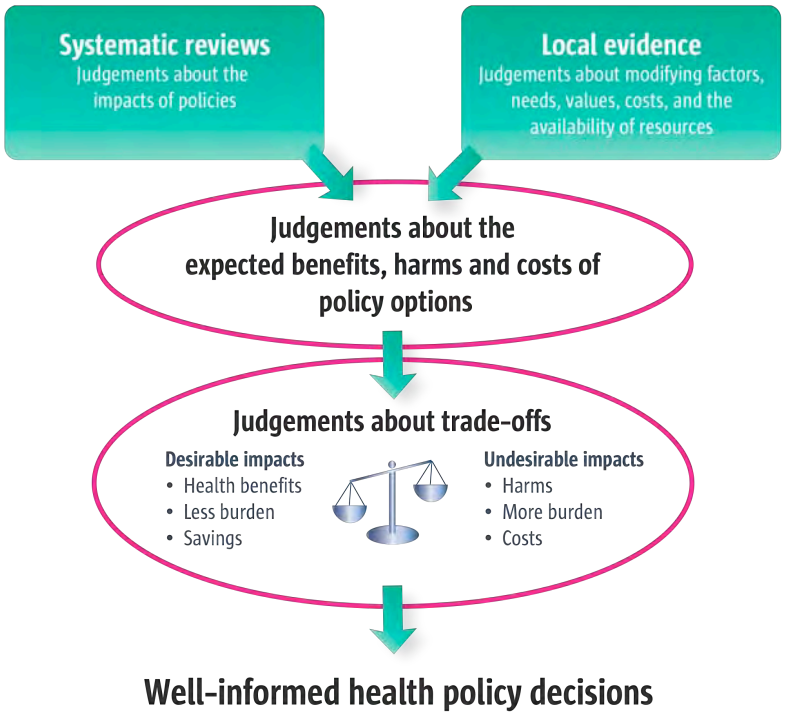


Table 1.2
An explanation and examples of systematic reviews

What is a systematic review?	Systematic reviews are summaries of research evidence that address a clearly formulated question using systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies. Structured summaries of systematic reviews of health system arrangements can be found on the SUPPORT web pages (www.support-collaboration.org), including the following examples:

Lay health workers in primary care for maternal and child health An example of a delivery arrangement [32]	Lay health workers have no formal professional education, but they are usually provided with job-related training. They can be involved in either paid or voluntary care. They perform diverse functions related to healthcare delivery and a range of terms is used to describe them, including village health workers, community volunteers and peer counsellors, among others. A systematic search for randomised trials of lay health workers up to August 2006 found 48 trials relevant to maternal and child health and high burden diseases. There was variation in the recruitment and training methods, targeted recipients, settings, and the outcomes that were measured. Key findings included: • The use of lay health workers in maternal and child health programmes shows promising benefits compared to usual care or no intervention in: – Increasing the uptake of immunisation in children – Promoting breastfeeding – Reducing mortality in children under five years, and – Reducing morbidity from common childhood illnesses • Little evidence is available regarding the effectiveness of substituting health professionals with lay health workers or the effectiveness of alternative strategies for training, supporting and sustaining lay health workers
Direct patient payments for drugs An example of a financial arrangement [33]	Policies in which consumers pay directly for their drugs when they fill a prescription include *caps* (the maximum number of prescriptions or drugs that is reimbursed), *fixed co-payments* (people pay a fixed amount per prescription or drug), *tier co-payments* (people pay a fixed amount per prescription or drug, the cost of which may depend, for example, on whether the prescription is for a brand (patented) drug or a generic), *coinsurance* (people pay a percentage of the price of the drug), and *ceilings* (for example, people pay either part of the price or the full price of a drug up to a set maximum amount over a year, and thereafter either no – or less – money). A systematic search for studies that evaluated the impacts of these policies found 21 studies reporting on 30 highly varied interventions. Key findings included: • Cap, coinsurance with a ceiling, and co-payment polices can reduce drug use and save expenditures for drug policies or health plans • Reductions in drug use were found for life-sustaining drugs and drugs that are important in treating chronic conditions, as well as for other drugs • Although insufficient data on health outcomes were available, large decreases in the use of drugs that are important for people's health may have adverse effects. This could lead to the increased use of healthcare services and therefore to increases in overall spending • Policies in which people pay directly for their drugs are less likely to cause harm only if non-essential drugs are included in these policies, or if exemptions are built into the policies to ensure that people receive needed medical care

Consumer involvement An example of a governance arrangement [34]	The importance of consumer involvement in healthcare is widely recognised, but a systematic review found that there is extremely sparse evidence about how best to do this for health policymaking. Consumers can be involved in developing healthcare policy through consultations to elicit their views or through collaborative processes. Consultations can be single events or repeated events, large- or small-scale. They can involve individuals or groups of consumers in order to allow debate. The groups may be convened especially for the consultation or they may be established consumer organisations. They can be organised in different forums and through different media. A systematic search up to May 2006 for studies that compared the effects of different methods of involving consumers found only one small study of methods designed to involve consumers in health policymaking. This study provided very low-quality evidence that telephone discussions and face-to-face group meetings engaged consumers better than mailed surveys for setting priorities for community health goals, and resulted in different priorities being set
Continuing education meetings An example of a strategy to bring about change [35]	Educational meetings (lectures, workshops and courses) are one of the most common types of continuing education for health professionals. The meetings can be highly variable in terms of content, number of participants, the degree and type of interaction, as well as length and frequency. A systematic search for randomised trials of audit and feedback up to March 2006 found 81 studies that met the inclusion criteria for the review. In most of the trials the participants were physicians. The interventions varied with respect to their content and format, and there was wide variation in outcome measures. Key findings included: • Educational meetings can improve professional practice and healthcare outcomes for the patients • The median effect is small to modest and comparable to the effect of other continuing medical education activities such as audit and feedback and educational outreach visits • There are large variations in the effects found in different studies and no firm conclusions can be drawn about what is the most effective form • The effect appears to be larger with educational meetings that include both interactive and didactic components

3. What is evidence-informed policymaking?

For health policy decision making to be well-informed rather than poorly informed, it is essential that more systematic and transparent processes are applied when accessing and appraising research evidence. Evidence-informed health policymaking is an approach to policy decisions that is intended to ensure that decision making is well-informed by the best available research evidence. How this is done may vary, and will depend on the type of decisions being made and their context. Nonetheless, evidence-informed policymaking is characterised by the fact that its access and appraisal of evidence as an input into the policymaking process is both systematic and transparent. This does not imply that the overall process of policymaking will be systematic and transparent. However, within the overall process of policymaking, systematic processes are used to ensure that relevant research is identified, appraised and used appropriately. These processes are transparent so

that others can examine what research evidence has been used to inform policy decisions as well as the judgements made regarding the evidence and its implications.

In this book, we describe ways in which evidence-informed health policymaking can address common policymaking problems through more systematic and transparent processes to facilitate well-informed decisions, clarify evidence needs, find and assess evidence, and go from evidence to decisions (as illustrated in Figure 1.2). The advantages of systematic and transparent processes, such as the ones that we describe in this book – compared to processes that are non-systematic and not transparent – are that they can help to protect against errors and bias. This is illustrated by systematic reviews, examples of which are shown in Table 1.2, which reduce the risk of being misled by chance or by the biased selection and appraisal of evidence.

Figure 1.2
How evidence-informed health policymaking addresses common policymaking problems

Different types of evidence are relevant to different questions, and legitimate differences of opinion may exist as to what constitutes the "best available evidence" for particular questions [36]. However, evidence-informed health policymaking aims to ensure that relevant evidence is identified and that judgements about issues such as what evidence is relevant, the reliability and the applicability of identified evidence are made systematically and transparently. Evidence-informed health policymaking also aims to ensure that conflicts of interest do not influence such judgements or any new research that is undertaken in support of policymaking.

Another essential characteristic of evidence-informed policymaking is that policymakers understand the systematic processes used to ensure that relevant research is identified, appraised and used appropriately, as well as the potential uses of such processes. This book is aimed at helping policymakers attain such an understanding.

Since the beginning of the 1990s, there has been a drive towards evidence-based medicine (EBM), which focused initially on decision making by physicians [37,38]. This drive has been extended to other health professionals and consumers, and referred to as 'evidence-based healthcare' or 'evidence-based practice' as a way of reflecting its broader scope. In the context of management and policymaking, to which this approach has also been extended, it is referred to as "evidence-based policy" [39]. In all of these arenas, debate has focused on what exactly is meant by an evidence-based approach, and how this approach differs from usual practices, as well as the relative benefits and risks. Both EBM and evidence-based policymaking have been criticised for assuming that practice or policy decisions are largely determined by research evidence [3,40-42]. This criticism is largely a misperception of what has been advocated. Neither decisions about individual patients nor policy decisions are determined by evidence alone. Judgements, values, and other factors, always play a role.

Although the terms 'evidence-based' and 'evidence-informed' can be used interchangeably, we have elected to use the term 'evidence-informed' because it better describes the role of evidence in policymaking and the aspiration of improving the extent to which decisions are well-informed by research evidence [3,43].

What evidence-informed policymaking is not

Like any other tool, those that are used to support the use of evidence to inform policymaking can be misused. Undesirable impacts arising from the inappropriate use of evidence can include inefficient bureaucratic processes, the inappropriate inhibition or delay of promising programmes, the misleading framing of problems, the manipulation of public opinion, and the distortion of the research agenda.

Ways in which evidence can be misused include using evidence selectively, stifling the appropriate use of evidence, and creating a spurious impression of uncertainty. The best way to detect and prevent the inappropriate use of evidence is to use processes that are systematic and transparent, as we will describe in subsequent chapters.

Conclusion

There is growing interest globally in making better use of research evidence in decisions related to health. In 2004, for example, the World Health Organization issued the World Report on Knowledge for Better Health, which included a chapter devoted to linking research to action [44]. The Ministerial Summit on Health Research held that same year in Mexico City, issued a statement on the importance of research for better health and for strengthening health systems [45]. Further, in May 2005, the 58th World Health Assembly passed a resolution acknowledging the Mexico Statement on Health Research, urging member states "to establish or strengthen mechanisms to transfer knowledge in support of evidence-based public health and health-care delivery systems, and evidence-based health-related policies" [46]. The need to continue building on the progress made since the Mexico Ministerial Summit was reflected too in the 2008 Bamako Statement issued by the Ministers of Health, Ministers of Science and Technology, Ministers of Education, and other Ministerial representatives of 53 countries [47]. A first key step towards achieving this objective is to ensure that policymakers and researchers have a shared understanding of what research evidence is and of the role of research evidence in helping to inform policy decisions.

Resources

Useful documents and further reading

- Evidence-informed health policy video documentaries: www.kunnskapssenteret.no/Artikler/2061.cms – These compelling video documentaries are part of a report on more than 150 organisations, particularly in LMICs, that are building bridges between evidence and policy (www.kunnskapssenteret.no/Publikasjoner/469.cms). The video documentaries tell the stories of eight case studies across six continents, where people are trying to improve health systems by using research evidence to inform decision making

- The Mexico statement on health research, 2004. www.who.int/rpc/summit/agenda/Mexico_Statement-English.pdf

- World Health Assembly. Resolution on health research, 2005. www.who.int/rpc/meetings/58th_WHA_resolution.pdf

- The Bamako call to action on research for health, 2008 www.who.int/rpc/news/BAMAKOCALLTOACTIONFinalNov24.pdf

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Links to websites

- *Evidence-Informed Policy Network (EVIPNet):* www.who.int/rpc/evipnet/en/ http://evipnet.bvsalud.org/php/index.php – EVIPNet is an initiative to promote the systematic use of health research evidence in policymaking. Focusing on low- and middle-income countries, EVIPNet promotes partnerships at the country level between policymakers, researchers and civil society in order to facilitate both policy development and policy implementation through the use of the best scientific evidence available

- *Alliance for Health Policy and Systems Research:* www.who.int/alliance-hpsr/en/ – The Alliance HPSR is an international collaboration housed in the World Health Organization (WHO). It aims to promote the generation and use of health policy and systems research as a means to improve the health systems of developing countries

- *Canadian Health Services Research Foundation:* www.chsrf.ca/home_e.php – This Foundation promotes and funds management and policy research in health services and nursing to increase the quality, relevance and usefulness of this research for health system policymakers and managers. In addition, the foundation works with these health system decision makers to support and enhance their use of research evidence when addressing health management and policy challenges

- *UK government's Policy Hub:* www.nationalschool.gov.uk/policyhub/index.asp – This site aims to promote strategic thinking and improve policymaking and delivery across government. It endeavours to provide users with access to a range of perspectives on policy matters

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2. Improving how your organisation supports the use of research evidence to inform policymaking

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Summary

In this chapter, we address ways of organising efforts to support evidence-informed health policymaking. Efforts to link research to action may include a range of activities related to the production of research that is both highly relevant to – and appropriately synthesised for – policymakers. Such activities may include a mix of efforts used to link research to action, as well as the evaluation of such efforts. Little is known about how best to organise the range of activity options available and, until recently, there have been relatively few organisations responsible for supporting the use of research evidence in developing health policy. We suggest five questions that can help to guide considerations about how to improve organisational arrangements to support the use of research evidence to inform health policy decision making. These are:

1. What is the capacity of your organisation for using research evidence to inform decision making?
2. What strategies should be used to ensure collaboration between policymakers, researchers and stakeholders?
3. What strategies should be used to ensure independence as well as effective management of conflicts of interest?
4. What strategies should be used to ensure that systematic and transparent methods are used for accessing, appraising and using research evidence?
5. What strategies should be used to ensure adequate capacity to employ these methods?

Scenario

There is a new Minister of Health in the Ministry where you work. One of the goals of the new Minister is to improve the capacity of the Ministry to use research evidence to inform decisions about how the health system is organised, financed and governed. You have been asked to put forward a proposal for strategies to improve how the Ministry supports its use of evidence to inform policy decisions

Background

In this chapter, we present five questions that policymakers and those who support them could ask when considering how to improve support for the use of research evidence to inform health policy decisions. Such questions could, for instance, be asked by any of the people in the scenario outlined above.

A number of theories have been proposed to explain the role of research evidence in policymaking. In addition, common wisdom about how to improve the appropriate use of research evidence is abundant. However, empirical evidence to support such ideas is difficult to find [1]. While increasing numbers of studies are being undertaken in low- and

middle-income countries [2-7] most evidence still comes from interview studies in high-income countries [8,9]. Systematic reviews of these studies suggest that [8,9]:

- Interaction between researchers and policymakers increases the likelihood of research being used by policymakers
- Good timing and timely research increase (and poor timing or lack of timeliness decrease) the likelihood of research being used by policymakers
- When policymakers have negative attitudes towards research evidence, the likelihood of research being used by them decreases
- When policymakers lack relevant skills and expertise, the likelihood of research being used by them decreases
- Policy networks and trust in researchers increase the likelihood of research being used by policymakers, and
- A lack of perceived relevance, the use of jargon, and the production of publications aimed at a scholarly audience are all factors that decrease the likelihood of research being used by policymakers

Activities aimed at improving the use of research evidence to inform policy have been referred to in various ways. These terms include: knowledge translation, knowledge transfer, knowledge exchange, research utilisation, implementation, diffusion, and dissemination [10]. Considerable confusion and misunderstanding exists about the definition and scope of these concepts, and the literature related to these issues is diverse and widely dispersed [11]. Several frameworks have been proposed as ways to organise these approaches and thus improve the use of research evidence by policymakers [10-19]. These frameworks have overlapping purposes and concepts.

One of these frameworks focuses on assessing country-level efforts to link research to action. This framework provides an inventory of a range of activities that can be considered when developing organisational arrangements to support the use of research evidence to inform health policy decisions [19]. It includes four elements: the general climate for research use, the production of research that is both highly relevant to – and appropriately synthesised for – policymakers, the mix of efforts used to link research to action, and the *evaluation* of efforts to link research to action. Within this framework, efforts to link research to action are categorised in four clusters of activities. These are: *push efforts* (efforts to communicate research findings which may include, for example, the tailoring of messages by researchers according to policymaker needs), *efforts to facilitate user pull* (such as rapid-response units to meet policymaker needs for research evidence), *user pull* (efforts to facilitate research use, such as efforts to train policymakers in how to access research evidence), and *exchange efforts* (partnerships between researchers and policymakers in which relevant questions are jointly asked and answered).

Little is known about how best to organise such a range of activities and, until recently, relatively few organisations were responsible for supporting the use of research evidence in developing health policy [20,21]. The questions that we propose in this chapter focus on the lessons learned from the experience of organisations engaged in activities to support evidence-informed health policymaking [20]. The evidence from which these lessons were drawn was collected from a survey of 176 organisations, followed by telephone interviews with 25 of these, and site visits to eight. The lessons are:

- Establish strong links between policymakers and researchers, and involve stakeholders in the work undertaken
- Be independent and manage conflicts of interest among those involved in the work
- Use appropriate methods and be transparent in the work

- Collaborate with other organisations
- Start small, have a clear audience and scope, and address important questions
- Build capacity among those working in the organisation
- Be attentive to implementation considerations even if implementation is not a remit

Questions to consider

Drawing on the above lessons, we suggest five questions that can be asked when considering how to improve support for the use of research evidence to inform health policy decisions. These questions address key strategies to improve how support for evidence-informed health policymaking is organised, as illustrated in Figure 2.1. They do not address broader questions about government policymaking processes and how these can be designed to promote the use of evidence. The questions are:

1. What is the capacity of your organisation for using research evidence to inform decision making?
2. What strategies should be used to ensure collaboration between policymakers, researchers and stakeholders?
3. What strategies should be used to ensure independence as well as the effective management of conflicts of interest?
4. What strategies should be used to ensure that systematic and transparent methods are used for accessing, appraising and using research evidence?
5. What strategies should be used to ensure adequate capacity to employ these methods?

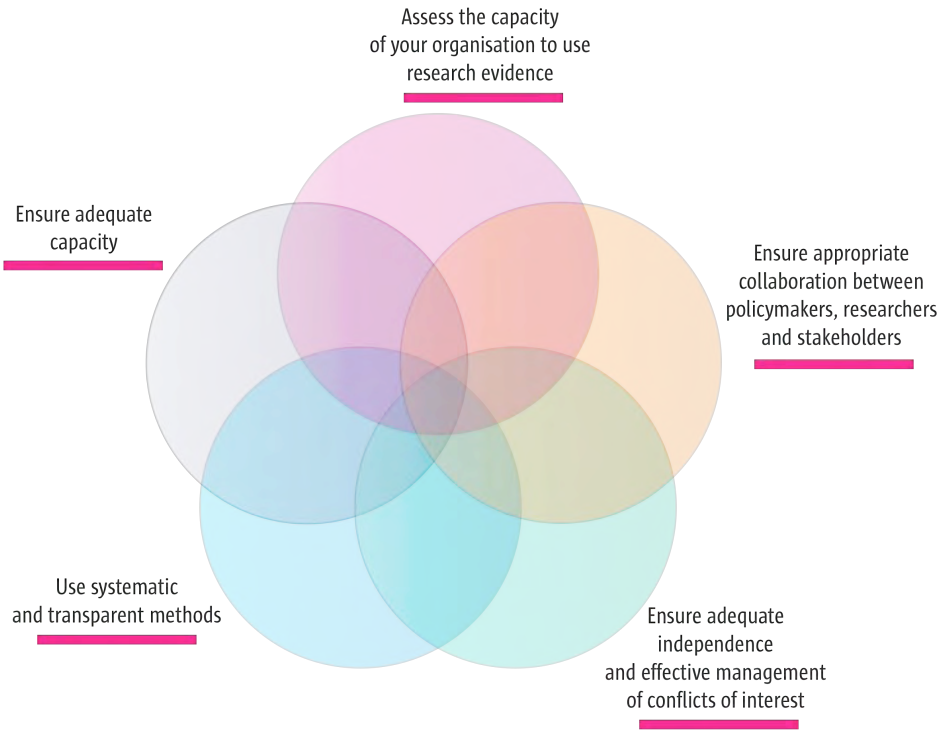

Figure 2.1
Strategies to improve how support for evidence-informed health policymaking is organised

1. What is the capacity of your organisation for using research evidence to inform decision making?

In order for organisations to improve the degree to which their decisions are well-informed by research evidence, sufficient capacity is needed to recognise the need for research evidence. This is necessary for acquiring research when it is needed, critically appraising it, using it to inform decisions, and measuring the impacts of policies and programmes that are implemented [19,22-26]. Capacities in these different areas vary widely both in governmental and non-governmental organisations [20,27]. A first step in the process of improving organisational capacity is therefore the assessment of an organisation's current capacity.

There are a number of validated instruments for measuring the competence of individuals to practice evidence-based medicine [28-30]. However, in this chapter, our focus is on *organisational* capacity rather than the competence of individuals. The Canadian Health Services Research Foundation (CHSRF) has developed a self-assessment tool for healthcare organisations to assist in identifying ways in which research can be gathered and used, as well as potential ways in which this can be improved [22,23,31,32]. This tool includes four key areas for the assessment of research use: the acquisition, assessment, adaptation and application of evidence. Lavis and colleagues have proposed a framework for assessing country-level efforts to link research to action [19]. Their framework includes a number of areas not covered by the CHSRF tool [22]. These include the extent to which the general environment supports the linking of research to action, research production, efforts to communicate research findings (so-called 'push' strategies), and efforts to facilitate the use of research findings (so-called 'user pull' factors).

The self-assessment tool that we present in Table 2.1 draws on both of these frameworks, and the CHSRF tool in particular. It addresses the key steps needed to ensure the appropriate use of research evidence to inform decisions related to health policies and programmes. This tool is intended to help organisations assess and improve their capacity to use research evidence. It has not been formally tested. Instead, it has evolved through iterative revisions based on workshops involving a variety of groups.

Table 2.1 is a 'scorecard' intended to provide the basis for discussion and for reaching agreement about the priorities and strategies needed for improvement. Often people in the same organisation have divergent perceptions of how well the organisation is doing. This is illustrated in Table 2.2, which summarises the application of a scorecard to the assessment of an organisation's performance. Identifying and discussing these discrepancies can help to develop a shared vision and a plan of action. The scorecard shown in Table 2.1 can be applied across departments in a large organisation (as highlighted in the illustrative example shown in Table 2.2), as well as within a department, or a combination of both. The scorecard can also be used to monitor how well an organisation is doing in its efforts to improve its use of research evidence.

Table 2.1
Self-assessment of organisational capacity to support the use of research evidence to inform decisions

Name of organisation, department or unit:

1. Do your organisational culture and values support the use of research evidence to inform decisions?

	Don't know 0	Strongly disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly agree 5
a.	Our **mission** or other **key organisational documents** support evidence-informed decisions	0	1	2	3	4	5
b.	**Leadership** in the organisation supports evidence-informed decisions	0	1	2	3	4	5
c.	We are active members in **networks** that support evidence-informed policymaking or actively follow the developments and the products of relevant networks	0	1	2	3	4	5
d.	We have **regular meetings** where highly relevant research evidence is discussed in relationship to decisions	0	1	2	3	4	5
e.	Our organisation has committed **resources** to ensure that research evidence is used to inform decisions	0	1	2	3	4	5
f.	Overall, our **organisational culture and values** support the use of research evidence to inform decisions	0	1	2	3	4	5

Comments about how your organisation is doing:

Additional information that is needed to assess how your organisation is doing or to resolve disagreements:

Priorities for improvements (suggested actions to address weaknesses or build on strengths):

2. Does your organisation do a good job of setting priorities for obtaining research evidence to inform decisions?

	Don't know 0	Strongly disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly agree 5
a.	We have **explicit criteria** for setting priorities for obtaining research evidence	0	1	2	3	4	5
b.	An **appropriate mix of people** with relevant types of expertise, responsibilities and interests make decisions about priorities for obtaining research	0	1	2	3	4	5
c.	We have an **appropriate process** for setting priorities for obtaining research evidence dynamically	0	1	2	3	4	5
d.	We have **appropriate priorities** for obtaining research evidence	0	1	2	3	4	5
e.	**Overall**, our organisation does a good job of **setting priorities** for obtaining research evidence to inform decisions	0	1	2	3	4	5

Comments about how your organisation is doing:

Additional information that is needed to assess how your organisation is doing or to resolve disagreements:

Priorities for improvements (suggested actions to address weaknesses or build on strengths):

3. Does your organisation do a good job of obtaining research evidence to inform decisions?

	Don't know 0	Strongly disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly agree 5
a.	We have **skilled staff** to search for and retrieve research evidence	0	1	2	3	4	5
b.	Our staff have **enough time, incentive and resources** or arrangements with external experts to find and obtain research evidence	0	1	2	3	4	5
c.	We have **good access to databases** such as PubMed and The Cochrane Library and publications that report relevant research	0	1	2	3	4	5
d.	We have **good access to national, provincial or local evidence** that we need to inform decisions (e.g. routinely collected data, surveys, one-off studies)	0	1	2	3	4	5
e.	**Overall**, our organisation does a good job of **obtaining** research evidence to inform priority decisions	0	1	2	3	4	5

Comments about how your organisation is doing:

Additional information that is needed to assess how your organisation is doing or to resolve disagreements:

Priorities for improvements (suggested actions to address weaknesses or build on strengths):

4. Does your organisation do a good job of assessing the quality and applicability of research evidence and interpreting the results to inform priority decisions?

	Don't know 0	Strongly disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly agree 5
a.	We have **skilled staff** to evaluate the quality and applicability of research evidence and interpret the results	0	1	2	3	4	5
b.	Our staff have **enough time, incentive and resources** to evaluate the quality and applicability of research evidence and interpret the results	0	1	2	3	4	5
c.	We have **arrangements with external experts** to evaluate the quality and applicability of research evidence and interpret the results	0	1	2	3	4	5
d.	**Overall**, our organisation does a good job of **assessing** the quality and applicability of research evidence and **interpreting** the results to inform priority decisions	0	1	2	3	4	5

Comments about how your organisation is doing:

Additional information that is needed to assess how your organisation is doing or to resolve disagreements:

Priorities for improvements (suggested actions to address weaknesses or build on strengths):

5. Does your organisation do a good job of using research evidence to inform recommendations and decisions?

	Don't know 0	Strongly disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly agree 5
a.	Our staff have **sufficient time, expertise and incentive** to ensure appropriate use of research evidence to inform **recommendations and decisions**	0	1	2	3	4	5
b.	Staff and appropriate stakeholders **know how and when they can contribute** research evidence to inform decisions and how that information will be used	0	1	2	3	4	5
c.	Our organisation ensures that **appropriate stakeholders are involved** in decision making and that they have access to relevant research evidence	0	1	2	3	4	5
d.	What evidence was used and how it was used is **transparent** in our decisions	0	1	2	3	4	5
e.	**Overall**, our organisation does a good job of **using research** evidence to inform **recommendations and decisions**	0	1	2	3	4	5

Comments about how your organisation is doing:

Additional information that is needed to assess how your organisation is doing or to resolve disagreements:

Priorities for improvements (suggested actions to address weaknesses or build on strengths):

6. Does your organisation do a good job of monitoring and evaluating policies and programmes?

	Don't know 0	Strongly disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly agree 5
a.	We **routinely consider the need** for monitoring and evaluation	0	1	2	3	4	5
b.	Our staff have **enough expertise** or adequate arrangements with external experts for monitoring and evaluation	0	1	2	3	4	5
c.	Our staff have the **incentive and resources** to conduct or commission monitoring and evaluation	0	1	2	3	4	5
d.	Our organisation ensures that **appropriate stakeholders are involved** in decisions about monitoring and evaluation	0	1	2	3	4	5
e.	**Overal**l, our organisation does a good job of **monitoring and evaluation** of policies and programmes	0	1	2	3	4	5

Comments about how your organisation is doing:

Additional information that is needed to assess how your organisation is doing or to resolve disagreements:

Priorities for improvements (suggested actions to address weaknesses or build on strengths):

7. Does your organisation do a good job of supporting continuing professional development that addresses important topics and is evidence-based?

		Don't know 0	Strongly disagree 1	Disagree 2	Neither agree nor disagree 3	Agree 4	Strongly agree 5
a.	Our staff have **enough time** for continuing professional development	0	1	2	3	4	5
b.	We have routines to **ensure that our staff continue to develop appropriate skills** for obtaining, appraising and applying research evidence	0	1	2	3	4	5
c.	Our staff **prioritise continuing professional development activities that are "evidence-based"** (i.e. with content that is based on research evidence and using continuing professional development methods that are based on research evidence)	0	1	2	3	4	5
d.	We have appropriate routines for **prioritising internal professional continuing development activities** that accommodate the needs of both new and long-term staff	0	1	2	3	4	5
e.	We have appropriate routines for **deciding whether to support participation in external continuing professional development activities** that accommodate the needs of both new and long-term staff	0	1	2	3	4	5
f.	**Overall**, our organisation does a good job of **supporting continuing professional development** that addresses important topics and is evidence-based	0	1	2	3	4	5

Comments about how your organisation is doing:

Additional information that is needed to assess how your organisation is doing or to resolve disagreements:

Priorities for improvements (suggested actions to address weaknesses or build on strengths):

Table 2.2
An example of an organisation's self-assessment of its capacity to use research evidence to inform decision making

Organisational culture and values

At a workshop, a group of people from different departments within an international organisation assessed the capacity of their organisation to use research evidence using a scorecard similar to the one shown in Table 2.1. None of the people involved were in leadership positions. Many people in the group had divergent viewpoints. Participants stated that they were unsure how well the organisation was performing in a number of areas, and perceived that there were variations in performance between different departments. There was a perception amongst the attendees that the organisational culture and values of the organisation supported the use of research evidence based on key documents and linkages to

international networks. Support from leadership varied, as did the frequency of meetings and the availability of resources. The workshop group agreed that organising regular meetings focused on highly relevant research and its usefulness to the organisation could help to improve the culture of the organisation with regard to its use of research evidence. Specific strategies for organising this were discussed. The group concluded that it would be important for the organisation's leadership to be involved in this process of organisational self-assessment

Setting priorities for obtaining research to inform decisions

The group was unsure about the use of explicit criteria for setting priorities in their organisation. They agreed generally that priorities in the organisation were set, at least broadly, by the board, which included an appropriate mix of people. This process, they felt, was largely a political one and that while it was transparent, it was not systematic. Most of the group felt that this system was appropriate. In some cases priority-setting within the organisation's departments was seen as ad hoc. It was felt that it could be improved by having more structured discussions involving all those affected and by having clearer criteria for deciding on priorities within the broader priorities set by the board

Obtaining research evidence

The group had divergent perceptions regarding their access to research evidence. These variations were shaped by their different geographical locations within the organisation as well as by differences between their departments. They also reflected the differing degrees of awareness amongst people of the services at their disposal. There was agreement that there were considerable constraints due to low staffing levels in the library, and that although there was good access to databases, there were varying degrees of difficulty with regard to accessing publications. Several strategies for improving access to research evidence were discussed, including the provision of training to improve awareness of available resources and developing searching skills. Discussions topics also included ways in which access to publications could be improved using channels already available, and capitalising on links with academic institutions

Critically appraising research evidence

The group agreed that although there were pockets of strength within the organisation and although there was good access to external experts, staff did not always have adequate skills. It was agreed that a substantial proportion of the staff could benefit from workshops to help them develop these skills. Several strategies for organising training were discussed, including incorporating the training into routine meetings where relevant evidence was discussed, as well as internal and external workshops, and online training.

Members of the group were aware of important shortcomings within the organisation's recommendations and policies. Plans for improvements included implementing standards for the development and reporting of recommendations and policies, through the establishment of a central mechanism. This mechanism would approve plans before work was started on developing recommendations or policies, and before approval was given for any final recommendations or policies. Training and the improved use of external methodological and topic experts were also recommended

Monitoring and evaluating the impacts of decisions

The group did not assess how well their organisation monitors and evaluates the impacts of its

policies and programmes. However, as with many governmental and non-governmental organisations, monitoring and evaluation were major organisational challenges due to limited resources and because of uncertainty about the actual impacts of most programmes and policies. The organisation did not routinely consider the need for monitoring and evaluation and had limited expertise in this area. Strategies to improve monitoring and evaluation for any organisation like this might include: building consideration of evaluation into routine processes for approving policies and programmes, using training or recruitment to increase the level of expertise within the organisation, better co-ordination with partner organisations, and making impact evaluation mandatory for policies and programmes that meet explicit criteria [33]

Professional development

As already noted, the group identified several needs within their organisation that could be addressed through continuing education. They also identified a variety of strategies that could meet those needs. They did not feel that they were in a position to set these priorities, or to address the challenges of dealing with the needs of both new and long-term staff. However, they decided that this was an important issue for them to take back to their organisation. They also noted that they would suggest in their workshop report that those in mid-level leadership positions in their organisation should undertake their own assessment, and consider how to make more effective use of the resources available within the organisation to ensure continuing professional development

2. What strategies should be used to ensure collaboration between policymakers, researchers and stakeholders?

Many organisations that support the use of research evidence in policymaking commonly involve policymakers in the selection of topics and the services undertaken. Personal communication between policymakers and researchers has been found to be particularly important, both by policymakers and those who support their use of research evidence [20]. Organisations that support evidence-informed policymaking view their close links with policymakers as a strength [20]. However, this strength brings with it a related challenge: the need to manage conflicts of interest that can emerge in any close relationship between researchers and policymakers.

Strategies that can help to ensure collaboration between policymakers and researchers include:

- Locating those who support the use of research by policymakers (by accessing, appraising and summarising evidence) within or close to those organisations responsible for policymaking
- Involving policymakers on an advisory board or steering committee in instances when organisations are located outside government or policymaking organisations
- Formal agreements linking academic organisations to policymaking organisations
- Using trusted individuals as 'knowledge brokers' to build relationships among researchers and policymakers [34]
- Involving policymakers in research processes such as the preparation of policy briefs [35]
- Involving researchers in policy-informing processes such as policy dialogues [36]

- Skill development programmes for both policymakers and researchers [37-39], including exchanges where researchers are seconded to a policymaking organisation and policymakers are seconded to a research organisation

An illustration of the need to manage potential tensions between policymakers and researchers who are working together is provided in Table 2.3.

Table 2.3
A case study of the need to manage tensions between policymakers and researchers in a long-term collaboration

Since the early 1990s, policymakers in the provincial government of the Free State in South Africa have worked closely with researchers on health and health policy-related topics, including the monitoring and evaluation of antiretroviral (ARV) therapy rollouts [20]. The evidence from these studies has exposed major deficiencies in the ARV rollout, and concerns have been raised that if the research findings become too critical, the privileged data access offered to researchers, and the collaboration offered on evaluations, may simply end. This has led to tensions in the relationship between the researchers and the provincial Health Department with both sides being very direct about these concerns. While acknowledging that it is challenging to manage the tensions, both the policymakers and the researchers are committed to learning how to manage this kind of conflict. From the Health Department's perspective, this is essential in order to evaluate and improve the services delivered by the provincial government. From the researchers' perspective, this is motivated by "a feeling that you are doing research that is actually relevant and addressing actual needs as opposed to just driving publications" [20].

Organisations that support the use of research evidence in policymaking also frequently cite the involvement of stakeholders as a key strength [20]. Stakeholder organisations include, for example, patient organisations, community groups, coalitions, advocacy groups, faith-based organisations, charities or voluntary organisations, professional associations, trade unions and business associations [40].

However, managing stakeholder involvement can be both challenging and demanding. There is a paucity of evidence comparing alternative ways of involving stakeholders in policymaking or research processes including [33]:

- The degree of involvement (consultation or collaboration)
- Different forums for communication (e.g. committee membership, permanent panels, town meetings, interviews, written consultation)
- Different methods for recruiting stakeholders (e.g. targeted personal invitations, advertisements, or the use of mass media)
- Different ways of training and supporting consumers or other stakeholders to ensure effective involvement
- Different degrees of financial support to facilitate the involvement of consumers or other stakeholders

There is a range of different types of collaboration that may be appropriate for different stakeholders. For some groups, ongoing interaction may be more useful than involving them directly in policymaking (e.g. groups that have an interest in one aspect of a policy, such as professional regulatory issues). For other groups, it may be desirable to keep them at arms length (e.g. pharmaceutical companies with a vested interest in a policy decision). For certain groups, it may be justifiable to exclude them completely from deliberations (e.g. tobacco companies that have falsified research results on the harmful effects of tobacco).

Strategies that can help to ensure appropriate levels of stakeholder involvement are similar to those highlighted above for ensuring collaboration between policymakers and researchers. These may include, for example, the involvement of stakeholders on an advisory board or steering committee, in research processes, and in policymaking processes. They may also include consultation with stakeholder groups, the use of skill-development programmes for stakeholders [41-43], and the communication of evidence to the wider public via the mass media [44].

An example of the use of extensive strategies for involving stakeholders by a public agency is provided in Table 2.4.

Table 2.4
An example of stakeholder involvement in healthcare decisions: the National Institute for Health and Clinical Excellence (NICE)

NHS National Institute for Health and Clinical Excellence

Few organisations have sought to integrate stakeholders (especially patients and their caregivers) more thoroughly than the National Institute for Health and Clinical Excellence (NICE) in England and Wales [45]. NICE has created effective strategies to involve stakeholder groups including [45-47]:

- A programme within the Institute with dedicated staff responsible for patient and public involvement
- The identification and recruitment of stakeholders, including lay people, to NICE's independent advisory committees
- The provision of training and support to lay people on NICE's committees
- The registration of stakeholder groups, which are then routinely consulted electronically and through meetings
- The involvement of stakeholders throughout the development of guidance and decisions from topic selection to reviews of draft guidance, through to consultation and active participation on committees
- Systematic and transparent responses to stakeholders' comments on drafts
- The development and dissemination of lay versions of NICE's guidance, versions for key stakeholder groups, and mass media briefings, as well as versions for clinicians and managers, and
- The involvement of stakeholders in guidance implementation

NICE's experience suggests that the involvement of stakeholders in healthcare decision making is possible and can work well, but requires strong commitment and specific arrangements. It can also be costly. Although NICE's investment in stakeholder involvement is widely valued, it is uncertain whether the right stakeholders are involved, both in terms of which stakeholder groups engage in the process and in terms of the extent to which the individuals who become involved appropriately represent various stakeholders. It is also uncertain whether the strategies they use are as efficient as they could be – in other words, whether the resources invested in those processes represent good value for money [46]. There are also concerns about the growing burden of managing stakeholder input. Although the number of submissions from stakeholders has been increasing, involvement at the individual level within stakeholder organisations may be less than desired.

3. What strategies should be used to ensure independence as well as effective management of conflicts of interest?

Independence is the most commonly cited strength of organisations that support the use of research evidence in policymaking [20]. Conversely, conflicts of interest are seen as a key

weakness. Financial and intellectual independence and freedom from government and industry influence are viewed as the key strengths of such organisations. But these need to be balanced against the desirability of arrangements that can ensure collaboration between policymakers and researchers. Independence is, of course, relative. No organisation is entirely independent.

Mutually agreed processes and methods are essential in order to manage possible competing tensions arising from the demands of both collaboration and independence. They are also important as ways to ensure the systematic and transparent access and appraisal of evidence as an input into the policymaking process.

Conflicting interests frequently underlie tensions arising between policymakers, researchers and other stakeholders. Although there is little empirical evidence to guide arrangements for managing conflicts of interest, the key options that warrant consideration include [48]:

- Specific, detailed, structured disclosure forms that solicit as much information as possible about the nature and extent of competing interests. Minimal or open-ended formats for disclosure forms are likely to be uninformative
- Explicit criteria to make decisions easier about whether a disclosed interest constitutes a conflict of interest
- A range of management strategies to address disclosed conflicts of interest, ranging from the public disclosure of conflicts associated with each meeting as a minimum prerequisite, through to the recusal of conflicted individuals as the most extreme measure
- A standard policy requiring all financial ties to be made public (e.g. that they be recorded in meeting minutes), may reduce the number of problematic cases
- A standing committee to review all financial disclosure statements prior to the commencement of committee meetings or hearings, to make management recommendations when necessary, and which can help to ensure that conflict of interest policies are enforced

Organisational arrangements should ensure responsiveness to the information needs of policymakers. At the same time, it is important to ensure independence with respect to the methods used to access, appraise and summarise research evidence. Arrangements to ensure that independence is maintained may include:

- Financial arrangements that minimise the risk of inappropriate influence on what evidence is summarised, or how it is summarised
- Management arrangements, including the involvement of independent stakeholders in advisory boards or steering groups
- Mechanisms for managing disputes such as independent arbitrators or appeal processes, particularly for governmental agencies that fund the work and for industry
- Ensuring that decision making is transparent in terms of how evidence is accessed, appraised, summarised and publicly reported

4. What strategies should be used to ensure that systematic and transparent methods are used for accessing, appraising and using research evidence?

The majority of organisations supporting the use of research evidence in policymaking use systematic reviews [20]. In addition to their independence, such organisations commonly state that their use of systematic and transparent methods (sometimes they are referred to as being “evidence-based”) is one of their key strengths. However, organisations that support governments to use research evidence in the development of health policies and programmes

are less likely to have guidelines describing the methods they use. They are also less likely to conduct or use systematic reviews relative to organisations that produce health technology assessments (HTAs) or clinical practice guidelines. In addition, using systematic and transparent methods brings a related challenge: the time-consuming nature of using more rigorous methods. As a consequence, many organisations, particularly HTA agencies, have attempted to develop more rapid methods that are "quick but clean enough" [49].

Given that evidence-informed health policymaking is characterised by the use of systematic and transparent methods to access and appraise evidence as an input into the policymaking process, it therefore follows that the use of agreed-upon methods for doing this is key for any organisational arrangement to support evidence-informed policymaking. Such methods should be described in easily accessible documents. Moreover, although organisational arrangements are likely to vary widely, a great deal of commonality in the methods that are used is likely, as is the case for clinical practice guidelines, for example [50]. Thus, in addition to helping to ensure the use of agreed-upon methods, accessible manuals that describe these methods can also benefit other organisations with similar interests.

Stakeholders who feel that they have lost out as the result of a particular decision are still likely to challenge the methods used if there is a substantial amount at stake, irrespective of the rigour and transparency applied. Nonetheless, the use of agreed-upon methods that are described in easily accessible form can make it easier to respond to such challenges.

An illustration of efforts to ensure the use of systematic and transparent methods to develop recommendations and policies is provided in Table 2.5.

Table 2.5
An example of ensuring the use of systematic and transparent methods in an international organisation

The World Health Organization (WHO) has had guidelines for guidelines since 2003, emphasising the use of systematic reviews for the evidence of effects, processes that allow for the explicit incorporation of other types of information (including values), and evidence-informed dissemination and implementation strategies. However, until 2007 systematic reviews were rarely used for developing recommendations [51]. Instead, processes usually relied heavily on experts in a particular specialty, rather than representatives of those who have to live with the consequences of those recommendations, or experts in particular methodological areas. To address these problems and to ensure the use of systematic and transparent methods, WHO has taken a number of actions, based on a review of its own work and the methods used by others [20,25,40,51-53]. These actions include:

- Revising and updating a manual describing the methods that are to be used, which is updated and revised based on both WHO's experience and new developments
- Establishing a committee with a mandate to review and approve plans for developing recommendations prior to initiating the work, and recommendations prior to their publication
- Developing checklists for assessing recommendations and plans for developing recommendations based on the manual
- Establishing a secretariat and a network to provide training and support to implement the methods described in the manual, and
- Monitoring and evaluating the impacts of these arrangements to ensure the use of systematic and transparent methods

5. What strategies should be used to ensure adequate capacity to employ these methods?

The most commonly cited weakness of organisations that support the use of research evidence in policymaking are a lack of financial and human resources. How adequate funding for supporting the use of research evidence can be ensured is a major challenge, particularly in low- and middle-income countries. Partly, this may be because this function falls between two stools – it is typically not funded by research funders, or by those interested in strengthening policymaking. Identifying appropriate sources of funding is critical to developing and sustaining adequate capacity for supporting evidence-informed health policymaking.

Three of the key messages that emerged from a review of these organisations relate to ensuring adequate capacity [20,54]:

- Collaborate with other organisations, both informally and formally, to learn from their experience in order to avoid the unnecessary duplication of efforts, to draw on their capacity, *and* to help build capacity (see Table 2.6 for examples of international collaboration)
- Build capacity among those working in the organisation through training, making the best use of available staff (numbers are often limited), and actions aimed at retaining skilled staff, and
- Start small, have a clear scope, and address important questions in order to ensure that available resources are focused on areas where they are needed most

As noted above, another strategy that many organisations identified was the use of more rapid methods that are rigorous but less resource-intensive – especially those that would result in a reduction in the time required of skilled staff.

Table 2.6
Examples of international collaborations that help to build capacity and support for the use of research evidence in health policymaking:

EVIPNet (the Evidence Informed Policy Network) – initiated by the World Health Organization and the Ministries of Health in 25 countries, its aim is to promote the use of research evidence in health policy formulation in order to strengthen health systems [21,55]. At the country level, EVIPNet takes the form of partnerships between policymakers, researchers and civil society and focuses on facilitating the use of research evidence. Launched in 2005, EVIPNet now supports activities in Africa, Asia and the Americas

Region of East Africa Community Health (REACH) policy initiative – established within the East African Community (EAC) (Kenya, Tanzania and Uganda, with the recent addition of Rwanda and Burundi) to bridge the gap between evidence and health policy and practice [56]. Its mission is to access, synthesise, package and communicate evidence required for policy and practice and to influence policy-relevant research agendas for improved population health and health equity in each of the member countries

Reforming States Group (RSG) – since 1991, leaders in health policy from the legislative and executive branches of state government, with the financial support and staff collaboration of the Milbank Memorial Fund, have shared their experiences and have worked on practical solutions to shared healthcare problems. They have focused increasingly on the use of research evidence to inform health policy decisions [38,39,57]. The RSG now also includes members outside the United States of America. The Center for Evidence-based Policy, which works with RSG members, was established in 2003 by former Oregon Governor, John Kitzhaber, to address public policy challenges by identifying and applying the best available evidence through self-governing

communities of interest [58]

Cochrane Collaboration – a global network whose aim is to improve healthcare decision making through the preparation and updating of systematic reviews of the effects of healthcare interventions. The Cochrane Collaboration ensures that these reviews are made accessible. See http://cochrane.org/

Conclusion

A scorecard, such as the one shown in Table 2.1, can be used to assess the capacity of an organisation to support its use of research evidence. This can provide a useful basis for discussion and for establishing consensus about an organisation's strengths, weaknesses, priorities and the strategies necessary for improvement. Although people in the same organisation often have divergent views about how well it is performing, identifying and discussing these discrepancies can help to develop a shared vision and plan of action. This may be achieved, for example, by sharing information within or across different sections or levels within the organisation, clarifying what different sections of the organisation can or should be doing, addressing misunderstandings, resolving communication problems or identifying information that is needed to resolve disagreements.

There is limited evidence regarding the effects of different strategies to improve how support for evidence-informed health policymaking is organised. Organisational arrangements should logically be tailored to address specific aims and circumstances. Nonetheless, a number of lessons can be drawn from the experience of organisations around the world. Reflection on the questions discussed in this chapter can help policymakers and those who support them to improve organisational arrangements supporting the use of research evidence to inform health policy decisions.

Resources

Useful documents and further reading

- Moynihan R, Oxman AD, Lavis JN, Paulsen E. Evidence-Informed Health Policy: Using Research to Make Health Systems Healthier. Rapport Nr 1-2008. Oslo: Nasjonalt kunnskapssenter for helsetjenesten, 2008. www.nokc.no/Publikasjoner/469.cms

- Alliance for Health Policy and Systems Research. Strengthening health systems: the role and promise of policy and systems research. Geneva: Alliance for Health Policy and Systems Research, 2004 www.who.int/alliance-hpsr/resources/Strengthening_complet.pdf

- Lavis JN, Lomas J, Hamid M, Sewankambo NK. Assessing country-level efforts to link research to action. Bull World Health Organ 2007; 84:620-8. http://www.scielosp.org/scielo.php?pid=S0042-96862006000800013&script=sci_arttext&tlng=en

- EUnetHTA Work Package 8. EUnetHTA Handbook on Health Technology Assessment Capacity Building. Barcelona: Catalan Agency for Health Technology Assessment and Research. Catalan Health Service. Department of Health Autonomous Government of Catalonia; 2008.

www.gencat.cat/salut/depsan/units/aatrm/pdf/eunethta_wp8_hb_hta_capacity_building.pdf

- Thornhill J, Judd M, Clements D. CHSRF Knowledge Transfer: (Re)introducing the self-assessment tool that is helping decision-makers assess their organization's capacity to use research. Healthc Q 2008; 12:22-4. www.longwoods.com/product.php?productid=20410

Links to websites

- *Evidence-Informed Policy Network (EVIPNet):* www.evipnet.org/php/index.php – EVIPNet promotes the systematic use of health research evidence in policymaking. Focusing on low- and middle-income countries, EVIPNet promotes partnerships at the country level between policymakers, researchers and civil society in order to facilitate both policy development and policy implementation through the use of the best scientific evidence available. EVIPNet comprises networks that bring together country-level teams, which are coordinated at both regional and global levels

- *Alliance for Health Systems Policy and Research:* www.who.int/alliance-hpsr/en/ – The Alliance for Health Policy and Systems Research is an international collaboration based in the WHO, Geneva. It has its origins in the recommendations of the 1996 report of the WHO's Ad Hoc Committee on Health Research which identified a lack of health policy and systems research as a key problem impeding the improvement of health outcomes in low- and middle-income countries. It aims to promote the generation and use of health policy and systems research as a means to improve the health systems of developing countries

- *Canadian Health Services Research Foundation:* www.chsrf.ca – The Foundation brings researchers and decision makers together to create and apply knowledge to improve health services for Canadians. It is an independent, not-for-profit corporation, established with endowed funds from the federal government and its agencies

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3. Setting priorities for supporting evidence-informed policymaking

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Summary

Policymakers have limited resources for developing – or supporting the development of – evidence-informed policies and programmes. These required resources include staff time, staff infrastructural needs (such as access to a librarian or journal article purchasing), and ongoing professional development. They may therefore prefer instead to contract out such work to independent units with more suitably skilled staff and appropriate infrastructure. However, policymakers may only have limited financial resources to do so. Regardless of whether the support for evidence-informed policymaking is provided in-house or contracted out, or whether it is centralised or decentralised, resources always need to be used wisely in order to maximise their impact.

Examples of undesirable practices in a priority-setting approach include timelines to support evidence-informed policymaking being negotiated on a case-by-case basis (instead of having clear norms about the level of support that can be provided for each timeline), implicit (rather than explicit) criteria for setting priorities, ad hoc (rather than systematic and explicit) priority-setting processes, and the absence of both a communications plan and a monitoring and evaluation plan. In this chapter, we suggest questions that can guide those setting priorities for finding and using research evidence to support evidence-informed policymaking. These are:

1. Does the approach to prioritisation make clear the timelines that have been set for addressing high-priority issues in different ways?
2. Does the approach incorporate explicit criteria for determining priorities?
3. Does the approach incorporate an explicit process for determining priorities?
4. Does the approach incorporate a communications strategy and a monitoring and evaluation plan?

Scenarios

Scenario 1: You are a senior civil servant and will be submitting a plan to the Minister about how to allocate staff and other resources in order to ensure that existing programmes are well administered, emerging issues are responded to appropriately, and that evidence-informed policymaking is well supported on high-priority issues. In the past, you have found that programme administration and reactive issue management have crowded out proactive efforts to support evidence-informed policymaking. In the plan, you want to include an approach to priority setting that will support evidence-informed policymaking

Scenario 2: You work in the Ministry of Health and are preparing a brief report about how the Ministry's decision support unit will serve other Ministry staff. This support ranges from providing fast-turnaround requests for the best available synthesised evidence about particular issues, through to more comprehensive evidence-informed problem assessments, options to address problems, and implementation considerations that may take several weeks or months. The report will consider how the unit will prioritise which issues will get particular types of support

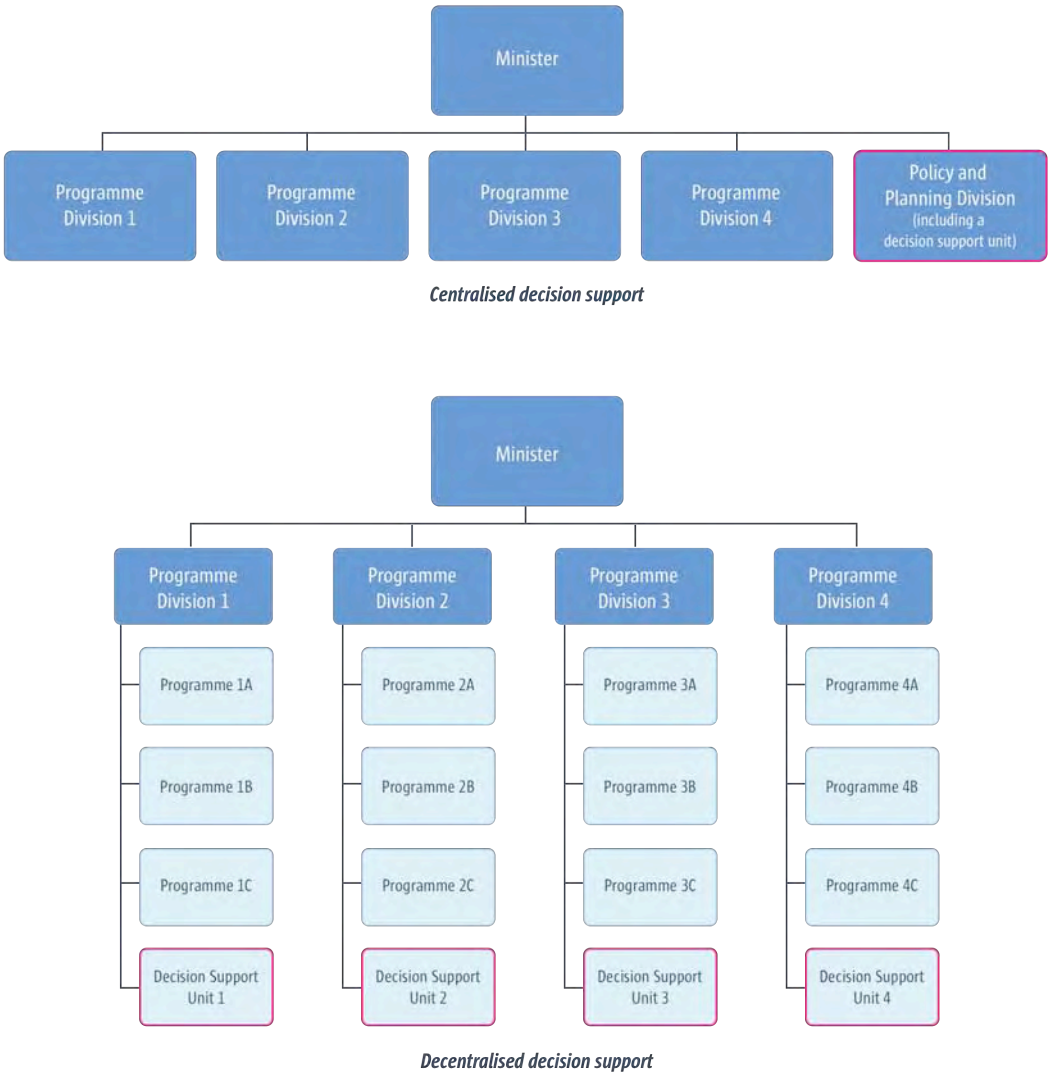
Scenario 3: You work in an independent unit that supports the Ministry of Health in its use of evidence in policymaking. You are preparing a detailed proposal for the Ministry of Health about how the unit will prioritise those issues requiring policy briefs and policy dialogues to support evidence-informed policymaking (both these issues are the focus of the SUPPORT tools discussed in Chapters 13 [1] and 14 [2])

Background

Policymakers and stakeholders have limited resources available for developing – or supporting the development of – evidence-informed policies and programmes. Such resource constraints include staff time but there are also constraints in terms of the capacity of those who support policymakers. This means that only a limited amount of skilled-staff time can be allocated to finding and using research evidence to clarify a problem, frame options to address a problem, and address how an option will be implemented (these issues are the focus of the SUPPORT tools discussed in Chapters 4-6 [3-5]), or to other efforts to support evidence-informed policymaking. The bulk of skilled staff time needs to be allocated to administering existing programmes and to responding to emerging issues in other ways. Resource limitations may also extend to staff infrastructural needs (such as access to a librarian or journal article purchasing), and to their continuing professional development.

Working within such resource constraints, policymakers and other stakeholders may choose to group together all staff who support evidence-informed policymaking, or else to spread them out within programme areas. Figure 3.1 provides a visual depiction of both a centralised approach and a decentralised approach to supporting evidence-informed policymaking. A centralised approach can facilitate the development of a common approach to priority-setting and common procedures, but it requires strong linkages with programme staff who know the issues and context well (this can be achieved potentially through the use of time-limited steering groups to oversee particular assessments of the available research evidence). A decentralised approach can facilitate the development of a culture of evidence-informed policymaking within each programme, but will require similarly strong linkages between the decision-support staff who perform similar functions in other programmes.

Figure 3.1
Centralised and decentralised decision support



Policymakers and stakeholders may also choose to contract out some or all of the work to independent units with skilled staff and appropriate infrastructure. But such options also may be limited by the financial resources available. As with a centralised 'in-house' approach, external contracts require strong linkages with policymakers and stakeholders who know the issues and context, using possible mechanisms such as time-limited steering groups.

Whether support for evidence-informed policymaking is provided in-house or contracted out to independent units, or whether the support is centralised or decentralised, resources always need to be used wisely in order to maximise their impact. Only a very limited number of issues can be subjected to a comprehensive assessment of the available research evidence. It is important to note, too, that resource limitations also come into play when deciding which policy or programme option to pursue, or which implementation strategy to pursue (these issues are the focus of Chapters 5 [4] and 6 [5]). In this chapter, the focus is on using resources wisely to find and use research evidence to support evidence-informed policymaking.

In Figure 3.2, the second column shows examples of possible undesirable practices which may be used in a priority-setting approach. For example, if timelines to support evidence-informed policymaking are negotiated on a case-by-case basis, policymakers will be unable to match the time constraints they face (e.g. a half-day, five-day or two-month period) to the support they could receive (a targeted search for a systematic review or a

comprehensive assessment of the available research evidence). When implicit criteria are used to set priorities or the priority-setting process is ad hoc, those policymakers whose needs for research evidence are not being met may become demoralised by the lack of attention to their programme or disillusioned with the rhetoric of evidence-informed policymaking. And without either a communications plan or a monitoring and evaluation plan, policymakers will not know *why* their evidence needs are or aren't being met, and be unable to learn whether and how their existing approaches can be improved.

Figure 3.2
Elements of priority-setting approaches and their features

Elements of a priority-setting approach	*Undesirable features*	*Desirable features*
Timeline	Negotiated case-by-case	Norms for each level of support
Criteria	Implicit	Explicit
Process	Ad hoc	Systematic and explicit
Communications/ monitoring and evaluation	Absent	Planned

Policymakers and stakeholders charged with developing a priority-setting approach to support evidence-informed policymaking, face difficult challenges:

- They have to combine a *proactive* approach to priority setting (e.g. what priority should an issue be given in a national strategic plan for the health sector?) together with a *reactive* approach that can respond to the pressing issues of the day (e.g. what priority should an issue receive when it appears on the front page of a newspaper or is discussed in the legislature?). A priority-setting approach needs to contribute to future plans while responding to existing potentially difficult circumstances
- Policymakers have to balance *a disease or illness orientation* (e.g. what priority should be given to HIV/AIDS or diabetes?), *a programme, service and drug orientation* (e.g. what priority should be given to a screening programme, a counselling service or a new class of drugs?), and *a health system arrangements orientation* (e.g. what priority should be given to a regulatory change in the scope of the practice of nurses, or to a change in the financial arrangements that determine how doctors are paid, or to a change in the delivery arrangements that determine whether some forms of care are provided only in high-volume facilities?). A priority-setting approach needs to function with multiple, often interacting, orientations at the same time
- They have to balance shorter-term confidentiality issues with longer-term commitments to transparency and public accountability. This is particularly true for policymakers who typically rely heavily on civil servants to assess issues for them. Strict confidentiality provisions are often set to ensure that issues are not discussed before they have been vetted by policymakers. This is important given that policymakers are accountable in a very public way (through periodic elections) for the decisions they make. A priority-setting approach – at least one based within government – needs to accommodate a mix of confidentiality and transparency provisions

Some desirable practices used in a priority-setting approach for evidence-informed policymaking are derived from available tools and resources used to support priority setting in other domains. These tools and resources can be divided into three key types:

- Many tools and resources address how to prioritise illnesses and injuries. These tend to focus on the use of available data on illness and injury prevalence or incidence [6-9]
- Most tools and resources focus on how to prioritise programmes, services and drugs that are targeted at illnesses and injuries, or at ill health more generally. Many of these tools and resources focus both on data on prevalence or incidence, and on research evidence about the effectiveness or cost-effectiveness of prevention and treatment options [10-12]. Few deal with a broader set of criteria or have a more holistic approach to setting priorities [13-15]
- Almost no tools and resources address the issue of how to prioritise health system arrangements (or changes to health system arrangements) that support the provision of cost-effective programmes, services and drugs [16], or how to prioritise actions to address the social determinants of health

Tools and resources are also available to support priority setting for both primary research and systematic reviews in the research sector [17-21], as well as for recommendations for the health sector (e.g. clinical practice guidelines) [22].

Elements of the tools and resources discussed above can be used to help to shape an approach to priority setting for those issues that will be the focus of evidence-informed policymaking. For example, burden-of-disease data may be used to inform assessments of the contribution of a particular disease to the overall burden of ill health. Research evidence about the effectiveness of programmes, services and drugs needs, can help to inform assessments of options to address ill health. Similarly, approaches to priority setting for basic research (which may use a 5-25 year time horizon), applied primary research (which may use a 2-5 year time horizon), and for systematic reviews (which may use a 6-18 month time horizon) can all provide insights into priority setting for policy briefs that are produced within a 1-6 month time horizon. (Chapter 13 addresses the preparation and use of policy briefs in further detail) [1]. Approaches to priority setting for recommendations can also give insights into priorities for finding and using research evidence to support evidence-informed policymaking. However, a recent review of priority setting for recommendations concluded that there was "little empirical evidence to guide the choice of criteria and processes for establishing priorities" [22].

Table 3.1 provides examples of organisations in which a priority-setting approach can be beneficial.

Table 3.1
Examples of organisations in which an approach to setting priorities for evidence-informed policymaking can be beneficial

A number of different types of organisations have emerged to support evidence-informed policymaking. For example:	
The Strategic Policy Unit, UK	The Strategic Policy Unit, based within the United Kingdom's Department of Health, was set up to examine high-priority issues that need to be addressed within a timeline of weeks to months
The Canadian Agency for Drugs and Therapeutics in Healthcare	The Canadian Agency for Drugs and Therapeutics in Healthcare (www.cadth.ca), a national government-funded agency, provides a rapid-response function (called the Health Technology Inquiry Service) to Provincial Ministries of Health seeking input about which health technologies to introduce, cover or fund. Timelines range from 1-30 days

Evidence-Informed Policy Network, Vietnam	An Evidence-Informed Policy Network (www.evipnet.org) in Vietnam has obtained funding to produce two policy briefs and convene two policy dialogues in the coming year to respond to the priorities of policymakers and stakeholders
The European Observatory on Health Systems and Policies	The European Observatory on Health Systems and Policies (www.euro.who.int/observatory) convenes a range of policy dialogues, including 'rapid reaction seminars' which can be organised at very short notice
The On-call Facility for International Healthcare Comparisons, UK	The On-call Facility for International Healthcare Comparisons (www.lshtm.ac.uk/ihc/index.html), located within the London School of Hygiene and Tropical Medicine, responds to direct requests from the United Kingdom's Department of Health about how health systems in other high-income countries are addressing particular issues [23,23]
Each of these organisations must, implicitly or explicitly, have timelines within which they are prepared to work. They also need criteria to decide which issues warrant significant periods of their time and which issues warrant less, or even none at all. Processes to make these decisions are also required.	

Questions to consider

The following questions can guide how to set priorities for finding and using research evidence to support evidence-informed policymaking:

1. Does the approach to prioritisation make clear the timelines that have been set for addressing high-priority issues in different ways?
2. Does the approach incorporate explicit criteria for determining priorities?
3. Does the approach incorporate an explicit process for determining priorities?
4. Does the approach incorporate a communications strategy and a monitoring and evaluation plan?

1. Does the approach to prioritisation make clear the timelines that have been set for addressing high-priority issues in different ways?

Policymaking processes may play out over days, weeks, or even years. Systematic and explicit priority-setting processes aren't typically appropriate for very short timelines (i.e. hours and days) because the priority-setting process could take longer than the time in which a decision needs to be made. However, explicit criteria can still help to inform judgements about which issues require an all-hands-on-deck approach to finding and using research evidence (e.g. for those moments when a Minister says "We need it now!"). Conversely, they also help to identify which issues could be dealt with over a longer time period or should be put aside entirely, and determining which issues fall somewhere in-between.

For policymaking processes that play out over weeks or months, explicit priority setting criteria and systematic and explicit priority-setting processes can offer value. This is particularly true if there is receptivity on the part of policymakers and stakeholders to seeking an independent assessment of the research evidence (such as a policy brief) (see Chapter 13 for further discussion of preparing and using policy briefs to support evidence-informed policymaking) or to seeking the evidence-informed input of stakeholders through a

policy dialogue (Chapter 14 discusses how to organise and use dialogues to support evidence-informed policymaking) [1,2]. Such a priority-setting process would need to be dynamic and have revisions done every few weeks or months, if it is to provide a meaningful balance of proactive and reactive approaches.

For 'perennial' policy issues, and those policymaking processes that play out over many months or even years, policymakers and other stakeholders can embrace a more strategic approach to priority setting. This could include commissioning researchers to conduct a systematic review of the research literature on a specific policy or programme question, or conducting an impact evaluation of a policy or programme (this topic is the focus of Chapter 18) [24].

An approach to prioritisation would ideally make clear the timelines that have been set for addressing high-priority issues in different ways. Policymakers and stakeholders could then match the time constraint that they're working under (a half-day, five-day or two-month period) to the kind of support they could receive, such as:

- A search for systematic reviews that address an issue
- A summary of the take-home messages from quality-appraised systematic reviews addressing many facets of an issue, or
- A comprehensive assessment of the research evidence available that will clarify a problem, frame options to address it, and address how an option will be implemented (i.e. a policy brief, as described in Chapter 13 [1])
-

The final column of Figure 3.2 highlights desirable practices that can be applied in a priority-setting approach, including the use of norms about timelines for different types of support. The other practices highlighted in this figure form the focus of Questions 2-4 below. Table 3.2 provides an example of timelines for (and capacity to provide) different types of support, as well as applications of the insights from Questions 2-4, to the priority-setting approach used in a Ministry of Health.

Table 3.2
Examples of a priority-setting approach

A Ministry's decision-support unit offers the following range of supports to other Ministry staff:

1. A search for systematic reviews that address an issue (Timeline: 1 day; Number that can be provided per quarter: 24)
2. A summary of the take-home messages from quality-appraised systematic reviews addressing many facets of an issue (Timeline: 1 week; Number that can be provided per quarter: 12), and
3. A comprehensive assessment of the research evidence available to clarify a problem, frame options for addressing it, and address how an option will be implemented (Timeline: 1 month; Number that can be provided per quarter: 3)

The unit maintains an inventory of requests, in which each request is allocated a score of between 0 and 56. On receipt, a request is reviewed by two unit staff who assign it a rating of between 1 and 7 points (where a rating of 1 indicates 'strongly disagree' and 7 is 'strongly agree') for each of the following three criteria:

- The underlying problem(s), if properly addressed, could lead to health benefits, improvements in health equity or other positive impacts now or in the future
- Viable options, if properly implemented, could affect the underlying problem(s), and hence lead to health benefits, improvements in health equity or other positive impacts, or could lead to reductions in harms, cost savings or increased value for money, and
- Political events could open (or political events may already have opened) windows of opportunity for change

The individual scores for the third criterion are doubled, as this is deemed to be twice as important as the other two (as a way of ensuring that the Minister's priorities are given adequate consideration). A maximum of 14 points can be assigned to criterion 1, 14 points to criterion 2, and 28 points to criterion 3. One of the two unit staff will note the nature of the support requested (support types 1, 2 or 3 above). The basis for these assessments is the request description and justification submitted by other Ministry staff (after approval from their respective divisional director). The request must address each of the three criteria using data and evidence (when these are available) and a discussion about the application of explicit criteria to the issues that are considered for prioritisation.

At the beginning of each week, the unit manager, together with all divisional directors, reviews the rank-ordered list of priorities for each of support types 1, 2 and 3. Collectively, they confirm that the top two requests for support type 1 will proceed that week and that the top request for support type 2 will proceed. They also confirm that the top request for support type 3 is on track and that preparations are being made to begin a new assessment for the second-ranked request type 3 as soon as the current assessment is completed. The unit manager (who has training in health policy research) facilitates the meeting, taking care to elicit the rationale for any ranking changes and to ensure that any requests for comprehensive assessments are well thought through in terms of the provisional problem clarification, options framing, and implementation considerations. The unit manager then posts the decisions and rankings on the Ministry's intranet and directs Ministry staff whose requests have not been addressed within one month of submission to submit an updated request.

Once a month, the unit manager reviews the unit's monitoring data with the divisional directors. The monitoring data includes the number of appeals submitted by Ministry staff and their resolution. Once every year, the unit re-evaluates the scale of its outputs to determine if it can provide more support within shorter time frames. Once every three years, the unit commissions an evaluation of its impacts on the policymaking process

2. Does the process incorporate explicit criteria for determining priorities?

Explicit criteria can help to guide those involved in a priority-setting process *and*, if confidentiality restrictions permit, in communicating the rationale for decisions about priorities to other policymakers and stakeholders. Three possible criteria for prioritising a given issue include:

- The underlying problem(s), if properly addressed, could lead to health benefits, improvements in health equity or other positive impacts, now or in the future
- Viable options, if properly implemented, could affect the underlying problem(s), and hence lead to health benefits, improvements in health equity or other positive impacts, or could lead to reductions in harms, cost savings or increased value for money, and
- Political events could open (or political events may already have opened) 'windows of opportunity' for change. For example, in 1993 Taiwan's President submitted a national health insurance bill to Parliament in order to pre-empt a challenge by an opposition party [25]. The pending challenge opened a significant window of opportunity for change, and for finding and using research evidence to support policymaking about national health insurance

The application of these criteria requires readily available data and research evidence, as well as collective judgement (based on these and other considerations) about whether an issue

warrants prioritisation. A thorough assessment would only be needed for a limited range of issues considered to be of higher priority.

The first criterion listed above relates, in part, to concerns such as the burden of illness and the likely severity of new or emerging illnesses. But it also relates to judgements about how likely it is that the underlying problem(s) can be addressed. These underlying problem(s) may vary in scope, ranging from a narrow focus on the specific characteristics of particular illnesses and injuries, through to the programmes, services and drugs used to prevent or treat these illnesses and injuries, and/or the health system arrangements that support the provision of programmes, services or drugs. Given that data and research evidence about underlying problem(s) may not be readily available or may be lacking entirely, other considerations may need to be introduced. (Chapter 4 provides an overview of the processes involved in using research evidence to clarify problems) [3].

The second criterion requires judgement about how likely it is that options will have acceptable costs and desired consequences (i.e. how likely it is that they would be considered viable). Framing options to address a problem – the focus of Chapter 5 – requires systematic reviews of studies to examine the benefits and harms of options, as well as data or research evidence about costs and cost-effectiveness [4]. Two recent developments, namely the growth of databases containing systematic reviews and the growing availability of policymaker-friendly summaries of systematic reviews that can be linked to from these databases (which are the focus of Chapter 7), have made preliminary assessments of this type increasingly feasible [26]. However, where research evidence about the viability of options is not readily available, other considerations will need to be introduced.

The third criterion requires judgement about whether a window of opportunity for action could open, or has opened [27]. As we review further in Chapter 4, such opportunities can occur because of the attention that is given to a problem at particular moments in time [3]. Significant media coverage, for example, may be given to documented cases of significant gaps in quality and access in cancer care delivery. These windows, however, can close equally fast because media attention tends to move on quickly. Windows of opportunity may also be opened by political events, such as, for example, the formation of a coalition of stakeholders who have chosen to take action on a particular issue, or when a politician with a personal interest in an issue is appointed as a Minister of Health. Some events related to problems or politics can be predicted, such as the publication of periodic reports by national statistical agencies, the development of a national health sector strategic plan, and the setting of annual budgets, as well as elections. But often the specific *nature* of the opportunity can't be.

3. Does the process incorporate an explicit process for determining priorities?

Explicit criteria do not make decisions – people do. And a systematic and explicit process can help them to make decisions in a defensible way. Four possible desirable features of a priority-setting process include:

- It is informed by a pre-circulated summary of available data and evidence and by a discussion about the application of explicit criteria to issues that are considered for prioritisation
- It ensures fair representation of those involved in, or affected by, future decisions about the issues that are considered for prioritisation
- A facilitator is engaged who uses well-constructed questions to elicit views about the priority that should be accorded to issues as well as the rationale for their prioritisation, and

- An experienced team of policymakers and researchers is engaged to turn high-priority issues into clearly defined problem(s) and viable options that will be the focus of more detailed assessments

The preparation of a pre-circulated summary of available data and evidence about possible priority issues is a highly efficient way of preparing participants for a priority-setting process. Gaps in the data and research evidence can be as important to describe as what is available. Such summaries can provide common ground for discussions.

A priority-setting process would ideally bring together the many parties involved in, or affected by, any future decisions related to the issues that are under consideration as possible priorities. Doing this requires careful mapping of the full range of stakeholders and then selecting appropriate individuals from different stakeholder groups. Confidentiality provisions may be particularly challenging in this process if they preclude the involvement of those who will be affected by any future decisions. Civil servants, and especially politicians, may then be required to participate on their behalf.

A skilled, knowledgeable and neutral facilitator is required to ensure that a priority-setting process runs well. In Chapter 14, we describe the rationale for this combination of attributes [2]. For a priority-setting process that is entirely internal to government, it may be ideal if the facilitator is drawn from a decision-support unit, rather than from divisions in charge of particular policy domains (e.g. human resources policy) or particular programmes (e.g. diabetes care).

An experienced team of policymakers and researchers is required to turn high-priority issues into clearly defined problem(s) as well as viable options that will form the focus of more detailed assessments. The team would ideally establish clear timelines for each issue that needs to be addressed. The team could also provide guidance about which issues could be addressed in-house, and which could be contracted out. If certain issues are deemed confidential, these too could either be dealt with in-house or contracted out with clearly stated confidentiality clauses in the work contracts.

While this process may sound complex, as described in Table 3.2, it can be put into operation in a very practical way in a given setting.

4. Does the process incorporate a communications strategy and a monitoring and evaluation plan?

A communications strategy is needed to ensure that policymakers and stakeholders are informed of the high-priority issues so that they can prepare input into the further clarification of the problems, the framing of options, and addressing how an option will be implemented. Ideally, a range of materials, fine-tuned for different stakeholders, would be produced as part of the communications strategy. However, in some contexts or for some issues, confidentiality provisions may not permit communication with certain stakeholders.

Even the best communications strategy will not reach everyone and it may not elicit the desired commitment to address the high-priority issues. A monitoring plan can help to address this by identifying when high-priority issues are not being addressed within the established timeframe. An accompanying evaluation plan can be used to examine particular issues in a more systematic way, such as the impacts of the priority-setting process on the policymaking process, and how and why stakeholders respond to the priorities identified.

Conclusion

Setting priorities for finding and using research evidence to support evidence-informed policymaking can all too easily be skipped over entirely or done too rapidly or in too cursory a manner. Moreover, the selected approach to priority setting may not be implemented or it may not be implemented fully. It may also not be possible to repeat a particular approach periodically given that windows of opportunity may open and close at different times. Any such failures in priority setting may mean that significant opportunities to support evidence-informed policymaking are missed and that the culture of evidence-informed policymaking is eroded. Close attention should therefore be paid to whether timelines for addressing high-priority issues in different ways are realistic and are being met, whether the criteria and process chosen for determining priorities are realistic and being used, and whether a communications strategy and monitoring and evaluation plan have been developed and are being implemented. Even in highly resource-constrained environments, attention to such issues is likely to ensure that existing resources to support evidence-informed policymaking are directed to where they can have the biggest impact.

Resources

Useful documents and further reading

- Healy J, Maxwell J, Hong PK, Lin V: *Responding to Requests for Information on Health Systems from Policy Makers in Asian Countries*. Geneva, Switzerland: Alliance for Health Policy and Systems Research, World Health Organization; 2007 [28]. – Source of lessons learned about organisations that support evidence-informed policymaking, but with little attention given to how priorities are set by these organisations (www.who.int/alliance-hpsr/RespondingRequests_HS_AsianCountries_Healy.pdf)

- Nolte E, Ettelt S, Thomson S, Mays N: Learning from other countries: An on-call facility for health care policy. *Journal of Health Services Research and Policy* 2008, 13 (supp 2): 58-64 [23]. – Source of lessons learned by an independent organisation that supports evidence-informed policymaking, with some attention given to how priorities are set by the organisation

Links to websites

- *Global burden of disease:* www.who.int/topics/global_burden_of_disease/en – Source of data and research evidence about the global burden of disease. This information can be one input among many in priority setting for evidence-informed policymaking

- *Disease Control Priorities Project:* www.dcp2.org/main/Home.html – Source of research evidence and recommendations about the programmes, services and drugs that should be prioritised in different types of countries. This information can be one input among many in priority setting for evidence-informed policymaking

- *CHOosing Interventions that are Cost-Effective (CHOICE):* www.who.int/choice/en – Source of data, research evidence and a tool about the programmes, services and drugs that should be prioritised in different regions and countries. This information can be one input among many in priority setting for

evidence-informed policymaking

- *Canadian Priority Setting Research Network:* www.canadianprioritysetting.ca – Source of published articles about priority-setting in healthcare, which may provide lessons for priority setting for evidence-informed policymaking

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Chapters 4, 5 and 6: Identifying needs for research evidence

4. Using research evidence to clarify a problem

John N Lavis, Michael G Wilson, Andrew D Oxman, Simon Lewin, Atle Fretheim

Summary

Policymakers and those supporting them often find themselves in situations that spur them on to work out how best to define a problem. These situations may range from being asked an awkward or challenging question in the legislature, through to finding a problem highlighted on the front page of a newspaper. The motivations for policymakers wanting to clarify a problem are diverse. These may range from deciding whether to pay serious attention to a particular problem that others claim is important, through to wondering how to convince others to agree that a problem *is* important. Debates and struggles over how to define a problem are a critically important part of the policymaking process. The outcome of these debates and struggles will influence *whether* and, in part, *how* policymakers take action to address a problem. Efforts at problem clarification that are informed by an appreciation of concurrent developments are more likely to generate actions. These concurrent developments can relate to policy and programme options (e.g. the publication of a report demonstrating the effectiveness of a particular option) or to political events (e.g. the appointment of a new Minister of Health with a personal interest in a particular issue). In this chapter, we suggest questions that can be used to guide those involved in identifying a problem and characterising its features. These are:

1. What is the problem?
2. How did the problem come to attention and has this process influenced the prospect of it being addressed?
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?
5. How can the problem be framed (or described) in a way that will motivate different groups?

Scenarios

Scenario 1: You are a senior civil servant and have been asked to submit a briefing note to the Minister about a health system problem in which she has a personal interest, namely that many of her constituents and family members say that they can't find a primary healthcare physician. You are concerned about whether the current draft of the briefing note prepared by a junior policy analyst does justice to the problem

Scenario 2: You work in the Ministry of Health and are preparing a briefing note about a health system problem. All that you have been told is that the problem is about many citizens not having access to primary healthcare providers and services

Scenario 3: You work in an independent unit that supports the Ministry of Health in its use of research evidence in policymaking and are preparing a policy brief for the Ministry of Health on barriers to accessing primary healthcare. You want guidance on how to clarify the problem in a systematic and comprehensive way

Background

For policymakers (Scenario 1), this chapter suggests a number of questions that they might ask their staff to consider when preparing a briefing note about a problem. For those who support policymakers (Scenarios 2 and 3), this chapter suggests a number of questions to guide the clarification of a problem based on the best available local and global evidence. This chapter is the first of three chapters about clarifying evidence needs (see also Chapters 5 and 6 [1,2]). Figure 4.1 outlines the processes involved in clarifying these needs.

Figure 4.1
Clarifying evidence needs

Policymakers and those supporting them often find themselves in situations in which they need to decide how best to define a problem. They may have:

- Identified a problem through an explicit priority-setting process (the focus of Chapter 3) [3]
- Read about a problem in a report from a national statistical agency or from an independent researcher
- Been asked a tough question about a problem in the legislature or by someone living in their constituency
- Found a problem highlighted on the front page of a daily newspaper, or
- Identified a problem through their personal experience of a health system

Some of these situations lend themselves to the proactive assessment of a problem, or what some might call an issue or challenge. But most typically they place policymakers in a reactive mode.

The motivation for policymakers to clarify a problem may be informed by a consideration of:

- Whether to pay serious attention to a particular problem that others assert is important
- What factors contribute to a problem
- How to measure the magnitude of a problem (whether it is getting better or worse, and whether it is responding to particular policies or programmes)
- How to convince others to agree that a problem is important (or that a favoured way forward is the optimal one given *how* it addresses a particular problem), or
- How to address misperceptions or manage expectations among those who (erroneously, in the eyes of the policymakers) see the problem as important

Debates and struggles over how to define a problem are a critically important part of the policymaking process [4,5]. The outcome of these debates and struggles will influence *whether* (and, in part, *how*) policymakers take action to address a problem.

Problems may come to light through:

- A focusing event
- A change in an indicator, or
- Feedback from the operation of a current policy or programme [6]

Focusing events are very common in the health sector because poor decision making may lead to extreme and often high-profile events such as illness and death. An example of a focusing event would be extensive newspaper coverage over a number of consecutive days of the provision of counterfeit prescription drugs and the deaths resulting from their use. A change in an indicator, though less dramatic, can also bring a problem to attention, particularly if it is a large change or it receives significant attention in a report or media release. A national statistical agency, for instance, may release a report showing that nurses' pay varies widely across a country and that this is contributing to nursing shortages in certain provinces. Or a problem may come to light through feedback from the operation of a current policy or programme. Informal feedback from a programme manager in charge of a provincial waiting-time reduction initiative might, for example, highlight the fact that the programme is failing to meet its target for wait-time reductions due to resource limitations.

However, not all problems that are brought to attention are deemed worthy of government action. A problem can be defined as warranting government action by:

- Comparing current conditions with values related to a 'more ideal' state of affairs
- Comparing performance with other jurisdictions, and
- Framing a subject in a different way (e.g. describing a problem as an impediment to achieve a national priority) [6]

Politicians from different political parties will reflect different values and interpretations related to what constitutes a 'more ideal' state of affairs. A Minister of Health might regard the performance of their own country's health system favourably relative to another in a neighbouring country. But he or she might not do so when it is compared less favourably to other but equally appropriate international examples. Similarly, a cabinet may decide to take action if a particular problem is defined in terms of a lack of patient choice among healthcare providers (given that this could potentially become a source of frustration for voters), but *not* if a problem is defined in terms of a lack of interest on the part of physicians in joining clinics that use collaborative practice models (this issue might be perceived by them as being too far removed from the concerns of voters).

Efforts to clarify problems are more likely to result in action if they:

- Reflect an awareness of concurrent developments related to policy and programme options (e.g. the publication of a report demonstrating the effectiveness of a particular option), and
- Are influenced by concurrent political events (such as the appointment of a new Minister of Health who may have a personal interest in a particular issue) [6]

If a problem is not defined in a way that 'fits well' with what are perceived to be viable options, or if it does not fit with broader political events, it is very unlikely to reach a decision agenda. An option can be deemed to be a viable solution if it is technically feasible, fits with dominant values and the public's current mood, and is acceptable both in terms of budget workability and likely political support or opposition [6]. Relevant political events can include swings in the public mood, changes in levels of support or opposition from interest groups, and changes to the governing party or prevailing legislative coalition [6].

Questions to consider

The following questions can guide how to identify a problem and characterise its features:

1. What is the problem?
2. How did the problem come to attention and has this process influenced the prospect of it

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

1. What is the problem?

A problem may relate to one or more of the following:
- A risk factor, disease or condition
- The programmes, services or drugs currently being used to address a risk factor, disease or condition
- The current health system arrangements within which programmes, services and drugs are provided, or
- The current degree of implementation of an agreed upon course of action (e.g. a policy or guideline)

The prevalence of a risk factor or the burden of a disease or condition in a province or country (e.g. incidence rate, prevalence rate, mortality rate) may constitute a problem. But more often, such issues are the manifestation of a problem: their *cause* is the real problem that needs to be addressed. The problem may instead lie with the programme or service, or relate specifically to the suitability of a drug that is currently being used to address a risk factor, disease or condition. Ineffective programmes, services or drugs may, for example, be in use to prevent or treat the risk factor, disease or condition.

Alternatively, a problem may be rooted in current health system arrangements within which programmes, services and drugs are provided. Potential problems may lie with governance arrangements/structures. These can include:
- Who has policy (e.g. regulatory), organisational, commercial and professional authority and accountability over particular programmes
- The services and drugs or the parts of the health system within which the programmes are located
- The services and drugs provided
- How authority is discharged, and
- How people who exercise authority are held accountable

Potential problems may also be rooted in financial arrangements. Such arrangements may affect who finances (i.e. who pays for) particular programmes, services and drugs and the parts of the health system within which these are provided, or how organisations are funded to deliver them. It may also relate to how professionals are remunerated to provide programmes, services or drugs, whether patients/consumers are offered incentives to use them, and how resources are allocated to them. Further, problems may be linked to current delivery arrangements. These may include: who is targeted by particular programmes, services and drugs, who they reach (or who accesses and uses them), who provides them and how, where they are they provided, what information and communication technology is used to provide them, and what safety and quality systems are provided. The taxonomy of governance, financial and delivery arrangements is addressed further in Chapter 5 [1].

Finally, a problem may be rooted in the *degree* of implementation of an agreed course of action about a programme, service or drug, or else an agreed course of action about the health system arrangements within which these are provided. A problem, for example, may already have been defined and a policy introduced to address it, but the policy may not yet have been translated into action. In this instance, one approach to identifying the problem is to identify potential barriers to implementation at one or more of four levels:

1. The healthcare recipient and citizen level (e.g. citizens are unaware that they can access a programme, service or drug free of charge)
2. The healthcare provider level (e.g. health workers do not fully adhere to national policies and guidelines)
3. The organisational level (e.g. organisations do not manage the performance of their staff), and
4. The system level (e.g. policies are not enforced).

The identification of barriers to implementation is the focus of Chapter 6 [2].

Policymakers and those who support them need to determine the causes of a problem. These problems may be related to: one or more risk factors; a disease or condition; the programmes, services or drugs currently being used; the current health system arrangements; or the current degree of implementation of an agreed-upon course of action. Doing so can be an iterative process. What at first glance may appear to be a seemingly unrelated issue, such as disincentives to manage chronic disease proactively in primary healthcare, may actually be the very problem that needs attention. Table 4.1 illustrates how this simple framework can be used to clarify a problem, using malaria treatment in sub-Saharan Africa as an example.

Policymakers and those supporting them could gain additional insights into this component of problem clarification from the fields of complexity theory, complex adaptive systems, and soft systems methodology. Examples of relevant resources are provided at the end of this chapter.

Table 4.1
Clarifying the problem underpinning the lack of widespread use of the recommended malaria treatment

Members of the Evidence-Informed Policy Networks (EVIPNet) in ten sub-Saharan African countries identified the problem of the lack of widespread use of the recommended artemisinin-based combination therapy (ACT) to treat malaria in their respective countries.

The following framework of four questions (and relevant sources of data and research evidence) [7] was used to clarify this problem:

Does the problem relate to a risk factor, disease or condition?

- Incidence of (and death rates from) uncomplicated falciparum malaria, by age (including separately for infants), sex (including separately for pregnant women and lactating women), HIV status, malnutrition status, and socio-economic status

Does the problem relate to a programme, service or drug currently being used to address a risk factor, disease or condition?

- Cure rates for, and drug resistance (or reduced drug sensitivity) to, ACT and other anti-malarial drugs, as well as the side effects and costs of the drugs
- The views and experiences of patients about particular anti-malarial drugs

Does the problem relate to the current health system arrangements within which programmes, services and drugs are provided?

- Governance arrangements
  - Regulations about which ACT and other anti-malarial drugs (i.e. drugs, dosage regimes, and packaging) can be registered/licensed for sale, how counterfeit or substandard drugs are safeguarded against, how patents for them and profits arising from them are handled, how they can be marketed, who can prescribe them and how, and who can sell or dispense them and how
  - National treatment guidelines and/or the national malaria control policy about the first-line (and second-line) drug therapy recommended for uncomplicated falciparum malaria, as well as their dosage regimes/packaging, targeting for particular populations, and targeting for areas with particular characteristics
  - National essential drugs list, particularly the list of anti-malarial drugs
- Financial arrangements
  - Drug and dispensing fees for first-line drug therapy (and for ACT if this is not the first-line therapy) for uncomplicated falciparum malaria, including any subsidies for particular populations, remuneration arrangements for health works prescribing and dispensing ACT
  - The views and experiences of patients about fees and subsidies and about financial incentives to promote adherence
- Delivery arrangements
  - Access rates for first-line drug therapy (and for ACT if this is not first-line therapy) for uncomplicated falciparum malaria (i.e. who has access to someone who can dispense drug therapy)
  - Coverage rates for first-line drug therapy (and for ACT if this is not first-line therapy) for uncomplicated falciparum malaria (i.e. who is dispensed which drug)
  - Treatment patterns for uncomplicated falciparum malaria (i.e. who dispenses what, when, where and how, including whether treatment is part of the Integrated Management of Childhood Illness or other 'horizontal' programmes)
  - Adherence patterns for the treatment of uncomplicated falciparum malaria (i.e. who takes what, when, where and how)
  - Arrangements for surveillance, pharmacovigilance and the diagnosis and treatment of atypical cases
  - The views and experiences of patients about particular providers (or delivery arrangements more generally)

Does the problem relate to the current degree of implementation of an agreed-upon course of action?

- For example, regulations can only help to address a problem if they are acted upon throughout the health system. Regulations may exist about the registration/licensure, marketing, prescribing and dispending of ACT and other anti-malarial drugs. However, if the regulations are not enforced, there may be many counterfeit or substandard drugs in circulation, false statements may be made in drug advertisements, and untrained individuals may be prescribing or dispensing ACT

The EVIPNet teams all concluded that the problem could be related to a risk factor, disease or condition, the programmes, services or drugs currently being used, the current health system arrangements and, in some cases, the current degree of implementation of an agreed-upon course of action. This had important implications for which options were considered appropriate to address this multi-faceted problem

2. How did the problem come to attention and has this process influenced the prospect of it being addressed?

Identifying a problem is often only the beginning of the process. Typically, a great deal of work will still need to be done in order to clarify a problem in a way that confirms whether or not there is a need to address it. If there is a need, it will also be necessary to build the support required to address it. Understanding how a problem first came to attention can be an important initial step in the process of clarification. As outlined in the Background section of this chapter, problems typically come to light through:

- A focusing event
- A change in an indicator, or
- Feedback from the operation of current policies and programmes

Key policymakers may (or may not) agree whether a problem warrants attention at the early stages of the problem-clarification process. Table 4.2 illustrates how the question discussed here in this sub-section (together with three additional questions) can be used to clarify a problem once it has been related to one or more of: a risk factor, disease or condition; the programmes, services or drugs currently being used; the current health system arrangements; or the current degree of implementation of an agreed-upon course of action.

Table 4.2
Clarifying the problem underpinning high rates of medication error

Questions 2-5 which were discussed earlier in this chapter can be used to clarify a problem once it has been related to one or more of the following: a risk factor, disease or condition, the programmes, services or drugs currently being used, the current health system arrangements and the current degree of implementation of an agreed-upon course of action. Consider the following example of the problem of high rates of medication error:

How did the problem come to attention and has this process influenced the prospect of it being addressed?

- The problem of medical error may come to attention through a focusing event (e.g. a child dies because a doctor prescribes the wrong drug dosage), a change in an indicator (e.g. there is a dramatic increase in the number of reported errors in a given month) or feedback from the operation of current policies and programmes (e.g. an evaluation report identifies more types of medication errors than have been routinely measured)
- An evaluation report may identify that one possible factor contributing to a problem is the lack of clear boundaries of the scope of practice between doctors, nurses and pharmacists, which makes accountability for prescribing, dispensing, administration and chart documentation unclear
- The same report may propose that the problem be turned into a statement of purpose that can be used to engage a diverse array of stakeholders. For example, policymakers may prefer to speak about how their country will become a leader in patient safety, rather than referring to current patient safety problems

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

- Policymakers may identify that no indicators are currently being measured accurately at the national level but that they are interested in starting to accurately measure both the number of medication error reports per quarter and the number of 'near misses' per quarter. Collecting such data would allow them to set a target level for the indicator

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

Policymakers may identify that they would like to make four types of comparisons:

- Comparisons over time within the country
- Comparisons to other appropriate comparator countries
- Comparisons against a target to be set as part of a national patient safety strategy
- Comparisons against what a national consumer association has said that it would like to see
  - Ideally a search for administrative database studies or community surveys would allow the policymakers to identify at least some existing research evidence and allow them to make immediate comparisons

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

Policymakers may find that:

- Pharmacists respond to the language used to describe a medication error
- Consumer groups respond to a stated purpose of achieving, for example, a 50% reduction in medication errors
- Regulators engage when the lack of clear boundaries between the scope of practice of healthcare providers is discussed as an important feature of the problem
- Hospital staff may respond positively when told of a plan to collect an indicator that identifies under-reporting in a way does not penalise units or departments who support full disclosure
- Hospital executives may engage most fully when comparisons are made among their facilities
- Ideally a search for qualitative studies would allow the policymakers to grasp the different meanings that different groups attach to a problem

If key policymakers *do* agree that a problem warrants attention and that they want to stake out a claim for what they would like to achieve in addressing the problem (e.g. through a statement of purpose or a goal), this will often leave little time to clarify the problem accurately. Before long, it may be necessary to move on to the specifics of considering how the options should be framed.

It is possible though that a focusing event could, on closer examination, turn out to be a significant aberration rather than reflecting a widespread problem. Similarly, an indicator may be found to have been poorly measured or not adjusted for seasonal variation. Or an internal report about the operation of current policies and programmes may, when read more closely, contain significant errors of interpretation. It may also be the case that policymakers erroneously link a problem to programmes, services or drugs currently being used when, in reality, the actual problem may lie elsewhere.

Alternatively, key policymakers may quickly decide that a problem does not warrant attention. They may focus on addressing misperceptions or managing expectations among those who first brought the problem to attention. In the interim, those supporting such policymakers may conduct a preliminary review and conclude that the problem *is* significant. In this case key policymakers will be left with the difficult task of having to make an argument for re-opening an issue that has been effectively closed – perhaps even in a highly visible way.

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

Depending on how a problem first comes to attention, it may or may not be necessary to examine closely which indicators related to a problem are currently being measured (or can and should be measured) accurately. If, for example, a problem comes to attention through a change in an indicator that is already known to be highly reliable, giving further attention to other indicators may not be needed. On the other hand, if a problem comes to attention through a focusing event, further work would be necessary. In such cases:

- Community surveys and vital registries are examples of good sources of indicators about a risk factor, disease or condition
- Healthcare administrative data (or what are sometimes called health management information systems), monitoring and evaluation data, community surveys, and healthcare provider surveys can be good sources of indicators about the programmes, services and drugs currently being used
- Legislation, regulation, policies, drug formularies, and policymaker surveys can be good sources of indicators about governance arrangements
- Health expenditure surveys and healthcare provider surveys can be good sources of indicators about financial arrangements
- Healthcare administrative data can be good sources of indicators about delivery arrangements, and
- Community surveys and healthcare provider surveys, as well as healthcare administrative data, can be good sources of indicators about the current degree of implementation of an agreed-upon course of action

Disaggregated data, such as data by ethnicity/culture, gender or socio-economic status, can often be particularly helpful in clarifying whether a problem is widespread or particularly pronounced in some groups. Chapter 11 addresses how to find and use local evidence, and Chapter 10 describes a categorisation scheme for groups which could be considered when incorporating equity-based approaches within the process of problem clarification [8,9].

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

While indicators can provide policymakers with some sense of the magnitude of a particular problem, implicit or explicit comparisons are what truly establish whether a problem is big or small, whether it is getting better or worse, or whether it appears amenable to change. At least four key types of comparisons can be made:

- *Comparisons over time within a country*: can help to establish whether a problem is getting better or worse. If corrective actions have already been taken, such comparisons can help to determine whether a problem appears amenable to change
- *Comparisons between countries and other appropriate comparators* (where the data are comparable): can help to establish whether a problem is big or small and what targets could be achievable, and help to mobilise support for addressing a problem
- *Comparisons against plans*: (e.g. national targets and the Millennium Development Goals) can help to mobilise support for addressing a problem, and
- Comparisons against what policymakers and/or stakeholders predicted or wanted: can also help to mobilise support for reaching goals

While clarifying a problem relies extensively on local data, research evidence can often provide comparisons that have been conducted in a systematic and transparent way.

Healthcare administrative database studies and community surveys, for example, which are often published in research literature, can help to clarify a problem and appropriate targets and mobilise support. Such studies can be highly useful to policymakers in addressing misperceptions or managing expectations. They can also be used to develop or refine a statement of purpose. For example, policymakers may want to change the trajectory of an existing indicator or measure a new indicator in ways that permit comparisons. Chapter 11 provides approaches to finding and using local evidence [8]. Table 4.3 also provides tips for finding healthcare administrative database studies and community surveys.

Table 4.3
Finding research evidence about a problem

While much of the task of problem clarification involves finding and using local evidence (the subject of Chapter 11 in this series), published administrative database studies and community surveys can provide insights about comparisons [8]. Qualitative studies can also provide insight into alternative framings for a problem.

The first set of steps involved in finding such studies includes:

- Drawing up a list of words or phrases that capture the problem (e.g. medication error, scope of practice), synonyms for each problem and factor (e.g. drug near-misses, professional regulation), and alternative spellings for each synonym (e.g. medication, medications)
- Deciding whether systematic reviews (the subject of Chapter 7) or single research studies are the focus of the search [10], and
- Providing any additional details that limit the search (e.g. children, adults)

The second set of steps includes:

- Choosing those words and phrases that would *all* need to be present in order for the article to be identified (e.g. medication error, systematic review, and children), connecting them with 'and', and putting them in brackets, and
- Choosing those words and phrases for which only one would need to be present (e.g. medical error and its synonyms), connecting them with 'or', and putting them in brackets, and
- Connecting both sets of brackets using 'and'

The third set of steps includes:

- Using the Internet to access the health-related database, PubMed. This database contains a 'hedge' (i.e. a validated search strategy or filter) for the types of studies of interest here [11]
- Clicking on 'special queries' in the left task bar
- Clicking on 'health services research' queries
- Entering the words and phrases, as well as the Boolean operators ('and'/'or') in the search field, and
- Clicking 'process assessment' or 'outcomes assessment' for administrative database studies and 'qualitative research' for qualitative studies

This approach increases the chances that the returned citations will be of the appropriate study type, though many other types of studies may be retrieved as well

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

How a given problem is categorised can have important consequences for the way groups may respond. Framing a problem in new or alternative ways is likely to result in the issues resonating in different ways among different groups. Canada, for example, has framed the field of study related to the social determinants of health most neutrally by referring to it as 'population health'. In contrast, in the United States of America (USA), the same field is often

referred to as ‘disparities in health’ – a term that conveys the existence of differences but not necessarily unfairness. In the United Kingdom, the term ‘inequalities in health’ is commonly used. This term seems explicitly to convey unfairness, and it only gained political traction when a new governing party was elected in the 1990s with a goal of reducing unfairness within health and other sectors. Some groups may respond more actively to a negatively-framed problem statement (e.g. “Our country has the highest infant mortality rate in the region”) while others may respond better to a positively framed statement of purpose (e.g. “Our country will, within five years, achieve the national health goals related to infant mortality”).

Some groups may rally around issues related to a particular disease or condition (e.g. rapidly rising rates of cardiovascular disease). Others may rally around one or more risk factors (e.g. smoking, diet, exercise or housing and working conditions). Even groups with a similar focus may be attracted to different indicators related to the same problem. Some may be motivated more by ‘hard’ indicators such as mortality. But others may be motivated by ‘soft’ indicators such as self-reported health status. Particular groups may be motivated only by indicators from the health sector, such as health-related quality of life. Other groups, in contrast, may be motivated by indicators from non-health sectors that can have an influence on health and healthcare, such as employment status. The importance of comparisons can also vary by group, with some groups more interested in a narrowly defined group of peers that share a range of key characteristics (such as large university-affiliated teaching hospitals), and others more interested in the full spectrum of organisations providing similar types of healthcare (such as all hospitals).

Qualitative research can shed light on the meanings that individuals or groups attach to a particular problem, the indicators used to measure it, and the comparisons made to establish its importance. Table 4.3 provides tips for finding this type of research. Conversations with different groups and available qualitative research can help policymakers identify which framings of a problem (or purpose) can best mobilise support among different groups to address a problem. A key challenge, however, is ensuring that the alternative framings being considered are consistent with the problem, as determined through the type of systematic analysis described above.

Conclusion

Problem clarification can all too easily be skipped over entirely, or else done too rapidly, or in too cursory a way. It may also not be done iteratively when additional data and research evidence are found regarding indicators and comparisons, or when policies and programmes encounter challenges or fail to yield results. Any such failures in problem clarification may mean that further resource investments based on existing conceptions of a problem will be misguided. Close attention should be paid therefore to indicators, comparisons and alternative framings to ensure that decisions about which particular problem to focus on are well-informed. The process of clarifying a problem will influence decisions about which particular options warrant serious consideration based on *how* they address a problem.

Resources

Useful documents and further reading

- Kingdon JW: *Agendas, Alternatives, and Public Policies*, 2 edn. New York, USA: Longman; 2003, pp. 90-115

- Rosenhead J, Mingers J (Eds): Rational Analysis for a Problematic World Revisited:. Problem Structuring Methods for Complexity, Uncertainty and Conflict. Chichester, UK: John Wiley & Sons Ltd.; 2001; pp 61-2

- Stone D: Policy Paradox: The Art of Political Decision Making. New York: W. W. Norton and Company; 1997

- Sweeney K. Griffiths F (Eds). *Complexity and Healthcare. An Introduction*. Oxford, UK: Radcliffe Medical Press; 2002, pp. 100

Links to websites

- *Program in Policy Decision-Making (PPD)/Canadian Cochrane Network and Centre (CCNC) database:*
  www.researchtopolicy.ca/search/reviews.aspx – Source of a taxonomy of governance, financial and delivery arrangements within health systems where problems may be located, as well as systematic reviews of administrative database studies, community surveys, and qualitative research addressing health system arrangements

- *PubMed Health Services Research (HSR) Queries:*
  www.nlm.nih.gov/nichsr/hedges/search.html – Source of 'hedges' (i.e. validated search strategies) to identify administrative database studies and community surveys that can help to put a problem in comparative perspective and to identify qualitative studies that can help to frame problem in ways that resonate with different stakeholders

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10. Lavis JN, Oxman AD, Grimshaw J, Johansen M, Boyko JA, Lewin S *et al.*: **7. Finding systematic reviews.** In *SUPPORT Tools for evidence-informed health Policymaking (STP)*. Edited by Oxman AD, Lavis JN, Lewin S, Fretheim A. Oslo: Norwegian Knowledge Centre for the Health Services; 2009.

11. Wilczynski NL, Haynes RB, Lavis JN, Ramkissoonsingh R, Arnold-Oatley AE: **Optimal search strategies for detecting health services research studies in MEDLINE.** *CMAJ* 2004, **171:**1179-85.

5. Using research evidence to frame options to address a problem

John N Lavis, Michael G Wilson, Andrew D Oxman, Jeremy Grimshaw, Simon Lewin, Atle Fretheim

Summary

Policymakers and those supporting them may find themselves in one or more of the following three situations that will require them to characterise the costs and consequences of options to address a problem. These are:

1. A decision has already been taken and their role is to maximise the benefits of an option, minimise its harms, optimise the impacts achieved for the money spent, and (if there is substantial uncertainty about the likely costs and consequences of the option) to design a monitoring and evaluation plan
2. A policymaking process is already underway and their role is to assess the options presented to them, or
3. A policymaking process has not yet begun and their role is therefore to identify options, characterise the costs and consequences of these options, and look for windows of opportunity in which to act

In situations like these, research evidence, particularly about benefits, harms, and costs, can help to inform whether an option can be considered viable. In this chapter, we suggest six questions that can be used to guide those involved in identifying policy and programme options to address a high-priority problem, and to characterise the costs and consequences of these options. These are:

1. Has an appropriate set of options been identified to address a 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 and which harms are likely to arise with each option?
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 could they alter its benefits, harms and costs?
6. Which stakeholder views and experiences might influence an option's acceptability and its benefits, harms, and costs?

Scenarios

Scenario 1: You are a senior civil servant and will be submitting a brief report to the Minister of Health regarding the evidence to support a number of options to address a high-priority problem. You are concerned about whether the current draft of the report includes a reasonable set of options. You are also concerned about whether the report addresses the likely questions about each option that can reasonably be answered through the use of research evidence

Scenario 2: You work in the Ministry of Health and are preparing a brief report about options to address a high-priority problem that you have been examining in great depth. All that you have been told is that the report should present three options and focus only on what the research

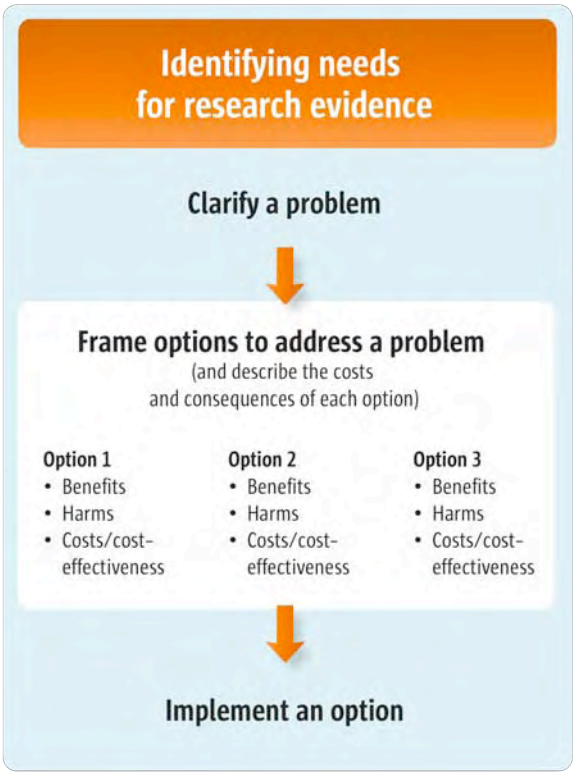
evidence says about each option

Scenario 3: You work in an independent unit that supports the Ministry of Health in its use of evidence in policymaking. You are preparing a detailed research report for the Ministry of Health about what is known and not known about options to address a high-priority problem. You have been told what options to examine but want guidance on the types of research evidence about each option that could be used to inform a choice between options

Background

Figure 5.1
Clarifying evidence needs

For policymakers (Scenario 1), this chapter suggests a number of questions that they might ask their staff to consider when preparing a brief report about options to address a problem. For those who support policymakers (Scenarios 2 and 3), this chapter suggests a number of questions to guide the identification of options and the characterisation of each option's costs and consequences. This chapter is the second of three chapters about clarifying evidence needs (see also Chapters 4 and 6 [1,2]). Figure 5.1 outlines the processes involved in clarifying these evidence needs.



Policymakers and those supporting them may find themselves in one or more of the following three situations that will require them to characterise the costs and consequences of options to address a problem. Firstly, a problem may already have been framed in a particular way, an option selected to address the problem, and a political constituency mobilised to support such decisions. (A variant of this situation is that an option may be selected first and then a problem identified later as a motivation for the option.) In this circumstance, the best option for those who support policymakers is to assist them in identifying how to maximise the benefits of the option, how to minimise its harms, and how to optimise the impacts achieved for the money spent. In addition, if there is substantial uncertainty about the likely costs and consequences of an option, a monitoring and evaluation plan can be designed to ensure that policymakers will have the right information to hand at a defined point in the future. This will help them to decide whether a policy should be left unchanged, modified or repealed (or whether a programme should be continued, modified or discontinued). Chapter 18 describes how to develop a monitoring and evaluation plan [3].

Secondly, policymakers may find themselves in a scenario in which they are actively engaged in a policymaking process. This may mean that policymakers will need to participate in events in which options are being actively debated, meet with 'policy entrepreneurs' who

want to persuade them to endorse a particular option, and respond to feedback about the operation of an existing policy or programme [4]. In this second scenario, they will need to assess the options presented to them, the degree of attention being given to the problem that the option is meant to address, and any political events that may present a window of opportunity during which particular actions could be undertaken.

Thirdly, policymakers may find themselves in a situation where they will have more open, strategic opportunities in which they are able to define a problem, to identify options, to characterise the costs of the options and their consequences, and to look for windows of opportunity to undertake preferred actions. Such opportunities are rare and calculations about when to act will need to be strategic.

A policy or programme can be deemed to be an appropriate solution if it is technically feasible, fits within dominant values and the current provincial/national mood, and is acceptable in terms of budget workability and the likely degree of political support or opposition [4]. Research evidence can form part of this mix in several ways and help to determine the following details about a chosen option:

- Whether it is technically feasible – for example, an option's benefits may have been shown to be substantial and its harms acceptably low. Alternatively, the key elements of the policy or programme may have been shown to be consistent with those elements critical to the success of the option in other settings
- Whether it fits with dominant values and the current national mood and is acceptable in terms of likely political support or opposition – interviews with stakeholders, for example, may reveal whether or not it is perceived to be acceptable, and
- Whether it is acceptable in terms of its budget impact – in other words, whether its value for money has been demonstrated

Interviews with policymakers have confirmed that they place a high value on research evidence about the benefits, harms and costs of options [5].

Questions to consider

The following questions can guide how to identify options and characterise their costs and consequences:

1. Has an appropriate set of options been identified to address a 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 and which harms are likely to arise with each option?
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 could they alter its benefits, harms and costs?
6. Which stakeholder views and experiences might influence an option's acceptability and its benefits, harms, and costs?

1. Has an appropriate set of options been identified to address a problem?

Initial work should focus broadly on the options that could affect the problem identified. Creative thinking about this topic can be encouraged by identifying options that affect either or both of the following:

- The provision of a cost-effective programme, service or drug, and
- The health system arrangements that determine whether cost-effective programmes, services or drugs are provided to those who need them

Policymakers and other stakeholders with clinical backgrounds often focus largely on issues related to programmes, services or drugs. But at the same time they also tend to neglect concerns related to the health system arrangements that are needed to ensure a high coverage rate for the very same programmes, services or drugs that matter both to them and to consumers. These health system arrangements may include:

- Delivery arrangements: such as who the programme, service or drug is targeted at; who it is provided by; where the care is provided and what information and communication technology is used to provide it; and the safety and quality systems used
- Financial arrangements: such as who finances the relevant parts of the system, programme, service or drug; how organisations are funded to deliver the programme, service or drug; how professionals are remunerated to provide these; how patients/consumers are presented with incentives to use it; and how resources are allocated to it, and
- Governance arrangements: such as who has the policy, organisational, commercial and professional authority and accountability for those parts of the health system that could play a role in addressing the problem

A key next step is then a consideration of whether these elements can stand alone as options or whether they can be bundled together to form new options appropriate to specific local contexts.

Policymakers may be able to identify existing frameworks that enable the identification of policy or programme options. These frameworks may be the focus of reports in their own right. For example, the Chronic Care Model provides a framework for considering how contributions to effective chronic care can be made through self-management support, decision support, delivery system design, clinical information systems, the health system, and the community more generally [6]. Alternatively, frameworks may be embedded in systematic reviews or in overviews of systematic reviews if they are used to structure the search for, and presentation of, research evidence. For example, an overview of systematic reviews provides a framework for addressing challenges related to human resources for health [7]. One dimension of this framework addressed the training, regulatory and financial mechanisms (i.e. the policy and programme options) that could be employed. The second dimension addressed the supply, distribution, efficient use and performance of healthcare providers (i.e. the option's potential consequences). However, multiple competing frameworks may exist, and there is often no empirical evidence to support the use of one framework over another. Moreover, like the options they are meant to help to identify, frameworks may not be mutually exclusive.

Table 5.1 provides an example of how the teams supporting the widespread use of artemisinin-based combination therapy in Africa identified relevant options and then approached the characterisation of their costs and consequences, using Questions 2 to 6 listed below as prompts.

Table 5.1
Supporting the widespread use of artemisinin-based combination therapy to treat malaria

The Evidence-Informed Policy Networks (EVIPNet) in ten sub-Saharan African countries described the costs and consequences of three options considered viable in these countries for the support of the widespread use of artemisinin-based combination therapy to treat malaria.	
The impetus for these activities was the 2006 WHO guidelines on malaria treatment which endorsed artemisinin-based combination therapy (ACT) to treat uncomplicated falciparum malaria [8]. In order to support the widespread use of ACT, national governments in regions with seasonal or endemic malaria had to determine whether to confirm or change: • *Delivery arrangements*: including who should dispense ACT (when, where and how), and who should be involved in surveillance, pharmacovigilance and the diagnosis and treatment of atypical cases • *Financial arrangements* for patients (e.g. drug subsidies) and for prescribers (amongst others), and • *Governance arrangements*: including which ACT and other anti-malarial drugs should be registered and licensed for sale (i.e. which drugs, the dosage regimes, and the packaging required), how they could be marketed, who could prescribe them (and how), who could sell or dispense them (and how), and what safeguards should be applied to protect against counterfeit or substandard drugs	
Type of information about each option	**Examples of the nature of the research evidence sought about each option**
Benefits	• People: everyone except children under five years of age (who were being treated under a separate programme) and pregnant women (whose cases of malaria were considered 'complicated' and hence beyond the remit of this element of the WHO guideline) • Option: see above • Comparison: status quo • Outcomes: both process indicators (e.g. coverage rates achieved) and outcome indicators (e.g. survival)
Potential harms	• As above except for outcomes where process indicators of interest included the adherence of community health workers to non-malaria related guidelines. This was because of a fear that ACT would be provided at the expense of treating other important conditions
Costs and cost-effectiveness	• Costs collected in their own setting • Economic evaluation conducted using a societal viewpoint given that policymakers were acting in their role as stewards for the entire health system, and not just as payers for publicly financed programmes, services and drugs
Key elements of the option (how and why it works)	• Policymakers had already invested heavily in community health workers and wanted to know whether the shared attributes of community health workers and lay health workers were sufficient to allow them to expect similar benefits to those achieved only with lay health workers [9]

Views and experiences of stakeholders	• Policymakers were aware that a large proportion of malaria treatments were dispensed by 'medicine sellers' [10] rather than health professionals or lay health workers. They therefore wanted to know more about the views and experiences of these sellers

EVIPNet teams from each participating country considered options consisting of different 'bundles' of heath system arrangements. One country, for example, considered:

- Using community health workers for the presumptive treatment of uncomplicated malaria with ACT (a delivery arrangement)
- Introducing ACT subsidies within the private sector to support their use (a financial arrangement) and regulating adherence to the subsidy policy (a governance arrangement), and
- Providing incentives to prescribers (specifically nurses and doctors) for a time-limited period to encourage transition to the new treatment (a financial arrangement)

The teams, consisting of individuals such as those involved in the second and third scenarios outlined earlier, then approached the task of describing the costs and consequences for each option using Questions 2-6 as prompts

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

The second stage in framing options involves characterising their costs and consequences. The first step in this second phase is to determine the likely benefits (or positive effects) of each option. Policymakers need to decide which benefits are likely to be important to those who will be affected by the decisions taken. Some of the studies consulted, for example, may focus on issues related to survival while others may address health-related quality of life issues. Still others may focus on 'intermediate' outcomes such as coverage rates for an effective treatment. Policymakers also need to decide whether they are more interested in particular groups of people (e.g. children, adults or the elderly) and particular comparisons (e.g. comparing the option of doing nothing with the option of providing standard care).

The acronym 'POCO' refers to the four key elements that must be considered in order to enable the identification of research evidence about the benefits of particular options, and to ensure that such evidence is used effectively:

- **P**eople (e.g. elderly patients with multiple chronic conditions)
- **O**ption (e.g. case management)
- **C**omparison (e.g. routine care), and
- **O**utcome (e.g. health-related quality of life)

Searches for evidence should be as precise as possible about identifying those option features that are most important to policymakers and other stakeholders. Policymakers should also assess the extent to which the evidence they find addresses the questions they are asking.

Those studies best suited to answering questions about benefits are randomised controlled trials, interrupted time series, and controlled before/after studies. All of these are characterised by the care taken to minimise the possibility that the measured effect of a policy is attributable to another factor which has not been measured (see Table 5.2 for an overview of the option information required and the associated study types). Very often policymakers will be able to find systematic reviews of these types of studies and this will

save them a significant amount of time. In Chapter 7, we discuss how to find systematic reviews [11]. Once such systematic reviews have been found, policymakers then need to assess their quality and examine the findings in terms of their local applicability and their incorporation of considerations related to equity (see Table 5.3).

Table 5.2
Types of study designs well-suited to providing particular types of information about options

Type of information about the option	Study designs well suited to providing the information	Definition
Benefits (i.e. positive effects)	*Randomised controlled trials*	• Experimental study in which individuals are randomly allocated to be exposed to different policy and programme options (e.g. using the toss of a coin or a list of random numbers generated by a computer)
	Interrupted time series	• Study using observations at multiple time points before and after a policy or programme is introduced (this is referred to as an 'interruption'). The design attempts to detect whether a policy or programme has had an effect significantly greater than any underlying trend over time
	*Controlled before/after studies**	• Study in which observations are made before and after the implementation of a policy or programme, both in a group that is exposed to the policy or programme and in a control group that is not. Data collection is done concurrently in the two groups
Potential harms (i.e. negative effects)	*Effectiveness studies*	• See above
	Observational studies	• Study in which observations are made about those exposed to a policy or programme. Data could be drawn from administrative databases, community surveys or other sources
Costs and cost-effectiveness	*Cost-effectiveness studies*	• Study in which the relative expenditures (costs) and outcomes (effects) of two or more courses of action are compared
Key elements of the option (how and why it works)	*Qualitative studies carried out alongside a study of effects (i.e. process evaluations)*	• Study conducted in natural settings and usually aimed at interpreting or making sense of phenomena in terms of the meanings people bring to them. Typically, narrative data are collected from individuals or groups of 'informants' (through interviews, focus groups, participant observation) or from documents. These are then interpreted by researchers
Views and experiences of stakeholders	*Qualitative studies*	• See above
	Observational studies	• See above

* These studies can be very time-consuming to find yet provide little information of value. This is due to the strong likelihood that those who have been exposed to an option, and those who have not been exposed to the option, differ in important ways. Impacts may be attributable therefore to differences between the groups rather than to differences in exposure to a particular option

Table 5.3
Issues to consider when assessing research evidence about the benefits, harms, and costs of options

Issue	Why it is important to consider the issue	Source of additional information
Quality	Research evidence of low quality (i.e. that is not valid, credible or rigorous) can give policymakers a false impression of the likely costs and consequences of an option	• **Chapter 8** in this series addresses how to assess the quality of systematic reviews [12] • **Chapter 16** addresses how to use a balance sheet incorporating assessments of the quality of evidence [13]
Applicability	Research evidence produced in other jurisdictions can be valuable, but policymakers need to consider how likely it is that the costs and consequences of an option would be different in their setting	• **Chapter 9** in this series addresses how to assess the applicability of the findings from systematic reviews to a specific setting [14]
Equity	Research evidence focused on overall effects or effects *among* advantaged groups can be valuable. However, policymakers need to consider how likely it is that the costs and consequences of an option would be different in disadvantaged groups	• **Chapter 10** addresses how to take equity into consideration when assessing the findings of a systematic review [15]

3. What harms are important to those who will be affected and which harms are likely with each option?

In this next step, the likely harms (or negative effects) of each option are determined. Again, policymakers will need to decide which harms are likely to be important to those who will be affected by the decisions they take. Some studies may address very infrequent outcomes such as death. Others may address frequent outcomes like the minor side effects of a drug, or focus on 'intermediate' outcomes such as the abandonment of routine tasks by lay health workers who have been asked to take on a new task. The 'POCO' acronym referred to earlier may also be used to structure searches for evidence of harms.

The types of studies best suited to answering questions about harms are more diverse. Information about harms can sometimes be derived from effectiveness studies. But more frequently, information can be found in observational studies that track those 'exposed' to an option, whether or not the exposure was part of a particular test of the option (e.g. a large-scale drug surveillance system). The pros and cons of these different data sources have been outlined elsewhere [16]. Policymakers will sometimes be able to find systematic reviews of these types of studies and will need to assess their quality and applicability, as well as incorporate equity considerations. (See Chapter 7 for further information on finding systematic reviews [11].) Local evidence about harms may also be found by policymakers and this issue is discussed in Chapter 11 [17]. Once potential harms have been identified, the next step is then to identify what, if any, mitigating actions can be taken to reduce these harms.

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

The next step in characterising the costs and consequences of the options is to determine the costs of each option and, if possible, its relative cost-effectiveness. Two options may both be effective but one may deliver better outcomes for a given cost, or it may achieve the same outcomes at less cost. Chapter 12 addresses ways in which research evidence about resource use and costs can be incorporated in the assessment of options [18]. In Chapter 12 we discuss how data about costs need to be collected in the setting where the options are being considered. And it includes a discussion on how research evidence about cost-effectiveness is often limited by a lack of rigour in estimating effects, as well as by challenges in interpreting the valuation of resources being used, and by the 'black box' nature of the modelling.

Economic evaluations can often provide a useful framework for thinking through issues related to cost-effectiveness – even if policymakers need to treat the results of any given economic evaluation cautiously, just as they would for other types of studies. Economic evaluations, it should be remembered, are always written from a particular perspective, whether it be that of a provider, a payer, or of society at large. Policymakers and other stakeholders need to be aware of the particular viewpoint they themselves adopt for any given economic analysis.

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

The penultimate step in characterising the costs and consequences of an option is to determine whether there might be significant interest in, or pressure, to *adapt* an option that has been tried elsewhere. In this instance, policymakers need to search specifically for qualitative studies (sometimes called *process evaluations*) carried out alongside studies of effects. Such studies can help to identify how and why an option works. These assessments can then be used to inform judgements as to whether particular elements of an option are critically important (and hence need to be retained), and which elements of an option are not important (and hence could be either dropped or modified). Chapter 4 provides tips for finding qualitative studies [1].

6. Which stakeholder views and experiences might influence an option's acceptability and its benefits, harms and costs?

The final step in characterising the costs and consequences of options is to determine whether the views and experiences of stakeholders could influence the acceptability and impact of the options. Stakeholders may include healthcare recipients and citizens, healthcare providers, managers working in healthcare organisations, and policymakers. If influence is likely, then policymakers and those who support them need to seek out qualitative studies that specifically examine the views and experiences of such stakeholders. (Again, Chapter 4 outlines tips related to finding qualitative studies) [1].

Table 5.4 provides guidance on identifying different types of research evidence.

Table 5.4
Finding research evidence about options

Characterising the costs and consequence of options involves finding and using many types of research evidence. When available, systematic reviews (the subject of Chapter 7) can help to characterise the benefits, harms, and key features of the options, as well as the views and experiences of stakeholders [11]. In the absence of systematic reviews, single studies must be found. Economic evaluations can help to characterise the cost-effectiveness of the options.

The first set of steps involved in finding such reviews and studies includes:

- Drawing up a list of words or phrases that capture the option (e.g. replacing 'health professionals who currently prescribe an anti-malarial drug' with 'lay health workers'), synonyms for each option (e.g. substitution), and alternative spellings for each option (e.g. doctor, doctors, physician, physicians, medical, medicine)
- Deciding whether systematic reviews or single research studies are the focus of the search, and
- Providing any additional details that limit the search (e.g. children, adults)

The second set of steps includes:

- Choosing those words and phrases that would *all* need to be present in order for the article to be identified (e.g. substitution, lay heath worker, and systematic review), connecting them with 'and', and placing each term in brackets
- Choosing those words and phrases for which *only one* would need to be present (e.g. physician and its synonyms), connecting them with 'or', and putting each term in brackets, and
- Connecting sets of brackets using 'and'

The third set of steps includes:

- Using the Internet to access the health-related database, PubMed. This database contains a 'hedge' (i.e. a validated search strategy or filter) for the types of studies of interest here [11]
- Clicking on 'special queries' in the left task bar
- Clicking on 'health services research' queries
- Entering the words and phrases, as well as the Boolean operators ('and'/'or') in the search field, and
- Clicking 'process assessment' or 'outcomes assessment' for administrative database studies and 'qualitative research' for qualitative studies
- Opening the relevant database in an Internet browser:
  - Program in Policy Decision-making/Canadian Cochrane Network and Centre (PPD/CCNC) database (www.researchtopolicy.ca/search/reviews.aspx) for systematic reviews of studies about health system arrangements (benefits, harms, key features, and stakeholders' views and experiences) – see Chapter 7 for additional information [11]
  - Cochrane Library's Cochrane Database of Systematic Reviews (CDSR) and Database of Abstracts of Reviews of Effects (DARE) (http://thecochranelibrary.com) for systematic reviews of programmes, services and drugs (benefits and possibly harms) – see Chapter 7 for additional information [11]
  - Cochrane Library's Economic Evaluation Database (EED) (http://thecochranelibrary.com) for economic evaluations
  - PubMed (www.ncbi.nlm.nih.gov/pubmed) for the 'hedges' (i.e. validated search strategies) to find specific types of single studies (harms, key features, and views and experiences of stakeholders) – see Chapter 4 for additional information [1]
  - Entering the words and phrases, as well as the Boolean operators 'and'/'or' in the search field, and
  - Clicking the appropriate icon to initiate the search

Conclusion

An appropriate set of options for a specific local context can be identified by combining creative thinking with generic taxonomies (like the one used to organise the PPD/CCNC database) or frameworks specific to a given issue or domain, or else bundling these combinations together. Each option can be assessed in terms of its likely local benefits, harms and costs or cost-effectiveness, and in terms of whether any adaptations might alter these benefits, harms and costs and related stakeholder views and experiences. Policymakers should take into account their quality and the local applicability of their findings when using systematic reviews to answer questions about benefits, harms and costs. They should also consider key equity considerations. These considerations form the focus of the following chapters: Chapter 8 (on assessing the quality of a systematic review), Chapter 9 (on assessing the local applicability of the findings of a systematic review) and Chapter 10 (on taking equity into consideration when assessing the findings of a systematic review). Policymakers should also be aware that they will face a practical challenge in assessing the relative value of the benefits, harms and costs and in making trade-offs between them. This topic is the focus of Chapter 16 which discusses the use of research evidence in balancing the pros and cons of different options.

Resources

Useful documents and further reading

- Kingdon JW: *Agendas, Alternatives, and Public Policies*, 2 edn. New York, USA: Longman; 2003, pp. 116-144

Links to websites

- *Program in Policy Decision-making (PPD)/Canadian Cochrane Network and Centre (PPD/CCNC) database*: www.researchtopolicy.ca/search/reviews.aspx – Source of systematic reviews of studies about health system arrangements (benefits, harms, key features, and the views and experiences of stakeholders)

- *Cochrane Library's Cochrane Database of Systematic Reviews (CDSR) and Database of Abstracts of Reviews of Effects (DARE):* http://thecochranelibrary.com – Source of systematic reviews of programmes, services and drugs (benefits and possibly harms)

- *Health-evidence.ca:* http://health-evidence.ca – Source of systematic reviews of public health programmes and services (benefits and possibly harms)

- *Cochrane Library's Economic Evaluation Database (EED):* http://thecochranelibrary.com – Source of economic evaluations

- *PubMed:* www.ncbi.nlm.nih.gov/pubmed – Source of 'hedges' (i.e. validated search strategies) to find select types of single studies (harms, key features, and the views and experiences of stakeholders)

- *BIREME's Virtual Health Library:* www.virtualhealthlibrary.org/php/index.php?lang=en – Source for many research products and databases available in the languages spoken in the Americas (Spanish and Portuguese primarily as well as English and French)

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6. Using research evidence to address how an option will be implemented

Atle Fretheim, Susan Munabi-Babigumira, Andrew D Oxman, John N Lavis, Simon Lewin

Summary

After a policy decision has been made, the next key challenge is transforming this stated policy position into practical actions. What strategies, for instance, are available to facilitate effective implementation, and what is known about the effectiveness of such strategies? We suggest five questions that can be considered by policymakers when implementing a health policy or programme. These are:

1. What are the potential barriers to the successful implementation of a new policy?
2. What strategies should be considered in planning the implementation of a new policy in order to facilitate the necessary behavioural changes among healthcare recipients and citizens?
3. What strategies should be considered in planning the implementation of a new policy in order to facilitate the necessary behavioural changes in healthcare professionals?
4. What strategies should be considered in planning the implementation of a new policy in order to facilitate the necessary organisational changes?
5. What strategies should be considered in planning the implementation of a new policy in order to facilitate the necessary systems changes?

Scenarios

Scenario 1: You are a senior civil servant with responsibility for the rollout of a new reform programme in the health services. You want to ensure that implementation takes place as effectively as possible

Scenario 2: You work in the Ministry of Health and have been instructed to prepare an implementation plan for the rollout of the government's recently adopted reform programme for the health services. You wish to explore what types of strategies to consider in such a plan

Scenario 3: You work in an independent unit that supports the Ministry of Health in its use of evidence in policymaking. You are preparing a document on the effects of various interventions that could be included in a national implementation strategy for the new health services reform programme, and need guidance on how to do this

Background

For policymakers (Scenario 1), this chapter suggests a number of questions that they might ask their staff to consider when the implementation of a new policy is being planned.

For those who support policymakers (Scenarios 2 and 3), this chapter suggests a number of questions that we believe are worth considering when discussing programme implementation and potentially useful approaches.

The process of translating policy into practice can be challenging and is often done in an unsystematic way. Careful planning is needed to prevent otherwise good policies being hampered by poor implementation. But the implementation process is not always a straightforward one: it may involve a complex set of actions at various levels of the health system as well as within communities.

Two key issues should be considered by those responsible for policy implementation, namely: "How can the activities related to the policy option be implemented to produce real changes on the ground?", and "Which strategies are available to facilitate effective implementation?"

A number of entry points can be used when planning policy implementation. Our suggested approach entails first identifying barriers to implementation, and then tailoring the implementation strategies to address the barriers – and facilitators – that are found.

This chapter is the third of three chapters about clarifying evidence needs (see also Chapters 4 and 5). Figure 6.1 outlines the processes involved in clarifying these needs.

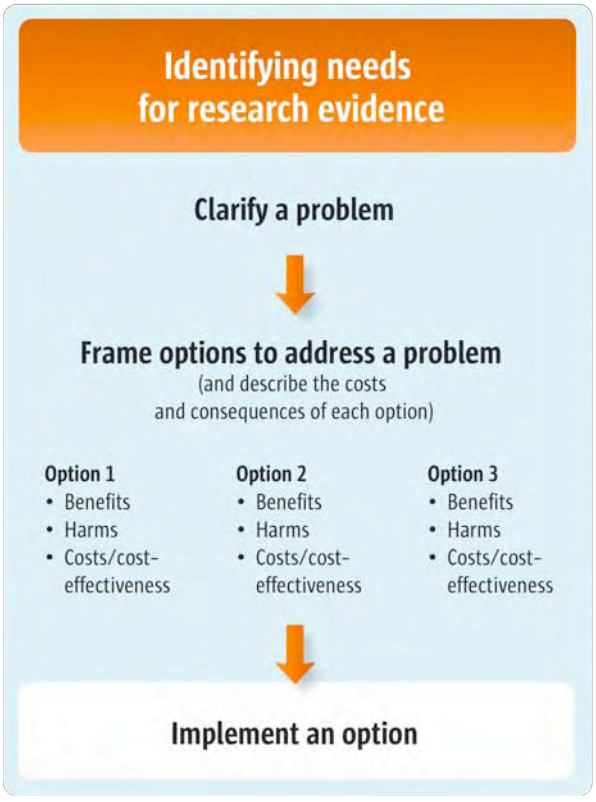

Figure 6.1
Clarifying evidence needs

Questions to consider

1. What are the potential barriers to the successful implementation of a new policy?
2. What strategies should be considered in planning the implementation of a new policy in order to facilitate the necessary behavioural changes among healthcare recipients and citizens?
3. What strategies should be considered in planning the implementation of a new policy in order to facilitate the necessary behavioural changes in healthcare professionals?
4. What strategies should be considered in planning the implementation of a new policy in order to facilitate the necessary organisational changes?
5. What strategies should be considered in planning the implementation of a new policy in order to facilitate the necessary systems changes?

1. What are the potential barriers to the successful implementation of a new policy?

A useful starting point for anyone wanting to elicit change is the identification of likely barriers to change. Knowing what – and where – the major hurdles are that may affect successful implementation is useful during the planning process. These challenges will often vary from policy to policy, and between different contexts. Both research findings on barriers to policy implementation in other settings, and lessons learnt from previous experiences may be informative, but they may not be sufficient.

There is no standard approach to identifying barriers to change. This process is often done informally by taking *perceived* barriers into account and in an implicit and unsystematic way. We propose a more structured approach to identifying barriers.

The people who will be affected by a policy – the stakeholders – are the ones likely to be best placed to foresee possible barriers to policy implementation. A number of methods can be used to explore the views of stakeholder groups about new policies including, for example, a 'mixed methods approach' for undertaking a so-called 'diagnostic analysis'. This approach may include brainstorming, focus group discussions, interviews and other qualitative methods, or a combination of these. Such activities can provide new insights into stakeholders' perceptions and identify both barriers – and facilitators – to policy implementation. Surveys can also be useful. For example, respondents could be asked to rate the extent to which a list of potential barriers actually represents obstacles to change. Practical examples of such processes are provided in Table 6.1 [1,2].

Table 6.1
Examples of how barriers to policy implementation can be identified

Accessing antiretroviral therapy (ART) in Tanzania [2]

ART has been freely available in selected reference hospitals in Tanzania since 2005 as part of the national government's policy to make ART more widely accessible. Making medicines available, however, does not automatically result in patients being able to access them. In order to identify barriers to ART access in a particular setting where the drugs were made available, a team of researchers conducted focus group discussions with community members and in-depth interviews with treatment seekers. The researchers found that "transportation and supplementary food costs, the referral hospital's reputation for being unfriendly and confusing, and difficulties in sustaining long-term treatment would limit accessibility". They noted too that a "fear of stigma framed all [patient] concerns, posing challenges for contacting those referrals who did not want their status disclosed or who had expressed reluctance to identify a "treatment buddy" as required by the programme"

Cholesterol-screening in the United States of America [1]
American researchers examined the barriers to participation in cholesterol screenings in both adults and children in West Virginia in the USA. Using the theory of 'planned behaviour' as a conceptual framework to provide a model for understanding decision making within particular belief systems and cultures, the researchers postulated that an individual's intention to perform an action is a central factor in determining whether an individual *will* perform that action. The researchers conducted semi-structured interviews using interview guides designed to elicit information relevant to the key constructs of the theory of planned behaviour. Their findings suggest that environmental, financial, *and* attitudinal barriers affected levels of participation in these health screenings. These include concerns about the outcomes of testing, the use of needles, privacy, a lack of knowledge in the community, and local traditional cultural beliefs

Several frameworks and checklists have been developed to help identify potential barriers to implementing health interventions. These are often based on a combination of behavioural theories, empirical data, and common sense, and may be useful tools in guiding the process of identifying barriers. Some frameworks cover a broad range of potential barriers in various parts of the health system. For example, in one framework, barriers are categorised according to the level at which the constraints operate [3]. These levels include: the household and community, delivery of health services, health sector policy and strategic management, public policies cutting across sectors, and environmental and contextual characteristics. Examples of barriers identified at each of these levels are shown in Table 6.2.

Table 6.2
Constraints to improving access to priority health interventions, by level (from [3])

Level of constraint	Type of constraint
I. Community and household level	• Lack of demand for effective interventions • Barriers to the use of effective interventions (physical, financial, social)
II. Health services delivery level	• Shortage and distribution of appropriately qualified staff • Weak technical guidance, programme management and supervision • Inadequate drugs and medical supplies • Lack of equipment and infrastructure, including poor accessibility of health services
III. Health sector policy and strategic management level	• Weak and overly-centralised systems for planning and management • Weak drug policies and supply system • Inadequate regulation of pharmaceutical and private sectors and improper industry practices • Lack of inter-sectoral action and partnership for health between government and civil society • Weak incentives to use inputs efficiently and respond to user needs and preferences • Reliance on donor funding that reduces flexibility and ownership • Donor practices that damage country policies
IV. Public policies cutting across sectors	• Government bureaucracy (civil service rules and remuneration, centralised management systems, civil service reforms) • Poor availability of communication and transport infrastructure

V. Environmental and contextual characteristics	• Governance and overall policy framework – Corruption, weak government, weak rule of law and enforceability of contracts – Political instability and insecurity – Low priority attached to social sectors – Weak structures for public accountability – Lack of free press • Physical environment – Climatic and geographic predisposition to disease – Physical environment unfavourable to service delivery

We have adopted a similar approach by focusing on constraints to policy implementation at three levels in the health system:

- Among healthcare recipients and citizens
- Among healthcare professionals
- At the organisational level

Once the likely barriers to policy implementation have been identified, the next step is to identify implementation strategies or interventions that can address these (Table 6.3 shows examples of possible links between barriers and interventions among healthcare recipients and citizens). The choice of strategies should also be guided by the available evidence of their effectiveness and costs, as well as stakeholders' views, etc. The issue of how to find and assess evidence that may be relevant is addressed in other chapters [4-8].

Table 6.3
Examples of possible links between barriers and interventions among healthcare recipients and citizens

Identified barrier to policy implementation	Possible interventions to address identified barriers
Current programmes are ineffective or of uncertain effectiveness	• Review the components of ongoing programmes, as well as the evidence from systematic reviews regarding other possible options for evidence of effectiveness • Conduct rigorous evaluations of programmes
Poor satisfaction with care	• Improve evidence-based strategies to improve the quality of care delivered
The relevant services are not within physical reach of some patients/citizens in need of them	• Creation of new services • Hiring of new personnel • Redistribution of resources
Denial of the severity of their problem	• Education and community awareness programmes
Transportation costs	• Provision of transportation or financial support for transport

2. What strategies should be considered in planning the implementation of a new policy in order to facilitate the necessary behavioural changes among healthcare recipients and citizens?

The behaviour of healthcare recipients and citizens, particularly in relation to the use of health services (e.g. under-utilisation, non-adherence to recommended lifestyle changes or treatment schedules, etc.), may be a potentially significant obstacle to successful policy

implementation. It is necessary to understand why the targeted recipients behave in particular ways as this will influence the choices they make in utilising health services. Well-conducted qualitative studies can provide insights into the behaviour of healthcare recipients [9].

One framework that can be used to identify factors that may influence the behaviour of healthcare recipients and citizens was proposed by a WHO working group on adherence to long-term therapies. They suggested five dimensions to consider [10]:

- Socio-economic related factors
- Health system and healthcare-related factors
- Therapy-related factors
- Factors-related to the particular health conditions of patients
- Patient-related factors

As these factors are related more specifically to clinical interventions, they may be particularly useful when considering barriers to the delivery of care arrangements. For example, some of the socio-economic factors that can affect adherence to treatment among patients with tuberculosis include: a lack of effective social support networks and unstable living circumstances, cultural and lay beliefs, ethnicity, gender, age, the high cost of medication and transport, and the role of criminal justice [10,11].

The Cochrane Consumer and Communication Review Group has extensively documented the effects of interventions to improve interactions between consumers and healthcare providers and systems, and has developed a taxonomy of interventions that target healthcare recipients and citizens [12]. This may be helpful when conceptualising and considering what kinds of interventions to use. The taxonomy includes:

- Provision of education or information
- Support for changing behaviour
- Support for developing skills and competencies
- Personal support
- Facilitation of communication and decision making, and
- System participation

Several studies and reviews have evaluated the effects of interventions that address constraints to effective health service delivery at the level of healthcare recipients and citizens. In one review, the authors found positive effects from community participation in overcoming such constraints [13]. In this instance, community participation was obtained using a variety of intervention approaches, including: health education (e.g. meetings, group teachings), encouraging a participative approach (mobilising leaders and stakeholders to understand and buy into the intervention), using an outreach strategy (targeting households and high-risk groups), and the training and supervision of providers (e.g. nurses and/or mothers). These interventions resulted in increased health-related knowledge and community empowerment and improved coverage in immunisation and sanitation practices.

Financial incentives, such as conditional cash transfers, may be worth considering if socio-economic related barriers are seen as playing an important role. This is because evidence, particularly from low- and middle-income countries, indicates that these may have an impact on the use of health services [14] (see Table 6.4 for details). A further illustrative example of evidence on the impacts of financial incentives is provided in Table 6.5 [15].

If patient-related factors, such as a lack of information appear to be important barriers to policy implementation, interventions to improve information provision might be worth

considering. A systematic review has shown that mass media interventions, for example, "can encourage increased utilisation of health services". But this finding should be approached with caution given that the study was based almost exclusively on studies from high-income countries [16] and therefore may not be applicable to other settings.

Table 6.4
Summary of key findings from systematic review of conditional cash transfer programmes in low- and middle-income countries [14]

- Overall, the evidence suggests that conditional cash transfer (CCT) programmes are effective in increasing the use of preventive services for children and women, and sometimes in improving health status
- Only one study evaluated the effect of providing different amounts of cash (from $1 to $3). The overall effect of the increase was a near doubling in the proportion of people returning for their HIV-test results (72% of people who had received incentives compared to 39% of those who had not)
- While the flows of money required for CCT programmes may be significant, the actual transfer budget may account for between only 4 to 28% of a total programme budget
- The cost-effectiveness of CCT programmes compared with classic supply-side interventions (e.g. improving the quantity and quality of infrastructure and services) has not been examined, as most CCT programmes have been implemented in settings with relatively adequate (health) infrastructures
- Unanticipated perverse effects can occur. For instance, one programme reported unexpected increases in the fertility rate when CCTs were used, possibly because only pregnant women were eligible for the subsidy

Table 6.5
An example of evidence that can inform the design of an implementation strategy targeted at healthcare recipients and citizens

Cash rewards for learning HIV-status, in Malawi [15]
Potential barriers to obtaining results from HIV-testing include the monetary costs of time and travel, and psychological costs (for example, stress, worry and fear, or the experience of social stigma). Monetary incentives may compensate directly for time and transport costs – and potentially for any psychological costs incurred. In a field experiment in rural Malawi, individuals were randomly assigned monetary incentives to learn their HIV results after testing. Where no incentives were offered, one-third of those tested obtained their results. In contrast, where small monetary incentives were provided, two-thirds went to obtain their HIV-test results

3. What strategies should be considered in planning the implementation of a new policy in order to facilitate the necessary behavioural changes in healthcare professionals?

The implementation of a policy or programme will often require changes in the behaviour of those healthcare professionals responsible for implementing the policy on the ground. Changes in professional behaviour do not always necessarily happen automatically. Active and directed approaches may therefore be necessary. The identification of barriers to change or factors that influence professional practice may help to inform the design of interventions for policy implementation. Cabana and colleagues conducted a systematic review of research addressing barriers to guideline adherence among physicians [17] and identified seven main categories of barriers. These can be used as a framework for identifying barriers to policy implementation among healthcare professionals:

- Lack of awareness
- Lack of familiarity
- Lack of agreement

- Lack of self-efficacy
- Lack of outcome-expectancy
- Inertia of previous practice
- External barriers

Examples of how identifying barriers can inform implementation are provided in Table 6.6.

Table 6.6
Examples of possible links between barriers and interventions among healthcare professionals

Identified barrier to policy implementation	Possible interventions to address identified barriers
Lack of knowledge	• Information delivery methods (educational outreach, training)
Disagreement with policy	• Identify opinion leaders who can act as advocates for the new policy
Time consuming	• Offer economic compensation

The Effective Practice and Organisation of Care (EPOC) Review Group in the Cochrane Collaboration has developed a taxonomy of provider-targeted interventions which gives an overview of the types of interventions that may be considered for implementation purposes [18]. These are:
- Educational materials
- Educational meetings
- Educational outreach visits
- Local opinion leaders
- Local consensus processes
- Peer review
- Audit and feedback
- Reminders and prompts
- Tailored interventions
- Patient-mediated interventions
- Multi-faceted interventions

Several strategies aimed at achieving behavioural change among healthcare professionals have been rigorously assessed [19-22]. Typically, these have taken the form of evaluations of guideline implementation strategies targeted directly at healthcare professionals. Most, but not all, have been conducted in high-income settings [23]. The findings demonstrate that many interventions can influence professional behaviour effectively to a modest or moderate extent. But passive interventions, such as the circulation of guidelines or the hosting of educational meetings, seem only to have smaller impacts. Educational outreach visits and multi-faceted interventions that specifically target identified barriers to change are among the more promising approaches.

Financial incentives may be used as a means of influencing professional behaviour but these have been evaluated almost entirely in high-income settings. These can be effective in influencing individual healthcare professionals when simple and well-defined behavioural goals are provided, such as increases in the delivery of immunisations – at least in the short term [24]. However, several potentially negative consequences of such programmes have been identified and the use of financial incentives may not necessarily be cost-effective.

Regulatory measures are an inexpensive and potentially effective means of eliciting changes in professional behaviour but may be poorly received by professional groups [25]. The impact of regulations per se as a means of achieving behavioural change among healthcare

professionals has not been reviewed systematically, therefore available knowledge about their effectiveness is limited [26].

See Table 6.7 for further illustrative examples of evidence on the effects of interventions to achieve behavioural change among healthcare professionals [27,28].

Table 6.7
Examples of evidence that can inform the design of implemetation strategies targeted at healthcare professionals

Financial incentives to health workers to increase institutional deliveries in India [27]
In 2005, the Indian government introduced the Janani Suraksha Yojana (JSY) programme which aimed to reduce maternal and neonatal mortality through the promotion of institutional deliveries. Cash payments to community health workers (ASHAs) for institutional deliveries amongst women under their care was one of the key programme components. Since the introduction of the programme, many Indian states have seen a substantial increase in institutional deliveries

Educational outreach visits to improve asthma care in South Africa [28]
South African researchers found that two 30-minute educational outreach visits to general practitioners conducted by a trained pharmacist led to clinically important improvements in symptom scores for children with asthma

4. What strategies should be considered in planning the implementation of a new policy in order to facilitate the necessary organisational changes?

Many organisational change strategies see the measures that should be taken as steps in a process that leads to change. Defining why there is a need for change and identifying barriers to change are tasks that are typically included in this process.

Pexton has proposed a list of the most common barriers to organisational change and this can also be used as a framework for barrier-identification [29]:

- Cultural complacency (resistance or scepticism)
- Lack of communication
- Lack of alignment and accountability
- Passive or absent leadership
- Micro-management
- An overloaded workforce
- Inadequate systems and structures

Ways to address each of these types of barriers are suggested in Table 6.8.

Table 6.8
Proposed list of common organisational barriers to changed (adapted from [29])

Barriers	Strategies to address barriers
Cultural complacency (resistance or scepticism)	• Deliver a few quick 'measurable wins' to demonstrate why change is needed
Lack of communication	• Develop a communication strategy targeted at identified communication barriers in the organisation

Lack of alignment and accountability	• Institute appropriate management structures
Passive or absent leadership	• Engage leaders in the proposed changes
Micro-management	• Empower the team and establish vision for the organisation among team members
Overloaded workforce	• Demonstrate the benefits of rethinking workflow to team members and of using new processes or technologies to reduce non value-added steps
Inadequate systems and structures	• Institute appropriate systems and structures to support the initiative
Lack of control plans to measure and sustain results	• Develop mechanisms to assess progress and maintain any positive results attained

Examples of the tools and approaches often recommended to organisations assessing preparations for change include [30]:

- Analytic models for understanding complexity, interdependence and fragmentation (such as Weisbord's six-box organisational model, the 7S model, and process models)
- Tools for assessing why change is needed, such as SWOT analysis
- Tools for determining who and what can change, such as force field analysis and total quality management
- Tools for making changes, such as organisational development, action research and project management

Most commonly used organisational change strategies are based almost entirely on theory, or else on one-off applications and opinion. Sometimes these are supplemented with case studies or anecdotes, mainly from high-income settings [30]. Evidence about the effectiveness of these strategies is hard to come by, making it difficult to predict whether or not a specific method is likely to lead to the desired organisational change.

Although the impacts of such change management strategies are uncertain, they may still be useful as processes allowing for active reflection on how change in an organisation can be facilitated.

5. What strategies should be considered in planning the implementation of a new policy in order to facilitate the necessary systems changes?

When a policy is to be implemented, changes at the general level of a health system may be necessary. These may include changes to governance arrangements, financial arrangements and delivery arrangements [31]. For example, when considering the financing of a policy option, should all costs be incurred by the government, or are additional sources of funding needed? Can the current system cope with the additional bureaucratic or logistical workload, or is a new mechanism needed to deliver the service? The body of evidence on how to implement such changes is small: those making decisions will usually have to draw on case studies and experiences in other jurisdictions. For particular policy implementation issues systematic reviews may be useful, such as those related to the costs of scaling up interventions [32] or factors that may affect the sustainability of health programmes [33]. In a recent overview, the authors summarised the evidence from systematic reviews on the effects of governance, financial and delivery arrangements, and implementation strategies

that have the potential to improve the delivery of cost-effective interventions in primary health care in LMICs [26].

When identifying the need for system changes it may be useful to review the components of a health system and to identify where changes are required. Table 6.9 shows a framework that can be used as a starting point for such analyses [34].

Table 6.9
Various components of health systems (adapted from Lavis et al [34])

Delivery arrangements	Financial arrangements	Governance arrangements
To whom care is provided and the efforts made to reach them (such as interventions to ensure culturally appropriate care)	**Financing** – e.g. how revenue is raised for programmes and services (such as through community-based insurance schemes)	**Policy authority** – who makes policy decisions (such as whether such decisions are centralised or decentralised)?
By whom care is provided (such as providers working autonomously versus those who work as part of multidisciplinary teams)	**Funding** – e.g. how clinics are paid for the programmes and services they provide (such as through global budgets)	**Organisational authority** – e.g. who owns and manages clinics (such as whether private for-profit clinics exist)
Where care is provided – e.g. whether care is delivered in the home or community health facilities	**Remuneration** – e.g. how providers are remunerated (such as via capitation)	**Commercial authority** – e.g. who can sell and dispense drugs and how they are regulated
With what information and communication technology is care provided – e.g. whether record systems are conducive to providing continuity of care	**Financial incentives** – e.g. whether patients are paid to adhere to care plans	**Professional authority** – e.g. who is licensed to deliver services, how their scope of practice is determined, and how they are accredited
How the quality and safety of care is monitored – e.g. whether quality-monitoring systems are in place	**Resource allocation** – e.g. whether drug formularies are used to decide which medications patients receive for free	**Consumer and stakeholder involvement** – who is invited to participate in policymaking processes from outside government and how their views are taken into consideration

Conclusion

A consideration of the aspects of policy implementation described in this chapter should enable policymakers and those who support them to employ a structured approach that includes the use of research findings in the design of implementation strategies. Currently, implementation plans often are developed on an ad hoc basis, and are rarely informed by available evidence. As the approach outlined in this chapter is not widely used, we encourage the sharing of experiences in this area of evidence-informed policy implementation.

Resources

Useful documents and further reading

- Shared decision-making in health care. Achieving evidence-based patient choice (2nd edition, Edited by Edwards A and Elwyn G). Oxford University Press, 2009.

- Changing Professional Practice (Edited by: Thorsen T and Mäkelä M) Copenhagen: Danish Institute for Health Services Research and Development, 1999 www.dsi.dk/projects/cpp/Monograph/DSI9905.pdf

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- NorthStar – how to design and evaluate healthcare quality improvement interventions. The SUPPORT Collaboration 2009: www.support-collaboration.org

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  www.sdo.nihr.ac.uk/files/adhoc/change-management-review.pdf

Links to websites

- *Cochrane Consumers and Communication Review Group Resource Bank:* www.latrobe.edu.au/chcp/ – The Cochrane Consumers and Communication Review Group is part of the Cochrane Collaboration, an international, non-profit organisation that aims to help people make well-informed decisions about healthcare. The Consumers and Communication Review Group co-ordinates the production of systematic reviews of interventions which affect consumers' interactions with healthcare professionals, services and researchers. This resource bank is a list of Cochrane systematic reviews relevant to people's health communication and participation needs, and has been produced by manually searching The Cochrane Library

- *Cochrane Effective Practice and Organisation of Care (EPOC) Review Group:* www.epoc.cochrane.org/en/index.html – EPOC is a Collaborative Review Group of the Cochrane Collaboration and produces systematic reviews of educational, behavioural, financial, regulatory and organisational interventions that are designed to improve healthcare professional practice and the organisation of healthcare services

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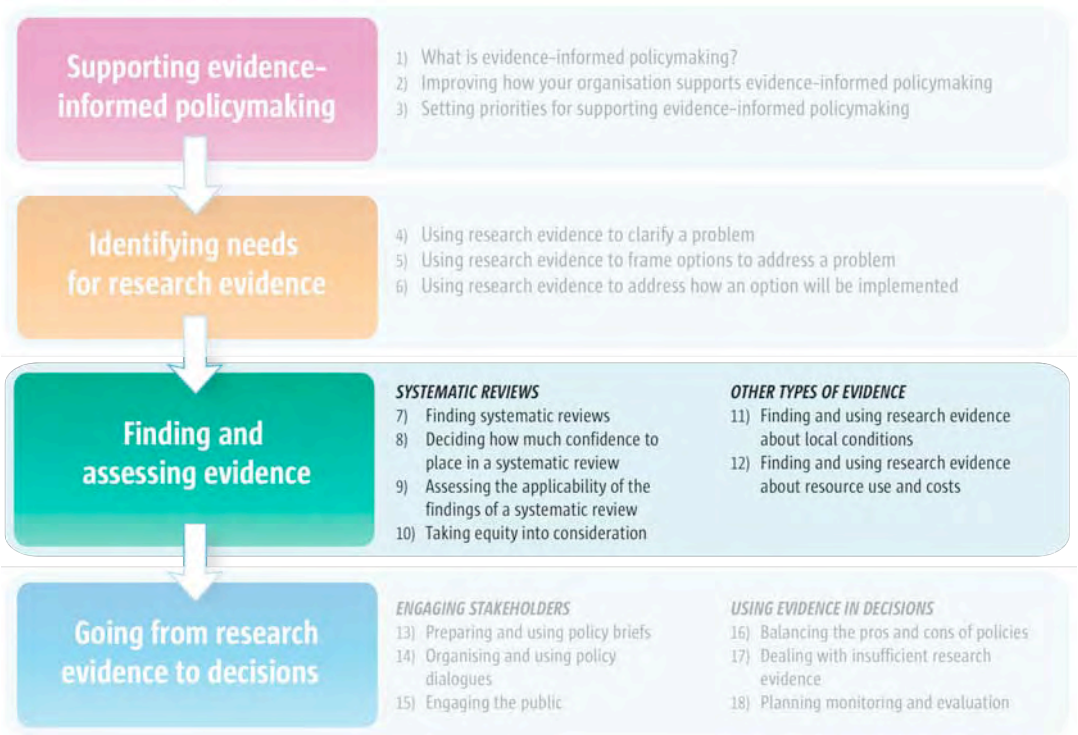
Chapters 7, 8, 9 and 10
Finding and assessing systematic reviews



7. Finding systematic reviews

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Summary

Systematic reviews are increasingly seen as a key source of information in policymaking, particularly in terms of assisting with descriptions of the impacts of options. Relative to single studies they offer a number of advantages related to understanding impacts and are also seen as a key source of information for clarifying problems and providing complementary perspectives on options. Systematic reviews can be undertaken to place problems in comparative perspective and to describe the likely harms of an option. They also assist with understanding the meanings that individuals or groups attach to a problem, how and why options work, and stakeholder views and experiences related to particular options. A number of constraints have hindered the wider use of systematic reviews in policymaking. These include a lack of awareness of their value and a mismatch between the terms employed by policymakers, when attempting to retrieve systematic reviews, and the terms used by the original authors of those reviews. Mismatches between the types of information that policymakers are seeking, and the way in which authors fail to highlight (or make obvious) such information within systematic reviews have also proved problematic. In this chapter, we suggest three questions that can be used to guide those searching for systematic reviews, particularly reviews about the impacts of options being considered. These are:

1. Is a systematic review really what is needed?
2. What databases and search strategies can be used to find relevant systematic reviews?
3. What alternatives are available when no relevant review can be found?

Scenarios

Scenario 1: *You are a senior civil servant and will be submitting a brief report to the Minister regarding evidence about a high-priority problem, options to address the problem, and implementation considerations. You are concerned about whether the current draft of the report profiles research evidence that has been synthesised in a systematic and transparent way. You want to ensure that your staff have found the most relevant systematic reviews in the limited time available to them*

Scenario 2*: You work in the Ministry of Health and have been given a few hours to prepare a brief report about a problem, options to address it, and implementation considerations. All that you have been told is that the report should draw on any relevant systematic reviews that can be found within this time frame*

Scenario 3*: You work in an independent unit that supports the Ministry of Health in its use of evidence in policymaking. You are preparing a detailed research report for the Ministry of Health about what is known and not known about a problem, options to address it, and implementation considerations. You have been told to find all relevant systematic reviews and you have been given two weeks to do this, but you want guidance on how to do this in a thorough and efficient way*

Background

This chapter suggests a number of questions that policymakers (Scenario 1) might ask their staff to consider when preparing a brief report regarding the evidence about a high-priority problem, options to address the problem, and implementation considerations. For those who support policymakers (Scenarios 2 and 3), this chapter suggests a number of questions to guide the search for systematic reviews, particularly reviews about the impacts of options being considered.

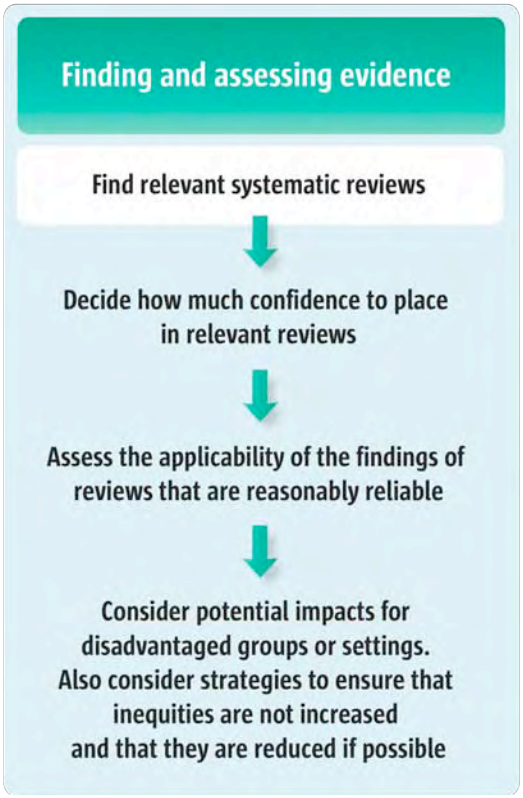

Figure 7.1
Finding and assessing systematic reviews to inform policymaking

This chapter is the first of four chapters about finding and assessing systematic reviews to inform policymaking (see also Chapters 8-10 [1-3]). Figure 7.1 outlines the steps involved in finding and assessing systematic reviews to inform policymaking.

Systematic reviews are increasingly seen as a key source of information for policymaking, particularly in assisting with framing options and describing their impacts [4]. Systematic reviews offer four key advantages over single studies in characterising the impacts of an option:

1. They reduce the likelihood that policymakers will be misled by research (by being more systematic and transparent in the identification, selection, appraisal and synthesis of studies)
2. They increase confidence among policymakers about what can be expected from an option (by increasing the number of units for study)
3. They allow policymakers to focus on *assessing* the applicability of the findings of systematic reviews to their own setting (instead of also having to find and synthesise the available research evidence on their own). The reviews also allow policymakers to focus on collecting and synthesising other types of evidence, such as local evidence about technical feasibility, the fit with dominant values and the current provincial/national mood, and the acceptability of potential options in terms of budget workability and their likely degree of political support or opposition, and
4. They allow stakeholders, including public interest groups and civil society groups to contest research evidence constructively because it is arranged in the reviews in a more systematic and transparent way [4,5]

The first two advantages listed above – namely, the reduction of bias and increase in precision (to use the terminology of researchers) – apply only to systematic reviews of impacts, some of which will include the statistical synthesis of findings as a final step. In these instances, the reviews are referred to as *meta-analyses* [6].

Although not the principal focus of this chapter, systematic reviews are also increasingly used as key sources of information in the clarification of problems and providing complementary perspectives on options. Systematic reviews can also be conducted for:

- Administrative database studies and community surveys that help to place problems in comparative perspective
- Observational studies that help to describe the likely harms of an option, and
- Qualitative studies that help to understand the meanings that individuals or groups attach to a problem, how and why options work, and stakeholder views about (and experiences with) particular options

These issues are discussed further in Chapter 4 (which focuses on the process of clarifying a problem) and Chapter 5 (which focuses on framing options to address a problem) [7,8]. There are many methodological approaches that can be used in systematic reviews of qualitative research evidence (or in systematic reviews of both qualitative and quantitative research evidence within the same review) including a narrative summary, thematic analysis, grounded theory, meta-ethnography, a meta-study, realist synthesis, cross-case techniques, content analysis, a case survey, qualitative comparative analysis, and Bayesian meta-analysis [9,10].

Several constraints have hindered the wider use of systematic reviews in policymaking. The first key constraint is the limited awareness of their value. Policymakers require synthesised research evidence and systematic reviews are able to provide this in a way that is both systematic and transparent. Many policymakers and researchers with influence in health systems initially believed that systematic reviews could only include randomised controlled trials and required some form of statistical synthesis [11]. For them, the value of these reviews lay only in assessing the effectiveness of healthcare interventions. This belief was underpinned by misconceptions. A second key constraint relates to the retrievability of systematic reviews. Policymakers need timely access to relevant high-quality systematic reviews that are retrievable using the terminology of policymakers. A systematic review of the factors that influence the use of research evidence in policymaking found that timing/timeliness increased the likelihood of research being used by policymakers [5,12]. In the past, policymakers have not been able to search databases using terms familiar to them [13] but this, as we discuss below, has now changed.

A third key constraint relates to the degree to which systematic reviews can be easily understood and interpreted. Policymakers need access to user-friendly summaries of systematic reviews that are written in ways that highlight what they need to know to clarify a problem or describe the costs and consequences of options to address the problem. In the past, even if searches were successful, they may have retrieved structured abstracts and full reviews that had been written in a way that failed to highlight the types of information that policymakers were seeking [13]. Again, as we explain below, this situation has also changed.

Questions to consider

The following questions can guide policymakers in the process of finding systematic reviews to inform policymaking:

1. Is a systematic review really what is needed?
2. What databases and search strategies can be used to find a relevant systematic review?
3. What alternatives are available when no relevant review can be found?

1. Is a systematic review really what is needed?

Before conducting a search for systematic reviews it is first necessary to confirm whether a systematic review is really what is needed. Systematic reviews may be appropriate if, for example, a policy question that is posed addresses a specific health system arrangement or a

specific programme, service or drug. They may also be useful for specific implementation strategies that target consumers (e.g. citizens and healthcare recipients) or healthcare providers (with or without some specification of the people, comparisons and outcomes of interest). Chapter 5 addresses how to structure questions related to the impacts of options [7].

But an overview of systematic reviews could provide helpful information if the question at hand relates to a broad category (or several broad categories) of health system arrangements, programmes, services or drugs, or implementation strategies. A particular overview of systematic reviews, for example, was found to be helpful by many policymakers because it examined the impacts of a full array of options that could be used to improve the supply, distribution, efficient use and performance of healthcare providers [14]. A policy brief that draws on a range of systematic reviews could also prove to be helpful. This would be the case if the question posed by policymakers addresses a spectrum of concerns ranging from the clarification of a problem, the framing of options and the description of their costs and consequences, through to key implementation considerations. The Program in Policy Decision-Making/Canadian Cochrane Network and Centre (PPD/CCNC) database described below could prove helpful in finding both overviews of systematic reviews and policy briefs, as well as systematic reviews. Policy briefs are described in further detail in Chapter 13 [15].

Systematic reviews are likely to be *unhelpful* if a question pertains to local evidence, such as local evidence about on-the-ground realities and constraints, the values and beliefs of citizens, interest group power dynamics, institutional constraints, and donor funding flows. Chapter 11 addresses considerations related to finding and using local evidence to inform policymaking [16].

2. What databases and search strategies can be used to find a relevant systematic review?

When it has been decided that a systematic review is needed, and when the question that the review needs to address relates to the impacts of (or more generally what is known about) health system arrangements, the PPD/CCNC database can be prioritised as a search tool. This is because it is accessible without charge, it has a particular focus on health system arrangements, and it provides links to user-friendly summaries (and, in their absence, scientific abstracts) (see Table 7.1 for a description of this and other databases). The database captures both systematic reviews that address questions about impacts *and* systematic reviews that address other types of questions.

Table 7.1
Databases to search for systematic reviews

PPD/CCNC - database www.researchtopolicy.ca/search/reviews.aspx
Features • Accessible online at no cost • Focused exclusively on governance, financial and delivery arrangements within health systems • Contains Cochrane reviews of impacts, other reviews of impacts, and reviews that address other types of questions (e.g. reviews of qualitative studies), as well as overviews of systematic reviews and policy briefs • Provides links to user-friendly summaries (when they exist) and to scientific abstracts ***What is in it?*** • Systematic reviews that address any type of question about governance, financial and delivery arrangements within health systems

- Overviews that identify and synthesise the many systematic reviews that address a specific health systems issue or challenge

How can it be searched?

- Type of governance, financial and delivery arrangement (by clicking on the relevant category)
- Type of systematic review, namely review of impacts, Cochrane review of impacts, and review addressing another type of question
- Type of overview, namely policy brief written primarily for policymakers and overview of systematic reviews written primarily for researchers

What resources are provided for search results?

- Link(s) to a user-friendly summary that highlights decision-relevant information (if available)
  - **Australasian Cochrane Centre (ACC) Policy Liaison Initiative** (primarily for policymakers in Australia)
  - **Database of Abstracts of Reviews of Effects (DARE)** (primarily for healthcare providers but no limitations per se)
  - **Effective Health Care Research Programme Consortium** (primarily for healthcare providers and policymakers in low- and middle-income countries)
  - **Health-evidence.ca** (primarily for public health practitioners and policymakers)
  - **Reproductive Health Library** (primarily for reproductive health practitioners and policymakers)
  - **Rx for Change** (primarily for policymakers interested in influencing prescribing behaviour or healthcare provider behaviour more generally)
  - **SUPPORT** (primarily for policymakers in low- and middle-income countries)
- Link(s) to a scientific abstract (when available)
- Link(s) to the full text (which may require a subscription or an access fee)

Cochrane Library – www.thecochranelibrary.com

Features

- Online version (without full-text reviews) accessible at no cost
- Contains health-focused Cochrane reviews of impacts (Cochrane Database of Systematic Reviews) and other reviews of impacts (Database of Abstracts of Reviews of Effects and Health Technology Assessment Database)
- Cochrane Database of Systematic Reviews provides access to scientific abstracts and user-friendly summaries (targeted at lay people). DARE provides links to user-friendly summaries, and the Health Technology Assessment Database provides access to structured scientific abstracts

What is in it?

- Systematic reviews that address questions about the impacts of clinical, health service/system and public/population health interventions, as well as health technology assessments (many of which will contain a systematic review)

How can it be searched?

- Search the entire Cochrane Library or (separately) one of its three most relevant constituent databases
  - Cochrane Database of Systematic Reviews (systematic reviews of impacts produced by members of the Cochrane Collaboration according to defined standards)
  - DARE (systematic reviews of impacts with no restriction on who produced them): Note that the most up-to-date version of this database can be searched separately and that

most reviews have a user-friendly summary prepared by the Centre for Reviews and Dissemination - www.crd.york.ac.uk/crdweb/Home.aspx

- Health Technology Assessment Database - (health technology assessments, which may contain a systematic review): Note that the most up-to-date version of this database can be searched separately and that most reviews have a summary of the HTA's objective prepared by the Centre for Reviews and Dissemination and a link to the full text (which typically does not require a subscription or access fee) - www.crd.york.ac.uk/crdweb/Home.aspx

PubMed/MEDLINE – www.pubmed.gov

Features

- Accessible online at no cost
- Contains many types of health-focused studies, not just systematic reviews. A hedge is available to find systematic reviews (including Cochrane reviews)
- Contains only peer-reviewed articles (i.e. no grey literature)
- Provides links to scientific abstracts only

What is in it?

- Both studies and systematic reviews that address any type of question that may be addressed in the biomedical, clinical, health service/system and public/population health literature

How can it be searched?

- Combine content terms AND terms that will yield systematic reviews, with the terms selected here designed to balance the sensitivity and specificity of a search (emphasising specificity over sensitivity) [17]
  - Cochrane Database Syst Rev [TA] OR search[Title/Abstract] OR meta-analysis[Publication Type] OR MEDLINE[Title/Abstract] OR (systematic[Title/Abstract] AND review[Title/Abstract])
- Possibly also combine with terms that will identify systematic reviews and studies focused on particular jurisdictions or regions (e.g. low- and middle-income countries) – See Appendix 2

What resources are provided for search results?

- A scientific abstract (if available)

Link(s) to the full text (which may require a subscription or an access fee)

Notes

- There are versions of MEDLINE that require a subscription (e.g. OVID/MEDLINE)
- PubMed contains many types of health-focused studies, not just studies of impacts, and hedges are available for many types of studies

However, if the question that a review should answer relates to the description of the impacts of programmes, services or drugs, or of implementation strategies targeting consumers and healthcare providers, then policymakers can access two databases used more commonly by healthcare providers. (The 'Resources' section later in this paper provides links to the databases mentioned.) The Cochrane Library – and specifically the Cochrane Database of Systematic Reviews and the Database of Reviews of Effects contained within it – only captures systematic reviews that address questions about impacts (see Table 7.1). PubMed captures systematic reviews that address many types of questions. *Hedges* (i.e. validated search strategies) are available to assist with finding systematic reviews in PubMed. Hedges are also used to find systematic reviews in three other databases: CINAHL, EMBASE, and PsycINFO (see Appendix 1 later in this chapter).

Two additional points are important to consider. Firstly, within any of the databases, policymakers who are interested in describing impacts but are pressed for time, may want to give priority to reviews produced by the Cochrane Collaboration (otherwise known as Cochrane reviews). These reviews have been found to be of higher quality and are updated more frequently than reviews produced by other groups [18]. Secondly, while health technology assessments (or HTAs) *should* typically include a range of economic, social, ethical and legal considerations, as well as a review of the research evidence about the effectiveness of a technology, some HTA reports contain a systematic review that can be applied in contexts other than the one for which the report was produced.

Table 7.2 provides an example of how groups of policymakers and those who support them can work together to find reviews to address a high-priority issue.

Table 7.2
Finding reviews to support the widespread use of artemisinin-based combination therapy to treat malaria

Evidence-Informed Policy Network (EVIPNet) teams of both policymakers and researchers from seven African countries wanted to come to grips quickly with several broad categories of health system arrangements that could be used to support the widespread use of artemisinin-based combination therapy (ACT). Their search identified three overviews of systematic reviews. The first overview was still in progress and focused on the impacts of particular governance arrangements related to prescription drugs like ACT [19]. The second overview focused on the impacts of alternative financial arrangements in health systems more generally [20]. And the third completed overview focused on the impacts of alternative human resources for health (HRH) configurations [14]. Their search also identified an overview of systematic reviews of the impacts of implementation strategies targeting healthcare providers [21].

Once they had read the overviews of systematic reviews, the policymaker/researcher teams searched for systematic reviews in domains not covered by the overviews. They found:

- Two systematic reviews about governance arrangements. One addressed the impacts of consumer involvement in decision making and the second addressed governance arrangements related to the private sector (however, the latter review is not a review of impacts per se)
- Six systematic reviews of the impacts of specific financial arrangements, including incentives for patients (i.e. conditional cash transfers), incentives for prescribers, physician-remuneration arrangements more generally, contracting with the for-profit sector to improve healthcare delivery, reference pricing and other pricing and purchasing policies, as well as one systematic review about what is known about financial arrangements within the private sector (again, this latter study was not a review of impacts as such), and
- Five systematic reviews of the impacts of specific HRH configurations, including home-based management, lay health workers, and the expansion of the role of outpatient pharmacists and either nurses or nurse practitioners instead of physicians. In addition, one systematic review was found about the activities of medicine sellers and how their practice can be improved (this, too, was not an actual review of impacts)

Given that the WHO malaria treatment guidelines of 2006 were based on a comprehensive search for systematic reviews about the impacts of anti-malarial drugs, the teams were able to restrict their additional searches to the time period that followed. Six systematic reviews about anti-malarial drugs were found (published in either 2006 or 2007) and one systematic review about unit-dose packaged anti-malarial drugs was also found.

The searches undertaken by the teams also allowed them to supplement the overview of systematic reviews of the impacts of implementation strategies with seven additional systematic

reviews of the impacts of different strategies for achieving desired outcomes. These outcomes included the dissemination and implementation of guidelines, the implementation of guidelines among allied health professionals specifically, influencing prescribing and dispensing, changing medication use, improving antibiotic prescribing in ambulatory care and in hospitals, and the enhancement of medication adherence. Seven systematic reviews were also found on the impacts of specific strategies for bringing about change, including audit and feedback, computerised support for determining drug dosage, continuing-education meetings, educational outreach visits, local opinion leaders, mass media campaigns, and tailored strategies to address identified barriers to change.

The teams found no systematic reviews of studies examining the feasibility and acceptability of ACT for the home-based management of malaria. They therefore conducted a search for single studies on this topic. One study was found which was conducted in four African sites and had been published in Malaria Journal.

3. What alternatives are available when no relevant review can be found?

Despite improvements in the ease with which policymakers can search and find systematic reviews in available databases, there will be occasional instances when no review can be found. If policymakers are able to wait between 6 and 18 months (depending on the complexity of the question being asked) and have the necessary resources, one option could be to commission a systematic review from an experienced research group [13]. If, however, the available timeline is shorter than this or resources are limited, policymakers can search for single studies instead. In doing so they are essentially conducting a review themselves, and the more systematically this is done the better. In such situations, policymakers can take issues related to ensuring the quality of reviews into consideration. A web-based tool to support such 'rapid evidence assessments' is described later in this paper, while a further discussion of the quality of reviews is provided in Chapter 8 [1].

Particular databases can also be prioritised when looking for single studies. PubMed, which includes over 20 million records, is often a good starting point. When searching PubMed, hedges can be used to restrict searches to the types of studies most relevant to a particular type of question. Hedges are also available for other databases. (Please refer to the 'Resources' section of this paper for a list of links to hedges that are particularly relevant to policymakers.)

Some policymakers will only require this basic level of detail related to finding systematic reviews or single studies if they have access to subscription databases and are able to rely on the expertise of librarians (Please see Appendix 1 for a list of subscription access databases). This may be either within their own organisation or through colleagues in other universities and settings. We have summarised additional details about high-priority databases in which to search for systematic reviews, including their content, how they can be searched, and what information is returned from search results (see Table 7.1). This is particularly useful for policymakers who want to gain access to additional information in order to establish clear expectations among those who support them, as well as for policymakers and librarians who will be conducting searches on their own.

Two additional points are worth noting. Firstly, there has been a steady growth in the number of groups and organisations providing user-friendly summaries highlighting the

decision-relevant information contained in systematic reviews. Such summaries are usually an excellent place for policymakers to start (Chapter 13 provides additional detail about these summaries [15]). Secondly, terms have been identified for PubMed in order to help with the identification of systematic reviews and studies focused on low- and middle-income countries. This is particularly useful for policymakers based in these countries. (Appendix 2 at the end of this chapter provides a list of terms that can be used in searches for systematic reviews or studies focused on these countries.)

While many of the prioritised databases above provide free online access, such access often does not include full-text systematic reviews. In such cases, it will be necessary for policymakers and those who support them (and librarians) to make use of the mechanisms that have been created to allow for the free or low-cost retrieval of the full-text systematic reviews they have identified through their database searches (see Table 7.3 for a list of these mechanisms).

Three key options are available:

1. The Health Inter Network Access to Research Initiative (HINARI), which provides institutions in low-income countries with free access to many published reviews and studies
2. The Cochrane Library, which provides free access to Cochrane reviews in low-income countries and in countries with a national subscription, and
3. Journals that make their content available free of charge either as soon as they are published or after a defined period of time (e.g. one year)

Table 7.3
Mechanisms through which to retrieve full-text systematic reviews free of charge or at little cost once identified through database searches

Mechanism	Comments
HINARI	***Who is eligible to use it?*** • Institutions in selected low- and middle-income countries have either free access or low-cost access. To check if an institution is already registered or if an institution is located in a country that is el igible for free or low-cost access, go to: HINARI ***How can it be accessed?*** • An institution must register and all staff are then given unlimited access • Alternatively if a computer is recognised as being based in an eligible country, users may access Highwire Free Access for Developing Countries (which includes HINARI and other selected resources) – ***What resources are provided for research results?*** • A scientific abstract and full-text article for all included journals
Cochrane Library	***Who is eligible to use it?*** • Institutions in selected countries have free access – to check if a country (or region) is covered by a programme for low-income countries or by a subscription, go to: Cochrane Library ***How can it be accessed?*** • Country-or region-specific access details are available at the same site ***What resources are provided for research results?*** • A scientific abstract, lay summary, and full-text review for all Cochrane reviews, as well a summary of some form for the three most relevant constituent databases described in Table 7.1 ***Note*** : The Cochrane Library can also be accessed through HINARI

Journals	***Who is eligible to use it?*** • Anyone ***How can it be accessed?*** • Websites of open-access journal publishers – BioMed Central (journals beginning with BMC and select others) – OpenJournals Publishing (many journals beginning with 'South African' and select others) – Public Library of Sciences (journals beginning with PLoS) – SciELO (Scientific Electronic Library Online) (many journals from Latin America and the Caribbean) • Directories of open-access and/or free journals – Director of Open Access Journals – Free Medical Journals – Open J-Gate • Repositories through which journal publishers make available articles (often after a defined time period) – PubMed Central – Bioline International (journals from Brazil, Cuba, India, Indonesia, Kenya, South Africa, Uganda, Zimbabwe) ***What resources are provided for research results?*** • A scientific abstract and full-text article for all included journals

Three additional methods warrant mention. It may be worthwhile identifying the institution where the authors of a review are based in case they have made it available free of charge on their institution's website. It may also be possible to contact the authors directly by email. Finally, Google Scholar may be used to track down a full-text review if the review is in the public domain and the correct citation is known.

Conclusion

Systematic reviews are increasingly seen as a key source of information to inform policymaking, particularly in assisting with framing options and describing their impacts. They are also used to assist with a range of questions about a problem, options to address the problem, and implementation considerations. The PPD/CCNC database is a good source for finding systematic reviews that address a range of questions about health system arrangements, as well as overviews of systematic reviews and policy briefs. The Cochrane Library (particularly the Cochrane Database of Systematic Reviews and the Database of Reviews of Effects) and PubMed are both good sources of systematic reviews that address questions about the impacts of programmes, services and drugs. When systematic reviews cannot be found and timelines and resources permit, policymakers could commission a systematic review or conduct their own rapid evidence assessment.

Resources

Useful documents and further reading

- McKibbon A, Wyer P, Jaeschke R, Hunt D. Finding the evidence. In Guyatt G, Rennie D, Meade MO, Cook DJ (Editors). Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice. Second Edition. New York: McGraw Hill Medical, 2008; pp. 29-58.

Links to websites

- *Program in Policy Decision-making/Canadian Cochrane Network and Centre (PPD/CCNC) database:* www.researchtopolicy.ca/search/reviews.aspx – Source of systematic reviews of studies about health system arrangements (benefits, harms, key features, and the views and experiences of stakeholders)

- *Cochrane Library's Cochrane Database of Systematic Reviews (CDSR) and Database of Abstracts of Reviews of Effects (DARE):* www.thecochranelibrary.com and www.york.ac.uk/inst/crd/signup_form.htm (to sign up for electronic updates from DARE) – Source of systematic reviews of programmes, services and drugs (including benefits and possibly harms), as well as health technology assessments, which sometimes contain systematic reviews

- *PubMed:* www.ncbi.nlm.nih.gov/pubmed and www.ncbi.nlm.nih.gov/corehtml/query/static/clinical.shtml#reviews (to use the 'hedge' for reviews) – Source of systematic reviews addressing a range of questions, as well as single studies

- *Health Information Research Unit:* http://hiru.mcmaster.ca/hiru/hiru_hedges_home.aspx – Source of 'hedges' (i.e. validated search strategies) to find systematic reviews and a variety of study types

- *Rapid Evidence Assessment Toolkit:* www.gsr.gov.uk/professional_guidance/rea_toolkit/index.asp – Web-based toolkit to assist policymakers and those who support them to find and use research evidence as comprehensively as possible within tight time constraints, which includes a summary of the differences between a rapid evidence assessment and a systematic review and when a rapid evidence assessment might be used

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Appendix 1. Databases that require subscription access and ideally the support of a librarian

Database	Comments
CINAHL	***What is in it?*** • Both systematic reviews and studies that address any type of question (i.e. not just reviews and studies of impacts) that may be covered in the nursing and allied health literature ***How can it be searched?*** • Combine content terms AND terms that will yield systematic reviews, with the terms selected here designed to optimise the sensitivity and specificity of a search [1] • Confidence intervals (in MH Exact Subject Heading) OR 'dt' (in Word in Major Subject Heading) OR Systematic review (in PT Publication Type) (in CINAHL provided by EBSCO) • Possibly also combine with terms that will identify systematic reviews and studies focused on particular jurisdictions or regions (e.g. low- and middle-income countries) ***What resources are provided for search results?*** • A scientific abstract (when available)
EMBASE	***What is in it?*** • Both systematic reviews and studies that address any type of questions that may be covered in the biomedical and clinical literature ***How can it be searched?*** • Combine content terms AND terms that will yield systematic reviews, with the terms selected here designed to optimise the sensitivity and specificity of a search [2] • Meta-analys:.mp. OR search:.tw. OR review.pt. (in EMBASE provided by Ovid) • Possibly combine also with terms that will identify systematic reviews and studies focused on particular jurisdictions or regions (e.g. low- and middle-income countries) ***What resources are provided for search results?*** • A scientific abstract (when available)
PsycINFO	***What is in it?*** • Both systematic reviews and studies that address any type of question that may be covered in the psychology literature ***How can it be searched?*** • Combine content terms AND terms that will yield systematic reviews, with the terms selected here designed to optimise the sensitivity and specificity of a search [3] – Control:.tw. OR effectiveness.tw. OR risk:.tw. (in PsycINFO provided by Ovid) • Possibly combine also with terms that will identify systematic reviews and studies focused on particular jurisdictions or regions (e.g. low- and middle-income countries) ***What resources are provided for search results?*** • A scientific abstract (when available)

Other databases for which optimal methodology filters for systematic reviews have not yet been developed	***Region-specific interfaces to several of the above-mentioned databases*** • Virtual Health Library (Latin America and Caribbean Region) ***Regional databases*** • African Index Medicus • African Journals Online • Index Medicus for the WHO Eastern Mediterranean Region • Index Medicus for South-East Asian Region • LILACS (Latin America and Caribbean Region) • Western Pacific Region Index Medicus ***Global databases with specific disciplinary areas of focus*** • EconLit (Economics) • International Bibliography of the Social Sciences (Social sciences) • International Political Science Abstracts (Political science) • ISI Web of Science (Arts and humanities, sciences, and social sciences – citation indices) • PAIS (Public Affairs Information Service) International (Public affairs) • Sociological Abstracts (Sociology) • Wilson Business Abstracts (Management) • Worldwide Political Science Abstracts (Political science) ***Disease/condition databases*** • TropIKA (Tropical diseases)

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Appendix 2. Terms that will identify in Ovid MEDLINE studies that mention low- and middle-income countries

1. Developing Countries/
2. Medically Underserved Area/
3. Africa/ or "Africa South of the Sahara"/ or Asia/ or South America/ or Latin America/ or Central America/
4. (Africa or Asia or South America or Latin America or Central America).tw.
5. (American Samoa or Argentina or Belize or Botswana or Brazil or Bulgaria or Chile or Comoros or Costa Rica or Croatia or Dominica or Equatorial Guinea or Gabon or Grenada or Hungary or Kazakhstan or Latvia or Lebanon or Libya or Lithuania or Malaysia or Mauritius or Mexico or Micronesia or Montenegro or Oman or Palau or Panama or Poland or Romania or Russia or Seychelles or Slovakia or South Africa or "Saint Kitts and Nevis" or Saint Lucia or "Saint Vincent and the Grenadines" or Turkey or Uruguay or Venezuela or Yugoslavia).mp. or Guinea.tw. or Libia.tw. or libyan.tw. or Mayotte.tw. or Northern Mariana Islands.tw. or Russian Federation.tw. or Samoa.tw. or

Serbia.tw. or Slovak Republic.tw. or "St Kitts and Nevis".tw. or St Lucia.tw. or "St Vincent and the Grenadines".tw. [UMIC]
6. (Albania or Algeria or Angola or Armenia or Azerbaijan or Belarus or Bhutan or Bolivia or "Bosnia and Herzegovina" or Cameroon or China or Colombia or Congo or Cuba or Djibouti or Dominican Republic or Ecuador or Egypt or El Salvador or Fiji or "Georgia (Republic)" or Guam or Guatemala or Guyana or Honduras or Indian Ocean Islands or Indonesia or Iran or Iraq or Jamaica or Jordan or Lesotho or "Macedonia (Republic)" or Marshall Islands or Micronesia or Middle East or Moldova or Morocco or Namibia or Nicaragua or Paraguay or Peru or Philippines or Samoa or Sri Lanka or Suriname or Swaziland or Syria or Thailand or Tonga or Tunisia or Turkmenistan or Ukraine or Vanuatu).mp. or Bosnia.tw. or Cape Verde.tw. or Gaza.tw. or Georgia.tw. or Kiribati.tw. or Macedonia.tw. or Maldives.tw. or Marshall Islands.tw. or Palestine.tw. or Syrian Arab Republic.tw. or West Bank.tw. [LMIC]
7. (Afghanistan or Bangladesh or Benin or Burkina Faso or Burundi or Cambodia or Central African Republic or Chad or Comoros or "Democratic Republic of the Congo" or Cote d'Ivoire or Eritrea or Ethiopia or Gambia or Ghana or Guinea or Guinea-Bissau or Haiti or India or Kenya or Korea or Kyrgyzstan or Laos or Liberia or Madagascar or Malawi or Mali or Mauritania or Melanesia or Mongolia or Mozambique or Myanmar or Nepal or Niger or Nigeria or Pakistan or Papua New Guinea or Rwanda or Senegal or Sierra Leone or Somalia or Sudan or Tajikistan or Tanzania or East Timor or Togo or Uganda or Uzbekistan or Vietnam or Yemen or Zambia or Zimbabwe).mp. or Burma.tw. or Congo.tw. or Kyrgyz.tw. or Lao.tw. or North Korea.tw. or Salomon Islands.tw. or Sao Tome.tw. or Timor.tw. or Viet Nam.tw. [LIC]
8. ((rural or remote or nonmetropolitan or underserved or under served or deprived or shortage) adj (communit$ or count$ or area? or region? or province? or district?)).tw.
9. ((developing or less$ developed or third world or under developed or poor$) adj (communit$ or count$ or district? or state? or province? or jurisdiction? or nation? or region? or area? or territor$)).tw.
10. ((middle income or low income or underserved or shortage) adj (communit$ or count$ or district? or state? or province? or jurisdiction? or nation? or region? or area? or territor$)).tw.
11. (lmic or lmics).tw.
12. or/1-11

Note:
1. The filter is based on the World Bank country list of upper-middle-income economies (UMIC), lower-middle-income economies (LMIC), and low-income economies (LIC), which is available at the following URL:
http://web.worldbank.org/WBSITE/EXTERNAL/DATASTATISTICS/0,,contentMDK:20421402~pagePK:64133150~piPK:64133175~theSitePK:239419,00.html.

8. Deciding how much confidence to place in a systematic review

Simon Lewin, Andrew D Oxman, John N Lavis, Atle Fretheim

Summary

The reliability of systematic reviews of the effects of health interventions is variable. Consequently, policymakers and others need to assess how much confidence can be placed in such evidence. The use of systematic and transparent processes to determine such decisions can help to prevent the introduction of errors and bias in these judgements. In this chapter, we suggest five questions that can be considered when deciding how much confidence to place in the findings of a systematic review of the effects of an intervention. These are:

1. Did the review explicitly address an appropriate policy or management question?
2. Were appropriate criteria used when considering studies for the review?
3. Was the search for relevant studies detailed and reasonably comprehensive?
4. Were assessments of the studies' relevance to the review topic and of their risk of bias reproducible?
5. Were the results similar from study to study?

Scenarios

Scenario 1*: You are a senior civil servant and will be submitting a proposal to the Minister regarding the evidence to support a number of policy and programme options to address a priority health issue. You are concerned about how much confidence can be placed in systematic reviews of the evidence for each option and want to ensure that these have been assessed appropriately by your staff*

Scenario 2*: You work in the Ministry of Health and are preparing a document regarding options to address a priority health issue. A number of systematic reviews of the effects of options have been identified and you have been asked to make an assessment of how much confidence can be placed in each review*

Scenario 3*: You work in an independent unit that supports the Ministry of Health in its use of evidence in policymaking. You are preparing a document for the Ministry on the likely impacts of options to address a priority health issue. You want guidance on assessing how much confidence can be placed in the systematic reviews of the impacts of each option*

Background

For decision makers (Scenario 1), this chapter suggests a number of questions that they might ask their staff to consider when deciding how much confidence to place in the findings of a systematic review of the effects of healthcare interventions.

For those who support policymakers (Scenarios 2 and 3), this chapter suggests a number of questions that can be used to guide a critical appraisal of systematic reviews of effects.

Systematic reviews of randomised controlled trials (RCTs) are widely accepted as providing the most reliable evidence about the effects of healthcare interventions [1,2]. Systematic reviews are characterised by their systematic and explicit approach to identifying, selecting and appraising relevant research, and to collecting and analysing data from included studies [2]. Increasingly, systematic reviews are also being used to identify, appraise and combine evidence on the economic consequences of interventions [3], such as the cost-effectiveness of breastfeeding promotion for infants in neonatal units [4] or the costs of different guideline dissemination and implementation strategies [5]. They are also used to summarise evidence from qualitative studies, such as consumer or provider views of health interventions [6-9]. In this chapter, we focus on systematic reviews of the effects of healthcare policies or programmes. These include reviews of delivery arrangements, such as the effects of substituting doctors with nurses in primary care [10], and of strategies to bring about change, such as the effects of continuing education meetings for health professionals [11].

The systematic and explicit approach used in a systematic review is intended to reduce the risk of bias and errors that occur by chance, and to help facilitate critical appraisal of these syntheses [12,13]. However, the rigour with which systematic reviews are conducted varies. Reviews are therefore not all equally reliable – that is, reviews may differ in the level of confidence that we can place in their findings. Simply relying on the fact that an assessment is called a 'systematic review' (or a meta-analysis) is therefore not sufficient when using findings to inform policy decisions.

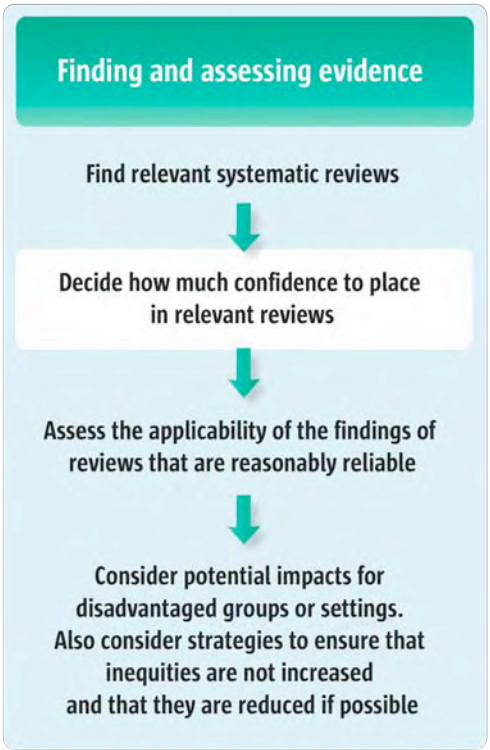

Figure 8.1
Finding and assessing systematic reviews to inform decisions about policy and programme options

When using systematic reviews of effects to inform policy decisions, policymakers and others therefore need to judge how much confidence they can place in this evidence. Using a systematic and transparent process can help to prevent the introduction of errors and bias in their judgements. A systematic and transparent process also allows other stakeholders, including the public, to understand and appraise these judgements. This is particularly important where such assessments influence recommendations or decisions regarding clinical interventions or services [14], or decisions to implement or stop programmes or policies.

Confidence in the findings of a systematic review may be limited for a number of reasons, including a failure to:

- Specify the question and methods of the review before undertaking the review, for example in a published review protocol
- Specify clear criteria for study inclusion and exclusion
- Adequately describe the studies included in the review
- Assess the risk of bias for studies included in the review
- Assess the risk of publication bias, i.e. the possibility that some studies, typically those with positive ('statistically significant') results, are more likely than others to be published and therefore included in a review
- Use appropriate methods for combining the results of the included studies (in a meta-analysis) where relevant

- Adequately examine differences in the findings of studies included in a review (i.e. the 'heterogeneity' of the findings)
- Base the conclusions of the review on the included data

Other potential limitations of systematic reviews include conflicts of interest (which can affect the reliability of a review in any of the ways listed above), and reviews being out-of-date.

Variations in reliability, for example, were noted in a study comparing the methodology and reporting components of Cochrane reviews with reviews published in paper-based journals. This study found that Cochrane reviews included components that made them less prone to bias. This overall reduction in the risk of bias in Cochrane reviews was found to be due specifically to both their clear descriptions of the criteria for inclusion and exclusion, and the formal assessment of the risk of bias of the studies included in each review [15]. Similarly, another study compared the methodological quality and conclusions in Cochrane reviews of drug trials with those in industry-supported reviews of the same drugs. This study found that Cochrane reviews scored higher on quality assessment. This was because Cochrane reviews considered potential for bias more frequently when compared to reviews that were industry-supported. Industry-supported reviews were also found to be significantly more likely to recommend the drugs in question without reservations [16]. A number of other studies of reviews have also reported differences in their quality and conclusions [17-20].

A number of tools have been designed to assess the quality of systematic reviews including AMSTAR (A MeaSurement Tool to Assess Reviews) [21], CASP (Critical Appraisal Skills Programme) [22], and one developed by Oxman and Guyatt [23] (also see [24,25]), but all contain similar criteria. (The AMSTAR tool is described in Table 8.1.) Several tools also include rating scales to score the level of confidence that can be placed in a review. Increasing numbers of reviews now include such assessments. In general, high ratings suggest that greater confidence can be placed in the findings of reviews. In contrast, low ratings indicate that less confidence can be placed in review findings and that reviews should be examined closely to identify their key limitations. Three points, though, should be noted: firstly, an overall score or rating does not necessarily indicate which particular aspects of a review were conducted reliably – some may have been conducted more reliably than others. Secondly, the scoring process itself also involves assigning weightings to different items in the assessment tool. It may be difficult to justify which items should be weighted more heavily [26]. Finally, rating tools can only assess the reliability of what is reported. When key information about the methods used in a review is not reported, it may be unclear what was done, or the extent to which what *was* done constitutes an important limitation.

Table 8.1
AMSTAR – A MeaSurement Tool to Assess Reviews (from [22])

AMSTAR – A MeaSurement Tool to Assess Reviews (from [22])	
1. Was an 'a priori' design provided? The research question and inclusion criteria should be established before the conduct of the review	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
2. Was there duplicate study selection and data extraction? There should be at least two independent data extractors, and a consensus procedure for disagreements should be in place	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
3. Was a comprehensive literature search performed? At least two electronic sources should be searched. The report must include the years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and, where feasible, the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialised registers, or experts in the particular field of study, and by reviewing the references in the studies found	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language, etc.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
5. Was a list of studies (included and excluded) provided? A list of included and excluded studies should be provided	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
6. Were the characteristics of the included studies provided? In an aggregated form such as a table, data from the original studies should be provided about the participants, interventions and outcomes. The ranges of characteristics in all the studies analysed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
7. Was the scientific quality of the included studies assessed and documented? 'A priori' methods of assessment should be provided (e.g. for effectiveness studies if the author(s) chose to include only randomised, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria). For other types of studies, alternative items will be relevant	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
8. Was the scientific quality of the included studies used appropriately in formulating conclusions? The methodological rigour and scientific quality of the studies should be considered in the analysis and the conclusions of the review, and explicitly stated when formulating recommendations	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable

9. Were the methods used to combine the findings of studies appropriate? For the pooled results, a test should be done to ensure the studies were combinable and to assess their homogeneity (i.e. Chi-squared test for homogeneity, I^2). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should also be taken into consideration (i.e. was it appropriate to combine the results?)	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
10. Was the likelihood of publication bias assessed? An assessment of publication bias should include a combination of graphical aids (e.g. a funnel plot, other available tests) and/or statistical tests (e.g. Egger regression test)	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
11. Was the conflict of interest stated? Potential sources of support should be clearly acknowledged in both the systematic review and the included studies	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable

An *assessment* of how much confidence can be placed in the findings of a review needs to be differentiated from an *understanding* of the results of the review itself. Table 8.2 provides guidance on what to look for in the results of a review of effects. Guidance for assessing how much confidence can be placed in the findings of reviews of qualitative studies and of reviews of economic studies is shown in Table 8.3.

Table 8.2
Interpreting the results of systematic reviews of effects

The following questions can help to guide policymakers in interpreting the findings of systematic reviews of effects (adapted from [27-29])*:

1. **What estimate of effect is presented?** Many reviews present an average estimate of effect across the included studies. This is often in the form of a risk ratio, odds ratio, or standardised mean difference
2. **Is an average estimate of effect across studies appropriate?** Reviews use statistical methods to summarise and combine outcome data from the studies included in the review. To ensure that the combining of outcome data is appropriate, it is useful to consider whether the included studies were sufficiently similar in terms of population, intervention, comparison, and the outcomes measured. Where an average estimate of effect is not possible, reviews usually present a narrative overview of the available data
3. **Are confidence limits for the estimate of effect presented?** The review should present confidence intervals around the average estimate of effect. The wider the confidence interval the less certain we can be about the true magnitude of the effect
4. **If the results of subgroup analyses are reported, are these appropriate?** A review may present findings for a particular subgroup of participants across all trials or for a subgroup of studies [30]. For example, a review of interventions to reduce diarrhoeal diseases in children less than 5 years of age might also consider the effects of the interventions on children less than 1 year of age. Similarly, a review may include a subgroup analysis of studies judged as having a low risk of bias. A subgroup analysis should make sense in relation to both the overall review question and prior knowledge of factors that may have influenced or moderated the effects of the intervention. For example, it might be anticipated that a higher intensity intervention may produce larger effects. Subgroup analyses should be planned before a review is undertaken and less confidence should be placed in these particular results. This is because they are less reliable than analyses based on all of the included trials and because

multiple statistical analyses may produce positive findings by chance alone

5. **If there is 'no evidence of effect' is caution taken not to interpret this as 'evidence of no effect'?** 'No evidence of effect' is not the same as 'evidence of no effect'. The former suggests that insufficient evidence is available to draw conclusions regarding the effects of the intervention in question. The latter suggests that there is clear evidence from the included studies that the intervention does not have the anticipated effects [31]
6. **Do the conclusions and recommendations (if any) flow from both the original review question and the evidence that is presented in the review?** It is important to consider whether the conclusions presented by the review authors emerge directly from the data gathered from the review and do not go beyond this evidence
7. **Is the evidence applicable to the policy question under consideration?** Differences in health systems can mean that a programme or intervention that works in one setting may not work the same way in another. Policymakers need to assess whether the research evidence from a review applies in their setting. Guidance on this is presented in Chapter 9 in this series [32]

* There is some overlap between the questions listed here and those intended to guide assessment of the reliability of systematic reviews. This is because reliability is an important element in assessing and understanding the results of a systematic review

Table 8.3
Assessing how much confidence can be placed in the findings of systematic reviews of qualitative studies and systematic reviews of economic studies

An increasing number of systematic reviews of qualitative studies are being undertaken. These use a wide range of approaches, including narrative synthesis, meta-ethnography and realist review. As well as providing important information in their own right, reviews of qualitative studies can also inform and supplement systematic reviews of effects [33,34]. However, it is important for the reader to assess the reliability of these reviews. To date, few tools have been designed for this specific purpose. Many of the questions used to guide policy makers when assessing the reliability of systematic reviews of effects, however, are also useful for reviews of qualitative studies. These include:

1. **Did the review address an appropriate policy or management question?** The review question should be amenable to being addressed using qualitative data and should be relevant to policymaking. Reviews of qualitative studies can provide insights about stakeholders' views and experiences regarding health and healthcare and thus help to clarify a problem [35]. Reviews of qualitative studies can also provide information on how or why options work (for example, through examining process evaluations conducted alongside the implementation of a policy or programme) and about stakeholders' views about the options and their relevant experiences [36,37]
2. **Were the criteria used to select studies appropriate?** The description of how studies were selected should be appropriate in relation to the research question
3. **Was a clear and appropriate explanation provided for the search approach used?** Some reviews of qualitative studies undertake comprehensive literature searches while others may use sampling approaches. The chosen approach should be clearly described and justified
4. **Was the approach used to assess the reliability of the included studies appropriate?** The review should describe how the reliability of the included studies was taken into account
5. **Was an appropriate approach used to analyse the findings of the included studies?** The review should use an accepted approach to synthesis and should describe the rationale for the approach chosen

Questions to consider when assessing the reliability of reviews of economic studies include (from [38]):

1. Is it unlikely that important relevant studies were missed?
2. Were the inclusion criteria used to select articles appropriate?
3. Was the assessment of studies reproducible?
4. Were the design and/or methods and/or topic of included studies broadly comparable?
5. How reproducible are the overall results?
6. Will the results help resource allocation in healthcare?

An assessment of the degree of confidence that can be placed in review findings also needs to be differentiated from any assessment that might be done of the *relevance* of reviews to particular policy questions. Considerations of relevance include, for example, questions related to whether a review provides evidence of the effects of the different policy or programme options under consideration, and whether the findings of a review are applicable to the setting in which the policy will be implemented. The process of assessing the applicability of the findings from systematic reviews is discussed further in Chapter 9 [32].

In this chapter, we suggest five questions that can be considered when deciding how much confidence to place in the findings of systematic reviews of the effects of options.

Questions to consider

The following questions can guide policymakers when deciding how much confidence to place in the findings of a systematic review of the effects of an option:

1. Did the review explicitly address an appropriate policy or management question?
2. Were appropriate criteria used when considering studies for the review?
3. Was the search for relevant studies detailed and reasonably comprehensive?
4. Were assessments of the studies' relevance to the review topic and of their risk of bias reproducible?
5. Were the results similar from study to study?

1. Did the review explicitly address an appropriate policy or management question?

A key first step in assessing the confidence that can be placed in the findings of a systematic review is to examine the *question* that is being addressed. The technical design and conduct of a review may well be excellent, but the findings of a review are unlikely to be useful in decision making if they have not explicitly addressed a policy or management question that is sensible, appropriate and relevant to the issue that a policymaker is considering.

An appropriate policy or management question will:

- *Be explicit*: in other words, it will be stated in detail rather than implied in the material presented. If the review question was not expressed explicitly or formulated clearly, it is difficult to assess the conduct of the review adequately. This is because the conduct of the review will need to be considered, at least in part, in relation to the question itself [39]. For example, an appraisal of whether the criteria used to select studies for a review were appropriate, needs to be done in relation to the review question that the studies were intended to answer. A clear question also helps readers to assess whether a review is relevant to their work [39]
- *Be established a priori*: in other words, *before* the review is conducted. It is important that the review question be specified before a review is conducted, preferably in a review

protocol or plan. All Cochrane reviews, for example, are preceded by a published review protocol and examples of these can be found in the Cochrane Library (http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME). If the review question is not specified before the review is conducted, there is a risk that the question may have been altered to suit the evidence found, thus undermining confidence in the findings

- *Address a question of relevance to policymaking or management*. This will need to be assessed in a specific context, based on the range of issues that are important in a particular jurisdiction at a particular time. A review question may not be relevant if:
  - *It is too narrow*: for example, a review may consider the effects of a programme on a specific age group of participants only, located in a particular setting, or for a restricted range of outcomes. It would not be possible, in this instance, to generalise the results to other populations, settings or outcomes
  - *It is too broad*: a review, for example, may define a programme as including a very broad range of practices and not all of these may be relevant to a particular jurisdiction. Or a review may pose a very broad question that is not useful from a decision-making perspective. A question such as whether nurses can effectively deliver health promotion programmes, for instance, will not be useful in deciding whether a particular cadre of nurses, such as enrolled nurses, can effectively deliver a health promotion programme for a specific health issue, such as HIV/AIDS prevention
  - *It does not specify an appropriate comparison group*: if, for example, a programme is compared to a 'no programme' scenario rather than to current best treatment for a condition

A well-formulated review question should specify *all* of the following: the types of population and settings that the review will cover (e.g. children aged between one month and six years of age living in a malaria-endemic area); the types of programmes and comparisons considered (e.g. anti-malarial drugs given at regular intervals (the intervention) compared to placebo or no drug (the comparison)); and the types of outcomes that are of interest (e.g. clinical malaria and severe anaemia) [40,41]. The acronym PICO (Population, Intervention, Comparison, Outcomes) is sometimes used to summarise these four key components of a review question.

While the need for a well-formulated review question may seem obvious, many narrative reviews fail to provide this. A review of a sample of such reviews published in major medical journals showed that 20% failed to state their purpose clearly [42].

2. Were appropriate criteria used when considering studies for the review?

Inclusion and exclusion criteria for a review are the detailed listings of the types of population, interventions, comparisons and outcomes that a review will consider. These criteria, specified in a review protocol, will determine which studies are included in a review. They will therefore influence strongly the findings of a review. It is important that these criteria are appropriate in relation to the review question.

The following questions should be examined when considering whether the criteria used to consider studies for a review are appropriate:

- Does the review specify clear inclusion and exclusion criteria? These criteria are important as a way of protecting against bias related to the inclusion of studies in the review. A recent assessment of the methodological quality of systematic reviews in general surgery, for example, found that only 70% of these reported the criteria used for deciding which studies to include in a review [17]

- Are the inclusion and exclusion criteria explicit in relation to the following: the types of population considered, the types of interventions and comparisons considered, and the types of outcomes considered?
- Are the inclusion and exclusion criteria congruent with the review question [27] ? For example, if a review aims to evaluate prophylaxis and intermittent treatment with anti-malarial drugs to prevent malaria in young children living in malaria-endemic areas, do the criteria indicate the inclusion of studies of children from the appropriate settings, and do they specify the forms of prophylaxis and treatment that will be considered? [41] Similarly, if a review aims to examine the effects of interventions to increase the proportion of health professionals working in rural and other underserved areas, do the criteria indicate the range of healthcare professionals that will be included and the types of educational or financial interventions that will be considered? [43]

3. Was the search for relevant studies detailed and reasonably comprehensive?

A key aspect of a systematic review is a thorough and reproducible search of the literature for studies that meet the eligibility criteria of a review. This approach is one of the elements that differentiates *systematic* reviews from *narrative* reviews. Systematic searching contributes to minimising bias in a review by ensuring that all relevant evidence is considered. It therefore helps to achieve reliable estimates of the effects of the policy or programme being examined [44].

Publication bias – that is, the selective publication of studies based on the direction and strength of their results [45] – is one route by which bias may be introduced into reviews. A recent review examined the extent to which the publication of randomised trials is influenced by whether or not positive results were found and the perceived importance of trial findings. It showed that trials with positive results were significantly more likely to be published than trials that presented negative findings [46]. This review and other research also showed that trials reporting positive findings are published sooner than others [47]. As a result, reviews may overestimate the positive effects of programmes unless attempts are made to identify both published and unpublished studies.

Systematic reviews vary in the extent to which they include comprehensive searching. A review of the reporting of published reviews on the treatment of asthma, for example, found that only 52% of the 33 examined reviews included a reasonably comprehensive search for evidence of effects [19]. It is therefore important to check how searches for relevant studies were conducted.

The following questions should be examined when considering whether the search for relevant studies was detailed and reasonably comprehensive [21]:
- Does a review describe in detail the strategy used to search for relevant studies? This reporting should include: 1. The list of sources searched, 2. The key words used to search these sources (where applicable), and 3. The years over which the sources were searched. Table 8.4 provides examples of the range of sources searched in reviews published in the Cochrane Library
- Did the search strategy include electronic databases of published studies? A wide range of electronic databases of published studies is available and several can be searched at no or very low cost. Key databases include PubMed/MEDLINE (compiled by the National Library of Medicine, USA), the Cochrane Central Register of Controlled Trials (CENTRAL – compiled by the Cochrane Collaboration), and regional databases such as

LILACS (Latin American and Caribbean Health Sciences). Chapters 4 [35] and 5 [36] provide further information on finding relevant research literature

- Were the searches of electronic databases supplemented by additional searching? This might have included an examination of the reference lists of relevant studies, making contact with authors and experts in the field, and the consultation of specialised registers of studies related to the topic area of the review. This additional searching is useful as a way of helping to identify both further published studies and unpublished studies (which may include studies available in the 'grey' literature, i.e. in sources of literature other than indexed, peer-reviewed journals)
- Are the searches up-to-date? Does the review specify the period covered by the searches and are the searches current? A published review, while relevant to a policy question, may have used searches that are now several years old. It is therefore possible that the review does not include all the latest relevant evidence and may therefore give an unreliable estimate of the effects of the policy or programme option

Table 8.4
Examples of sources searched in systematic reviews

Review	Sources searched
Health systems review *Example: Systematic review of lay health worker interventions in primary and community healthcare [48]*	1. Electronic databases of published studies – MEDLINE – Cochrane Central Register of Controlled Trials (CENTRAL) and specialised Cochrane Registers (EPOC and Consumers and Communication Review Groups) – Science Citations – EMBASE – CINAHL (Cumulative Index to Nursing and Allied Health Literature) – Healthstar – AMED (Allied and Complementary Medicine Database) – Leeds Health Education Effectiveness Database 2. Bibliographies of studies assessed for inclusion 3. All contacted authors were asked for details of additional studies
Public health review *Example: Systematic review of male circumcision for prevention of heterosexual acquisition of HIV in men [49]*	1. Electronic databases of published studies – MEDLINE – EMBASE – Cochrane Central Register of Controlled Trials (CENTRAL) 2. Electronic databases of conference abstracts – AIDSearch Conference databases 3. Electronic databases of ongoing trials – ClinicalTrials.gov – Current Controlled Trials 4. Contacted researchers and relevant organisations in the field 5. Checked the reference lists of all studies identified by the above methods and examined any systematic reviews, meta-analyses, or prevention guidelines identified during the search process

Clinical review *Example: Systematic review of statins for the prevention of dementia [50]*	1. Electronic databases – The Specialized Register of the Cochrane Dementia and Cognitive Improvement Group – Cochrane Central Register of Controlled Trials (CENTRAL) – MEDLINE – EMBASE – PsycINFO (a database of psychological literature) – CINAHL – SIGLE (Grey Literature in Europe) – LILACS (Latin American and Caribbean Health Science Literature) 2. Electronic databases of conference abstracts – ISTP (Index to Scientific and Technical Proceedings) – INSIDE (British Library Database of Conference Proceedings and Journals) 3. Electronic databases of theses – Index to Theses (formerly ASLIB) (United Kingdom and Ireland theses) – Australian Digital Theses Program – Canadian Theses and Dissertations – DATAD – Database of African Theses and Dissertations – Dissertation Abstract Online (USA) 4. Electronic databases of ongoing trials: searched a large range of such databases

4. Were assessments of the studies' relevance to the review topic and of their risk of bias reproducible?

Authors of systematic reviews need to make two important judgements regarding each primary study that might be included in a review. Firstly, does the study meet the criteria for inclusion in their review – in other words, is it relevant to the review topic? Secondly, what is the risk of bias in the results of the study? Risk of bias refers to the risk of "a systematic error, or deviation from the truth, in results or inferences" [26]. It also relates to the question of whether the results of a study can be assumed to be accurate [26]. Because these judgements will affect the findings of a review, it is important that they are presented in a way that is transparent and reproducible. Others need to be able to understand how these judgements were made and to be able to repeat these assessments.

As discussed above, reviews need to specify clear inclusion and exclusion criteria in order to protect against bias in the process of selecting studies for inclusion. These criteria and judgements will necessarily affect the findings of the review by influencing the studies selected for inclusion. Bias or errors in these judgements can be minimised in the following ways: firstly, two reviewers should decide independently on which studies to include in a review. Additional discussions with other reviewers can also be used to resolve disagreements related to the inclusion of a particular study. Secondly, reasons for the inclusion of a study (and for excluding a study that appears relevant) should be recorded in the published review. This will allow readers to make their own judgements regarding eligibility decisions. It also provides a transparent 'audit trail' for the review, ensuring that the process is reproducible.

The ability of a systematic review to reach conclusions regarding the effects of a policy or programme also depends on the validity of the data obtained from each included study. Pooling the results of the studies, or creating a summary of them in a review, may give a misleading result if the validity of the individual studies included in the review is low. Evaluating the risk of bias in the results of the included studies is therefore an important element of a systematic review. Such assessments should feed into the interpretation and conclusions of a review [26].

A number of different approaches for assessing quality or risk of bias have been developed for randomised trials [26,51,52]. While we do not discuss these different approaches here, it is important to note that reviews should be explicit regarding the approaches used and should apply these consistently.

When assessing the relevance of the included studies to the review topic and the potential risk of bias, the following questions should be considered:

- Was an explicit and transparent approach used to assess the relevance of studies to the review topic? A review should state how relevance was assessed and provide a list of both included and excluded studies
- Was an explicit and transparent approach used to assess the risk of bias in the included studies? A review should report the tool used to assess the risk of bias, how the assessment was conducted, and the results of the assessment
- Were the results of the risk of bias assessment taken into account in interpreting the results of a review? When the risk of bias in the included studies is high, for example, we might have less confidence in the findings of a review

5. Were the results similar from study to study?

The findings of the studies included in a review may be very similar – or they may vary – in terms of the effects of the programme on a particular outcome. This variability among the studies included in a review is usually referred to as 'heterogeneity' [26]. The variability among studies included in a review depends in part on the scope of the review. Where the scope is wide, the range and therefore the variability of the included studies might also be expected to be wide. In contrast, where the scope of a review is narrow, the included studies are likely to be more similar to each another.

If the participants, interventions or outcomes of the studies included in a review are very different, this may lead to variation or heterogeneity if the intervention effect is affected by these factors. Because the true intervention effect will be different across these studies, in these instances the average effect across the studies will not be helpful.

Depending on the level of variability, reviews may use different approaches to summarising information from the studies included, for example:

- *Calculating the average (or pooled) effect across studies*: this approach is useful when the variability across studies is low. For example, a systematic review of 'early hospital discharge combined with hospital at home' programmes (i.e. programmes in which active treatment is given by health providers in a patient's home for a health issue that would otherwise require acute hospital inpatient care) found that the studies included were sufficiently similar to be able to estimate the average effect of the programme. The review found insufficient evidence of economic or health benefits from 'early discharge hospital at home' programmes [53]
- *Calculating the average effect for subgroups of studies included in a review*: this may be useful when the overall variability of studies included in a review is high (and it is

therefore unhelpful to calculate an average affect), but where variability is low among subgroups of studies. For example, a review of lay health worker interventions in primary and community healthcare grouped studies according to the health issues addressed by the lay health workers. For some of the groups, such as lay health workers to promote immunisation and breastfeeding, it was possible to calculate an average effect across the relevant studies. The review found evidence that lay health workers can improve immunisation and breastfeeding uptake [48]

- *Describing the range of effects sizes*: where studies are not sufficiently similar to make calculating an average effect useful, it may still be possible to describe the range of effects found in the studies. For example, a review of the effects of audit and feedback on the practice of healthcare providers showed that compliance with desired practice ranged from a decrease of 16% to an increase of 70%, with a median of 5%. The review indicated that audit and feedback can make practice more effective but that the effects are generally small to moderate [54]
- *Cataloguing the types of interventions to address a particular issue*: the wide scope of some reviews, and therefore the variability of the studies within them, means that it is not sensible to attempt to quantitatively combine the findings of the included studies – or even to describe the range of effect sizes. In these cases, a narrative review can be undertaken. For example, a systematic review of the effectiveness of health service interventions aimed at reducing inequalities in health included studies that assessed programmes designed to reduce inequalities in health and that could be implemented within the health system alone, or in collaboration with other agencies. The range of included studies was large, extending from programmes to improve control of blood pressure, through to health promotion interventions. No statistical pooling was therefore attempted [55]

Where results differ from study to study, the following questions should be considered:

- *Is there a compelling explanation for the differences that were found?* This might include differences in the participants, interventions, comparison groups, outcomes, settings or time periods across the included studies. For example, some studies may have included participants who had a wider age range or different pre-existing health conditions
- *If a pooled estimate was made, is this likely to be meaningful?* If the studies included in a review are varied, a pooled estimate may not be meaningful. Further exploration of the data, through subgroup analysis, may be conducted but the results of such exploratory analyses may not be reliable

As the number of available systematic reviews increases, it is becoming more common to find more than one systematic review for a particular policy question. Sometimes the results or conclusions of these reviews may be different. Table 8.5 provides guidance on how policymakers might approach such situations.

Table 8.5
What should policymakers do when different systematic reviews that address the same question have different results?

When looking for evidence to inform a particular policy decision, it is not uncommon to identify more than one relevant systematic review. Sometimes the results of these reviews may be different, and this may result in review authors drawing different conclusions about the effects of an intervention. This scenario differs from one in which the findings of two or more reviews agree but in which researchers or others disagree on the interpretation of these findings [18].

There are many reasons why the results of different systematic reviews may differ. These include differences in: the questions addressed by the reviews, the inclusion and exclusion criteria used, which data were extracted from the studies, how the quality of the studies was assessed, and decisions regarding (and methods for) statistical analysis of the data [18].

The following series of questions designed by Jadad and colleagues can be used to assist with identifying and addressing the causes of discordance [18]:

1. Do the reviews address the same question? If not, the review that is chosen should be the one which addresses a question closest to that of the policy question for which evidence is needed. Alternatively, it should assess outcomes most relevant to the policy question
2. If the reviews address the same question, do they include the same trials or primary studies? If they do not include the same trials, the review that includes studies most relevant to the policy question being considered should be selected
3. If the reviews include the same studies, are the reviews of the same quality? If not, the higher quality review should be used

Where both reviews are relevant, for example where they address different aspects of the same question, it may be useful to draw evidence from both.

Conclusion

Variations are evident in the rigour with which systematic reviews of effects are conducted. It is therefore important to assess the reliability of reviews used to inform policy decisions, in order to be able to judge how much confidence can be placed in this evidence. A systematic and transparent approach to such assessments should be used and a number of tools have been developed for this purpose. However, these tools can only be used to assess what is reported. This is why any assessments that are made using these tools need to be undertaken carefully and thoughtfully.

Where the reliability of a systematic review is poor, policymakers should have less confidence in the findings and should be cautious if using them to inform policy decisions (as summarised in Figure 8.2). When making decisions informed by the evidence presented in a review, policymakers need to consider assessments of the reliability of a review alongside other information, such as the usefulness of the review in relation to the policy question and evidence on the local context.

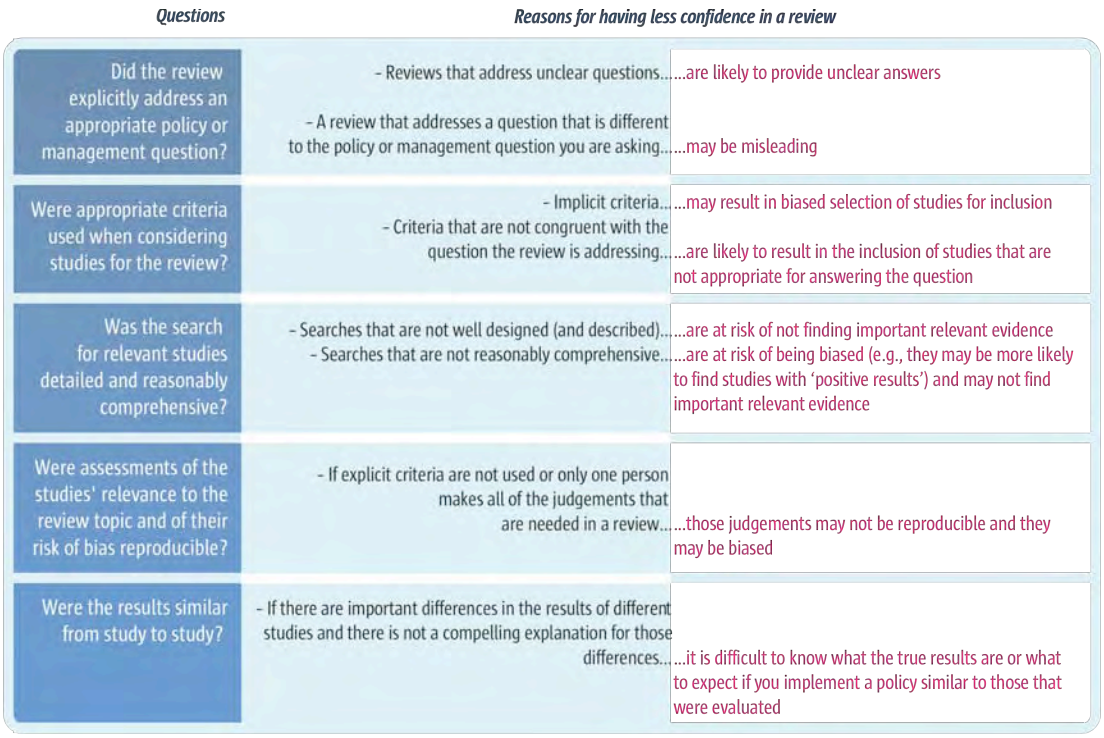

Figure 8.2
Ways in which reviews may be unreliable and misleading

Resources

Useful documents and further reading

- Higgins JPT, Altman DF: **Chapter 8: Assessing risk of bias in included studies.** In *Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.1 (updated September 2008).* Edited by Higgins JPT, Green S. The Cochrane Collaboration; 2008. Available at: www.cochrane-handbook.org

- Counsell C: **Formulating Questions and Locating Primary Studies for Inclusion in Systematic Reviews.** *Ann Intern Med* 1997, **127:** 380-387

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Links to websites

- *The Rx for Change database:* www.cadth.ca/index.php/en/compus/optimal-ther-resources/interventions – This summarises current research evidence about the effects of strategies to improve drug prescribing practice and drug use. This database includes summaries, including reliability assessments, of systematic reviews that evaluate the effects of strategies targeting professionals, the organisation of healthcare, and consumers

- *Cochrane Effective Practice and Organisation of Care (EPOC) Review Group:* www.epoc.cochrane.org/en/index.html – The Review Group provides guidance on assessing the reliability of different types of studies of effectiveness

- *The SUPPORT (SUPporting POlicy relevant Reviews and Trials) Collaboration:* www.support-collaboration.org/index.htm – This project produces summaries of high priority reviews for low- and middle-income countries. These include assessments of reliability

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9. Assessing the applicability of the findings of a systematic review

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Summary

Differences between health systems may often result in a policy or programme option that is used in one setting not being feasible or acceptable in another. Or these differences may result in an option not working in the same way in another setting, or even achieving different impacts in another setting. A key challenge that policymakers and those supporting them must face therefore is the need to understand whether research evidence about an option can be applied to their setting. Systematic reviews make this task easier by summarising the evidence from studies conducted in a variety of different settings. Many systematic reviews, however, do not provide adequate descriptions of the features of the actual settings in which the original studies were conducted. In this chapter, we suggest questions to guide those assessing the applicability of the findings of a systematic review to a specific setting. These are:

1. Were the studies included in a systematic review conducted in the same setting or were the findings consistent across settings or time periods?
2. Are there important differences in on-the-ground realities and constraints that might substantially alter the feasibility and acceptability of an option?
3. Are there important differences in health system arrangements that may mean an option could not work in the same way?
4. Are there important differences in the baseline conditions that might yield different absolute effects even if the relative effectiveness was the same?
5. What insights can be drawn about options, implementation, and monitoring and evaluation?

Even if there are reasonable grounds for concluding that the impacts of an option might differ in a specific setting, insights can almost always be drawn from a systematic review about possible options, as well as approaches to the implementation of options and to monitoring and evaluation.

Scenarios

Scenario 1*: You are a senior civil servant and will be submitting a brief report to the Minister regarding the evidence to support an option that has been provisionally selected to address a high-priority problem. You are concerned about whether the findings of a relevant high-quality systematic review that was used to make the selection are likely to be applicable to your specific setting, and you want to ensure that this issue has been assessed by your staff*

Scenario 2: *You work in the Ministry of Health and are preparing a brief report about an option that is being considered to address a high-priority problem. All that you have been told is that the report should summarise the findings from the most relevant high-quality systematic review and assess the applicability of the findings to your setting*

Scenario 3: *You work in an independent unit that supports the Ministry of Health in its use of evidence in policymaking. You are preparing a detailed research report for the Ministry of Health about what is known and not known about an option to address a high-priority problem. You have been told that policymakers have found a particular systematic review to be persuasive but you want guidance on how to assess whether the findings of the review are applicable to your setting*

Background

For policymakers (Scenario 1), this chapter suggests a number of questions that they might ask their staff to consider when preparing a brief report about a systematic review that could form the basis for selecting an option and communicating the rationale for the selection. For those who support policymakers (Scenarios 2 and 3), this chapter suggests a number of questions to guide the assessment of the applicability of the findings of a systematic review to a specific setting. This chapter is the third of four chapters about finding and assessing systematic reviews to inform policymaking (see also Chapters 7, 8 and 10 [1-3]). Figure 9.1 outlines the steps involved in finding and assessing systematic reviews to inform policymaking.

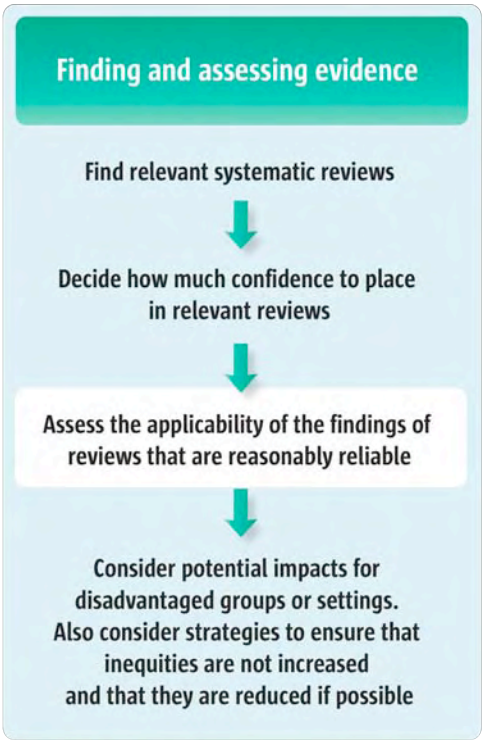

Figure 9.1
Finding and assessing systematic reviews to inform policymaking

Commonalities in human biology mean that a clinical procedure or drug will often work the same way in different patients. However, this is not always the case and questions have thus been developed to help healthcare providers to assess the applicability of research evidence to their patients [4]. Differences between health systems often mean that a policy or programme option being used in one setting may not be feasible or acceptable in another setting. These differences may also mean that an option may not work the same way in another setting or that it may achieve different impacts in another setting [5,6]. For example, the implementation of user fees failed to achieve consistent positive impacts in many sub-Saharan African countries compared to countries in other regions. In part, this was due to a number of contextual considerations, such as people's lack of familiarity with paying for public health services [7]. A key challenge that policymakers and those supporting them must face, therefore, is to determine whether research evidence about the impacts of an option are applicable to their setting.

Systematic reviews make this task easier by offering a single summary of studies from different settings. The word 'settings', in this instance, refers to political/country *jurisdictions* (e.g. Canada or Cameroon, or their constituent provinces). But settings can also include *sectors* (e.g. primary care or hospital care), and *locales* (e.g. urban or rural). Systematic reviews can also assist with the process of making judgements about the applicability of the evidence to specific settings by providing a framework and, when available, research evidence that can be used to identify those factors that are essential for an

option to work – or that might modify its impacts. A systematic review of pharmaceutical policies (i.e. referencing pricing, other pricing, and purchasing polices for drugs), for example, provided a summary of the factors that could influence the impacts of reference pricing, as well as the rationale for each factor [8]. These factors included the equivalence of the drug, incentives, exemptions, drug availability, price levels, and electronic information systems.

Unfortunately, many systematic reviews do *not* do the following:

- Highlight the features of the settings in which studies were conducted, particularly those features that might modify the impacts of an option
- Provide a framework for identifying potential modifying factors, or
- Provide research evidence about modifying factors

In these cases, policy analytic articles or narrative reviews may provide more helpful frameworks that could be used to inform judgements about the applicability of the evidence in a systematic review.

A framework for understanding corruption in the health sector and its determinants, for example, highlighted how health system arrangements (e.g. governance arrangements that limit monopolies, require transparency, and support enforcement) and other factors, influenced 'opportunities' and 'pressure' to abuse, as well as the rationalisation for abuse, and how this in turn influenced the abuse of power for private gain [9]. But, ideally, a systematic review about the impacts of anti-corruption efforts also would have described the relevant health system arrangements in the settings where the studies were conducted. Those features that might influence opportunities and pressure to abuse and the rationalisation of such behaviour, would be of particular interest as they would allow the reader to link the determinants identified by the framework with the findings presented in the review.

Applicability considerations are equally, if not more important, for other types of systematic reviews. Reviews of administrative database studies and of community surveys can help to place problems in comparative perspective, for example, and reviews of observational studies can help to characterise an option's likely harms. Reviews of qualitative studies can assist in understanding the meanings that individuals or groups assign to particular problems, how and why particular options work, and stakeholder views about experiences with particular options. What follows in this chapter, however, is more focused on systematic reviews about the impacts of an option. That said, this may provide some help in assessing the local applicability of the findings of reviews of observational studies about harms, be supported by reviews about how and why particular options work, and give some insights into how to approach local applicability assessments of other types of reviews.

Questions to consider

The following five questions can guide how to assess whether the findings from a systematic review are applicable to a specific setting:

1. Were the studies included in a systematic review conducted in the same setting or were the findings consistent across settings or time periods?
2. Are there important differences in on-the-ground realities and constraints that might substantially alter the feasibility and acceptability of an option?
3. Are there important differences in health system arrangements that may mean an option could not work in the same way?
4. Are there important differences in the baseline conditions that might yield different absolute

effects even if the relative effectiveness was the same?

5. What insights can be drawn about options, implementation, and monitoring and evaluation?

1. Were the studies included in a systematic review conducted in the same setting or were the findings consistent across settings or time periods?

If the studies included in a systematic review were conducted in the *same* setting where policymakers are based, or else in very *similar* settings, there may be little reason to be concerned about the applicability of the findings. Similarly, if the findings have been shown to be consistent across settings or time periods then similar impacts might be expected. On-the-ground realities and constraints, health system arrangements and baseline conditions, are likely to differ across settings and change over time, so consistent findings in these circumstances are likely to mean the findings are broadly applicable. (These three issues are the focus of the next three questions that follow in this section.)

The following information in systematic reviews can be used by policymakers to inform judgements related to such issues:

- Information about the settings of studies and specifications regarding the time periods over which the studies were conducted. This can typically be found in a section of the review entitled 'Characteristics of included studies' (or similar)
- Information about the consistency of findings can typically be found in the review abstract or in its 'Results' section

When information about settings and time periods is lacking in a systematic review, policymakers and those who support them could contact the authors of the review to see if they have this information and did identify key local applicability considerations. If this contact yields little of value, they could then retrieve the original studies to locate this information if the issue is of sufficiently high priority, and if resources and time allow. A potential benefit of the direct contact with review authors is that it may encourage them to give attention to information needed for local applicability assessments and considerations in future reviews.

Research comparing mortality rates in not-for-profit hospitals with mortality rates in for-profit hospitals provides an example of how such data can be used [10]. This research had been conducted over several decades in the United States of America during which the health system had changed dramatically. The research demonstrated remarkable consistency over time in the significant survival advantage of being treated in not-for-profit hospitals. Based on these findings, a policymaker from Canada might then conclude that a similarly consistent finding would be seen in a Canadian setting. And this conclusion might lead them to avoid the introduction of for-profit hospitals into the current system which consists only of not-for-profit hospitals (or at least to avoid using health benefits as a justification for doing so).

2. Are there important differences in on-the-ground realities and constraints that might substantially alter the feasibility and acceptability of an option?

If the studies included in a systematic review were conducted in settings with largely similar resource and capacity constraints to the setting where the findings may be applied, and largely similar perspectives and political influence amongst health system stakeholders,

policymakers might reasonably expect that an option would be both feasible and acceptable in their own setting. However, policymakers will rarely be able to find information about resource and capacity constraints and stakeholder influence in a systematic review. Instead, they will find a description of the option that was studied. Typically they will be sufficiently familiar with the resources, capacity, and stakeholder influence in their own setting to enable them to judge the feasibility and acceptability of the option.

Policymakers in a setting with very significant resource and capacity constraints will have to think twice about the feasibility of an option [11]. Some settings, for example, may face a shortage of nurse practitioners and therefore any option requiring a significant role for this category of healthcare provider might not be feasible in the short-term [12]. Similarly, some settings have such limited financial resources that an option shown to have significant impacts, such as artemisinin-based combination therapies (ACT) to treat malaria, might not be considered feasible on a large scale without significant donor support [13]. Some health systems may be too overstretched to accommodate an increase in demand that may accompany the introduction of conditional cash transfers (i.e. the provision of money to households on the condition that they comply with certain health and healthcare-seeking behaviours) [13,14]. Or settings may lack the capacity within governments or among managers, healthcare providers and consumers (i.e. healthcare recipients and citizens) to support the widespread use of a particular option. Audit and feedback (i.e. the provision of healthcare providers with data about their performance), for example, might not be feasible in settings where routinely collected data are unreliable.

In a setting in which stakeholders are opposed to an option and have significant influence on practice and policy, policymakers may have to assess the likely acceptability of an option particularly carefully. Healthcare provider associations, such as nursing associations, for example, may resist the introduction or expansion of a lay health worker programme if they perceive that the income or status of nurses might be affected [13,15]. Civil society organisations, too, may actively oppose changes that would reduce prescription drug use among consumers, particularly for life-sustaining drugs, and drugs that are important in treating chronic conditions [13,16]. Such changes could include the introduction of caps (i.e. consumers are reimbursed up to a set maximum number of prescriptions), co-insurance (i.e. consumers pay a percentage of the price of the prescription drug), and co-payments (i.e. consumers pay a fixed amount per prescription drug).

Significantly, many on-the-ground realities and constraints can be addressed over time. Nurse practitioner training programmes, for example, can be scaled up and donors can subsidise the cost of an expensive drug like ACT. Similarly, governments can improve the quality of routinely collected data, and healthcare provider associations and civil society organisations can become engaged in a series of negotiations or dialogues.

3. Are there important differences in health system arrangements that may mean an option could not work in the same way?

If the studies included in a systematic review were conducted in settings with *largely similar* health system arrangements to the setting where the findings may be applied, particularly those that might substantially alter the potential impacts of an option, policymakers might reasonably expect similar relative effectiveness in their setting. Deciding whether health system arrangements might alter the impacts of an option requires an understanding of how *and* why an option might work. Within a systematic review, policymakers may find both a framework and research evidence that will identify those factors essential for an option to work – or that might modify its impacts. Policymakers may also find a summary of those

features of the settings in which studies were conducted that might modify the impacts of an option.

If a systematic review does not provide the information necessary to determine whether particular health system arrangements might result in an option not working in the same way, policymakers could look for:

- Policy analytic articles or narrative reviews incorporating helpful frameworks that could be used to identify factors that might modify the impacts of an option, and
- Detailed descriptions of the health system arrangements, specifically those that might substantially alter the potential impacts of an option, in the settings where the studies were conducted

The European Observatory on Health Systems and Policies publishes, and periodically updates, profiles of the health systems of a large number of middle- and high-income countries. These 'Health in Transition' (HiT) profiles can be found online (www.euro.who.int/observatory/hits/20020525_1) and downloaded free of charge. The Health Policy Monitor provides a searchable online database of key health system features in some of the same countries (www.hpm.org/en/Search_for_Reforms/Search.html). Many World Health Organization regional offices also provide profiles of the health systems of countries in their region (e.g. www.searo.who.int/EN/Section313/Section1515_6038.htm).

Policymakers in a setting with very different health system arrangements, specifically arrangements that appear significant in determining whether an option will function in the same way, should be cautious about assuming that comparable relative effectiveness could be achieved. For example, in a review of reference drug pricing [8], six of the ten studies were conducted amongst older people/pensioners in British Columbia, Canada. Policymakers in other settings may well conclude that they will *not* be able to achieve comparable impacts to those seen in the Canadian example if they have any of the following issues within their own health system arrangements:

- Inadequate incentives for consumers, healthcare providers, pharmacists and pharmaceutical companies to comply with the reference drug price system, and
- An electronic processing system that lacks the capacity to realise the low administration costs associated with identifying, prescribing and dispensing the reference drugs and with handling exemptions

Similarly, other pricing policies examined in competitive pharmaceutical markets may yield a different relative effectiveness in markets with monopolies.

Unlike the possibility of associated change in on-the-ground realities that we discussed in Question 2 earlier, there is less chance that health system arrangements could be modified. Health system arrangements are difficult to change and typically the rationale underpinning a change would need to be more compelling than only the *possibility* that it would enhance the impact of a single option.

4. Are there important differences in the baseline conditions that might yield different absolute effects even if the relative effectiveness was the same?

If the studies included in a systematic review were conducted in settings with *largely similar* baseline conditions to those in which the findings may be applied, such as in terms of a programme's or policy's coverage of the population, policymakers might reasonably expect similar absolute effects in their setting (provided the answer they gave to Question 3 above

led them to expect similar relative effectiveness). Policymakers will often be able to find information about baseline conditions within systematic reviews in a section titled 'Characteristics of included studies'. Alternatively, they may have to retrieve the original studies included in the review in the hope that baseline conditions were better described in them. Policymakers will typically be able to find local evidence about baseline conditions in their own setting. (Chapter 11 addresses how to find and use local evidence [17].)

Policymakers in a setting with *different* baseline conditions may expect different absolute impacts. The absolute impact of audit and feedback, for example, is likely to be larger than in instances where the baseline compliance to recommended practice is low [18]. Similarly, the absolute impact of a pay-for-performance initiative may be larger in low- and middle-income countries (where small financial incentives may be larger relative to wages) than in high-income countries [19].

This question highlighting the link between baseline conditions and absolute effects is also highly relevant in clinical settings in which the relative effectiveness of a clinical intervention is often the same across patients but where patients' baseline risks may vary quite dramatically [20,21]. The question is also highly relevant in public health settings where immunisation programmes, for example, might be introduced in countries with very different baseline conditions. Chapter 16 discusses the use of balance sheets to summarise important impacts and provides further detail about relative effectiveness and absolute impacts [22].

5. What insights can be drawn about options, implementation, and monitoring and evaluation?

Even if the findings from systematic reviews are not directly applicable to a given setting, important lessons can still be drawn. Policymakers may be provided with an idea for an option that they might otherwise not have considered. They may also gain insight into how options have been implemented in other settings. And they may be able to draw directly on the systematic review itself in developing a monitoring and evaluation plan. Policymakers may learn, for example, about a new approach to supporting team-based care, the importance of engaging both mid-level managers and front-line nurses in the implementation of an option, and what types of outputs and outcomes they should track as they monitor and evaluate the implementation of a selected option.

Table 9.1 and Table 9.2 provide examples of an assessment of the applicability of a systematic review.

Table 9.1
An assessment of the local applicability of a systematic review about home care (from the perspective of a Canadian policymaker)

Policymakers assessing the applicability of a 2005 review of home care could apply the series of questions discussed earlier as follows [23]*:*

1. Were the studies included in the systematic review conducted in the same setting or were the findings consistent across settings or time periods?

- ***22 studies were included in the review***
  - 9 from the United Kingdom (UK)
  - 3 from Australia
  - 1 each from Italy, Norway, and the United States of America
  - 7 were not described in a way that identified the country in which the study was conducted
- Findings were not consistent across settings
- Two studies were published in 1978 while the others were published from 1992 onwards. Many did not specify a time period, making it difficult to support the contention that the findings were consistent over time periods

2. Are there important differences in on-the-ground realities and constraints that might substantially alter the feasibility and acceptability of an option?

- In Canada, nurses are in tremendous demand (particularly in hospitals) and many are not used to the scope of practice required in home care settings. This means that many nurses might not embrace career opportunities in home care settings
- In Canada, unlike in the UK where 9 of 13 identifiable studies were conducted, citizens differ in whether they have supplementary coverage permitting more intensive home care. This means that relatively more wealthy people may get access to home care than the less well-off
- In Canada, unlike in the UK, home care recipients and their families may have to travel very long distances if they have to seek acute care. Some may therefore delay their discharge from hospital; others may suffer if a hospital transfer is difficult
- In Canada, nurses may face a drop in pay if they move from hospitals to the community. Many of them may therefore actively oppose a shift from hospital care to home care
- In Canada, there is even more of a separation between health and social services (at least outside the province of Quebec) than there is in the UK, which means that caregivers may face a greater burden that is not covered by social services

3. Are there important differences in health system arrangements that may mean an option could not work in the same way?

- In Canada, as suggested earlier, home care recipients and their families cannot rely on the same breadth of services available to those in the UK (at least outside the province of Quebec)
- In Canada, unlike in the UK, there is a governmental commitment to first-dollar coverage for hospital-based and physician-provided care but not for home care, which means that Canadian home care recipients and their families may face significant financial barriers to accessing home care
- In Canada, unlike in the UK, most Canadians are not 'attached' to a multi-disciplinary primary healthcare practice, and some Canadian home care recipients would not even have a regular primary healthcare provider

4. Are there important differences in the baseline conditions that might yield different absolute effects – even if relative effectiveness was the same?

- In Canada, home care is already well established for most types of care, which means that the benefits may be small in absolute terms, at least for those not facing financial barriers

5. What insights can be drawn about options, implementation, and monitoring and evaluation?

- In Canada, admission-avoidance schemes may be a relatively unknown option compared to well-established schemes, such as the early discharge of elderly medical patients, or patients following surgery, or care of terminally ill patients

The review has now been updated and divided into two separate reviews, one of which deals specifically with admission-avoidance schemes and would be particularly relevant to Canada [24]

Table 9.2
An assessment of the local applicability of a systematic review on lay health worker interventions (from the perspective of a South African policymaker)

Policymakers assessing the applicability of a 2006 review of lay health worker (LHW) interventions for maternal and child health in primary and community healthcare could apply the following series of questions [25,26]:

1. Were the studies included in the systematic review conducted in the same setting or were the findings consistent across settings or time periods?

- 48 studies were included in the review
  - 25 from the United States of America (USA)
  - 3 from the United Kingdom (UK)
  - 2 each from Brazil, South Africa and Tanzania
  - 1 each from Bangladesh, Canada, Ethiopia, Ghana, India, Ireland, Mexico, Nepal, New Zealand, Pakistan, Philippines, Thailand, Turkey, and Vietnam
- Findings were not always consistent across settings
- Most studies were published from 1995 onwards although one study was published in 1980. It is not clear from the review whether the findings were consistent over time periods

2. Are there important differences in on-the-ground realities and constraints that might substantially alter the feasibility and acceptability of an option?

- In South Africa, concerns have been expressed about the capacity of the health system and non-government organisations (NGOs) to provide clinical and managerial support for a very large scale-up of LHW programmes, particularly in currently under-resourced areas where, it could be argued, they are most needed. Capacity may be different from the high-income settings (US, UK) in which many of the studies were conducted
- In South Africa, there is some resistance among nurses, and within nursing professional associations, to extending the scope of practice of LHWs. This may restrict the range of tasks that LHWs are able to take on. While the acceptability of LHWs to consumers seems reasonable, based on observations from existing programmes, this is likely to vary across settings in the country and for different tasks (e.g. immunisation, breastfeeding promotion)
- In South Africa, most LHWs are currently involved in providing home-based care to people living with HIV/AIDS and treatment support to this group and to people with TB. It is not clear how feasible it would be to extend their roles to include the areas shown to be effective

in the review (immunisation promotion, treatment of childhood infections, breastfeeding promotion). Furthermore, the LHW interventions shown to be effective in the review were focused on very specific health issues, such as the promotion of breastfeeding or immunisation uptake. Little evidence was identified regarding the effectiveness of more 'generalist' LHWs who are given responsibility for delivering a range of primary healthcare interventions.
- In South Africa, norms and traditions regarding breastfeeding as well as differing baseline levels of breastfeeding and high rates of HIV/AIDS among mothers may alter the applicability of the review findings on LHWs for breastfeeding promotion

3. Are there important differences in health system arrangements that may mean an option could not work in the same way?
- In South Africa, LHWs are not licensed to dispense antibiotics for the treatment of acute respiratory infections in children or to dispense anti-malarial drugs. It may therefore be difficult in the short- to medium-term to extend their scope of practice in this way, even if shown to be effective in a review
- In South Africa, most LHWs are employed by NGOs, who receive funding from the government for the LHWs' salaries. It is not clear how secure this funding mechanism is

4. Are there important differences in the baseline conditions that might yield different absolute effects – even if relative effectiveness was the same?
- Baseline immunisation rates may be lower in South Africa than in some of the settings where the studies on LHWs for immunisation were conducted (Ireland, USA). Higher absolute effects might therefore be anticipated in South Africa

5. What insights can be drawn about options, implementation, and monitoring and evaluation?
- Most of the LHW interventions shown to be effective were focused on single tasks. The effectiveness of 'generalist' LHWs who deliver a range of primary healthcare interventions needs evaluation

Conclusions

Assessments of the applicability of the findings of a systematic review can take a lot of time to do well. Such assessments are critical, however, when an option is being proposed on the basis of a relevant high-quality systematic review. Policymakers and other stakeholders need to know whether they can expect similar findings in their own settings. Unlike an assessment of the quality of a review, which can often be delegated to researchers, a local applicability assessment must be done by individuals with a very good understanding of on-the-ground realities and constraints, health system arrangements, and the baseline conditions in the specific setting. The assessment of local applicability is a domain in which policymakers and those who support them need to be actively engaged.

Resources

Useful documents and further reading

- Dans AL, Dans LF, Guyatt GH: **Applying results to individual patients.** In *Users' Guides to the Medical Literature. A Manual for Evidence-Based Clinical Practice.* Edited by Guyatt GH, Rennie D, Meade MO, Cook DJ. New York, USA: McGraw Hill; 2008.

- Haynes RB: **Can it work? Does it work? Is it worth it?: The testing of healthcare interventions is evolving.** *BMJ* 1999, **1999:** 652-653.

Links to websites

- *SUPPORT Collaboration:* www.support-collaboration.org – Example of a source of policymaker-friendly summaries of systematic reviews that provides an assessment of the applicability of the findings of each review (in this case to low- and middle-income countries), and that highlights the factors that policymakers need to bear in mind when assessing the applicability of the findings to their own setting

- *European Observatory on Health Systems and Policies:* www.euro.who.int/observatory/hits/20020525_1 – Example of a source of (Health in Transition) profiles of the health systems of a large number of middle- and high-income countries

- *Health Policy Monitor:* www.hpm.org/en/Search_for_Reforms/Search.html – Searchable online database of key health system features in a number of middle- and high-income countries

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10. Taking equity into consideration when assessing the findings of a systematic review

Andrew D Oxman, John N Lavis, Simon Lewin, Atle Fretheim

Summary

In this chapter we address considerations of equity. Inequities can be defined as "differences in health which are not only unnecessary and avoidable but, in addition, are considered unfair and unjust". These have been well documented in relation to social and economic factors. Policies or programmes that are effective can improve the overall health of a population. However, the impact of such policies and programmes on inequities may vary: they may have no impact on inequities, they may reduce inequities, or they may exacerbate them, regardless of their overall effects on population health.

We suggest four questions that can be considered when using research evidence to inform considerations of the potential impact a policy or programme option is likely to have on disadvantaged groups, and on equity in a specific setting. These are:

1. Which groups or settings are likely to be disadvantaged in relation to the option being considered?
2. Are there plausible reasons for anticipating differences in the relative effectiveness of the option for disadvantaged groups or settings?
3. Are there likely to be different baseline conditions across groups or settings such that that the absolute effectiveness of the option would be different, and the problem more or less important, for disadvantaged groups or settings?
4. Are there important considerations that should be made when implementing the option in order to ensure that inequities are reduced, if possible, and that they are not increased?

Scenario

You work in the Ministry of Health. Improving drug insurance coverage for essential medicines is a government priority. The Minister of Health has asked you to present options for increasing coverage, including the expected impacts of such options on disadvantaged populations. You decide to commission a policy brief from a unit that supports the Ministry of Health in using evidence in policymaking. You ask them to pay particular attention to the likely impacts of alternative policies on inequities

You work in the Ministry of Health. Improving drug insurance coverage for essential medicines is a government priority. The Minister of Health has asked you to present options for increasing coverage, including the expected impacts of such options on disadvantaged populations. You decide to commission a policy brief from a unit that supports the Ministry of Health in using evidence in policymaking. You ask them to pay particular attention to the likely impacts of alternative policies on inequities.

Background

In this chapter, which is the fourth addressing the use of systematic reviews to inform policy decisions (see Figure 10.1), we suggest four questions that policymakers can consider when assessing the potential impacts a policy or programme is likely to have on disadvantaged populations and on equity. Such questions could be applied, for instance, in the scenario outlined above. For policymakers, such as a Health Minister or senior staff member in a Ministry, this chapter suggests a number of questions that staff might be asked to consider when preparing a policy brief regarding impacts on inequities. For those who support policymakers, such as those who are asked to prepare policy briefs, this chapter suggests questions that can be used to guide considerations when using research evidence regarding impacts on inequities, particularly when using evidence from systematic reviews [1].

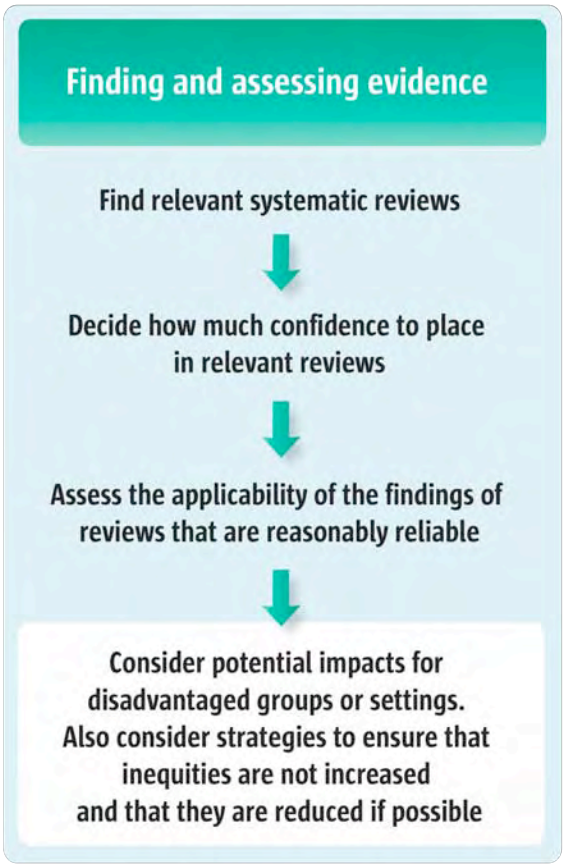

Figure 10.1
Step 4 in finding and assessing systematic reviews to inform policymaking: equity considerations

We will not provide guidance for addressing inequities, which must be considered in relation to specific settings and policies. Rather, we will present a structured approach to considering the impacts of policy and programme options on inequities, to inform decisions about what options to implement and how to implement them.

Braveman and Gruskin define equity as "the absence of disparities in health that are systematically associated with social advantage or disadvantage" [2]. Margaret Whitehead emphasises the elements of disadvantage even more clearly by defining inequity as "differences in health which are not only unnecessary and avoidable but, in addition, are considered unfair and unjust" [3].

Inequities in health and healthcare are well documented in relation to a variety of social and economic characteristics. Disadvantaged populations almost always have poorer health [4], poorer access to healthcare [5], and receive poorer quality healthcare [6]. Policies or programmes that are effective can improve the overall health of the population. However, their impact on inequities may vary: they may have no impact on inequities, they may reduce inequities, or they may exacerbate them regardless of their overall effects on population health. It is therefore not sufficient for policymakers simply to know that a policy or programme is effective. They also need to consider how a policy or programme may impact on inequities. If it is likely to exacerbate these they also need to consider how such effects could be ameliorated. Many effective interventions to reduce smoking, for example, are taken up more readily by more advantaged groups, and this can lead to the widening of differences in smoking rates and health inequities if specific actions are not taken to address this.

Questions to consider

The following questions can guide assessments of the potential impacts a policy or programme option is likely to have on disadvantaged populations and equity:

1. Which groups or settings are likely to be disadvantaged in relation to the option being considered?
2. Are there plausible reasons for anticipating differences in the relative effectiveness of the option for disadvantaged groups or settings?
3. Are there likely to be different baseline conditions across groups or settings such that that the absolute effectiveness of the option would be different, and the problem more or less important, for disadvantaged groups or settings?
4. Are there important considerations that should be made when implementing the option in order to ensure that inequities are reduced, if possible, and that they are not increased?

The logic behind these questions is illustrated in Figure 10.2.

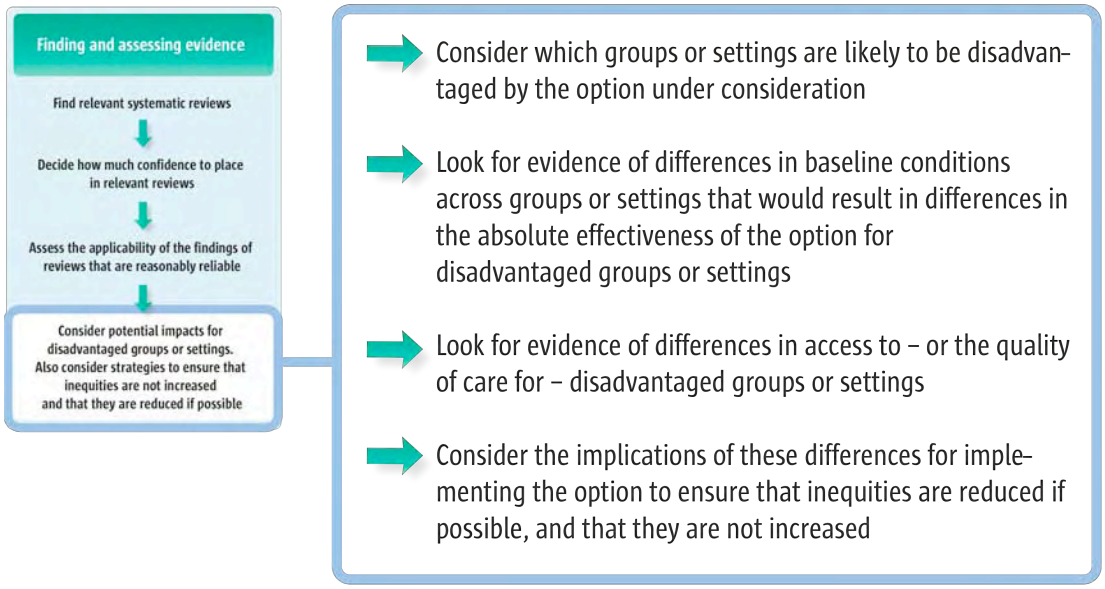

Figure 10.2
Four steps to identifying and incorporating equity considerations when assessing the findings of a systematic review

1. Which groups or settings are likely to be disadvantaged in relation to the option being considered?

Disadvantage may be related to economic status, employment or occupation, education, place of residence, gender, ethnicity, or combinations of these characteristics. Different societies give greater or lesser attention to particular factors due to historical circumstances. For example, in the United States of America there is often a greater focus on issues of race, while in the United Kingdom it is social class that draws attention. Other countries may focus on specific ethnic groups.

The relevance of these characteristics may vary depending on the policy or programme of interest. While there may be good reasons for prioritising particular groups or settings generally, for specific policies or programmes it is often important to consider inequities in relation to a range of potentially disadvantaged groups or settings. Subsequent attention should focus on those groups or settings for which there is a reason to anticipate significant differential effects.

Generally, researchers and policymakers should be concerned about differential effects whenever there is an association between the mechanism of action of the policy or programme, and particular characteristics. For example:

- *Economic status*: low-income populations are more likely to be responsive to changes in the prices of goods and services. Because they have less disposable income, tobacco tax increases, for example, could make such populations more likely to quit. But they would also be made more vulnerable as a result of having to spend more money on tobacco if they did *not* quit smoking
- *Employment or occupation*: employer-funded insurance schemes may result in differences in coverage, with less coverage being likely for those who are unemployed, self-employed or employed in small companies
- *Education*: school-based programmes would be expected to differentially affect those who attend versus those who do not attend schools. Information campaigns that rely on printed materials to improve the utilisation of health services might have differential impacts on illiterate or less-educated populations
- *Place of residence*: access to care is commonly more difficult in rural areas. Any strategy, therefore, that does not take into account the need to improve the delivery of effective clinical or public health interventions is likely to be less effective in rural areas
- *Gender*: strategies for involving stakeholders in priority-setting may affect women and men differently, resulting in priorities that may have different impacts on women and men
- *Ethnicity*: ethnic groups (e.g. those groups who consider themselves, or are considered by others, to share common characteristics which differentiate them from other groups in society [7]) may have beliefs and attitudes relating to the acceptability of a particular policy or programme. Delivery strategies that do not take these perspectives into account are likely to be less effective amongst ethnic groups where an otherwise effective policy or programme might not be readily accepted

2. Are there plausible reasons for anticipating differences in the relative effectiveness of the option for disadvantaged groups or settings?

In Table 10.1 we present an example of a scenario in which one might anticipate differences in the relative effectiveness of a policy or programme. As described in the table, there are plausible reasons for anticipating differences in the relative effects of requiring user fees to pay for drugs or other health services on disadvantaged populations (such as the poor), compared to other populations that are not disadvantaged. When attempting to reduce disparities in such circumstances, policymakers should look for evidence of the impacts of the considered options on relevant disadvantaged populations. This evidence should be taken into consideration when deciding what action to take. For example, should user fees be used at all? And if they are used, how could they be designed and implemented in order to minimise their adverse effects on the poor?

Table 10.1
An example of a plausible reason for anticipating differences in relative effectiveness

User fees were widely introduced in sub-Saharan Africa as part of the Bamako Initiative adopted by Health Ministers of the WHO African Region in 1988 [8]. The Initiative advocated selling drugs to users at a profit: the intention was to use the profit, in addition to user consultations payments, to improve access to care and quality of service. Opinion remains divided on the impact of introducing user fees for accessibility to services, particularly on the very poor. This initiative has been the subject of much debate for more than 15 years but there can be no doubt that user fees are a financial barrier for poor people needing drugs or other health services [9,10].

In other instances where a third party pays all drug costs, patients may potentially have inappropriately high utilisation rates [11]. Direct cost-share policies shift part of the financial burden from insurers to patients and therefore increase patient financial responsibility for prescription drugs. These policies are intended to be an incentive to reduce the following: the overall overuse of drugs; the use of drugs of limited efficacy or those used for conditions where other, more cost-effective treatments are available; and third party payer expenditures. Patients are expected to respond to direct payments by decreasing drug use, by shifting to cheaper drugs, or by paying more costs out-of-pocket. By reducing the financial burden for third party payers and facilitating rational drug use, overall health levels may be improved by saving resources and reallocating them to other healthcare services.

However, a too-restrictive drug insurance policy may have unintended consequences. For example, a shift of cost from insurer to consumer may lead to the discontinuation of necessary drugs by patients. In turn, this may cause a deterioration of health and an increase in healthcare utilisation and expenditures for both patients and insurers. This is an unintended effect that is likely to have a larger impact amongst low-income or other vulnerable populations because such costs are likely to represent a more substantial proportion of total income. Schemes involving direct payment for drugs by patients are therefore controversial because increased cost sharing for drugs may present a financial barrier to the poor and other disadvantaged groups. Placing a cap on reimbursement for prescriptions has been shown to be linked to a reduction in the use of essential drugs in vulnerable subgroups of both elderly patients and severely disabled patients, and increases in hospitalisations and nursing home admissions [11].

Evidence of the effects of policies or programmes on inequities is sparse. Finding this evidence is also difficult [12], and publication bias may be an additional problem given that studies identifying statistically significant differences in effects are more likely to be published than those that do not [12]. Tsikata and colleagues, for instance, found that only 10% of controlled trials assessed the efficacy of a policy or programme across socio-economic subgroups [13]. Similarly, Ogilvie and colleagues found that Cochrane reviews of studies of tobacco control rarely assessed the impact of the policy or programme across socio-economic factors, both in the actual reviews and the primary studies in those reviews [14]. Systematic reviews generally tend not to provide evidence of differential effectiveness [14-18]. Because of this, it may be necessary to search for a wider scope of evidence than that which is typically found in systematic reviews. Such evidence may be needed to support or refute plausible hypotheses of differential effects, or the effects of policies or programmes on reducing inequities.

When subgroup analyses are undertaken in systematic reviews to explore whether there are differential effects, policymakers should be aware that these can be misleading. This is because studies may be too small to reliably detect differences in effects, resulting in false negative conclusions. Also, testing multiple hypotheses regarding factors that might moderate the effectiveness of a policy may result in false positive conclusions [19-23]. The results observed in subgroups, for instance, may differ by chance from the overall effect observed across studies [21,24]. Paradoxically, the best estimate of the outcome of a policy or programme in a subgroup may be the *overall* results (across different subgroups) rather than the specific results for the subgroup of interest [21,25,26]. General guidelines for interpreting subgroup analyses (see Table 10.2) should be applied with a healthy scepticism whenever subgroup analyses, including subgroup analyses based on socio-economic factors, are considered [27].

Similarly, there is often a lack of direct evidence related to disadvantaged populations given that they may not actually have been included in studies. In these circumstances, policymakers need to consider the applicability of the available evidence, as discussed in Chapter 9 [28].

Table 10.2
Guidelines for interpreting subgroup analyses

The following questions can help in the process of deciding whether a decision should be based on a subgroup analysis or the overall results:

Is the magnitude of the difference important?
If the magnitude of a difference between subgroups will not result in different decisions for different subgroups, then the overall results can be used.

Is the difference between subgroups statistically significant?
To establish whether a policy or programme has a different effect in different situations, the magnitudes of effects in different subgroups should be compared directly with each other. The statistical significance of the results within separate subgroup analyses should *not* be compared, as this is likely to be misleading. For example, if a subgroup analysis showed that the effect of a policy or programme was not statistically significant for women but was statistically significant for men, it is likely that this could simply be because few women were included in the studies. It does *not* answer the question of whether the difference between the size of the effect in women and men was greater than would otherwise have been expected if this had occurred by chance. If there is both an important difference in effects and that difference is statistically significant (i.e. it is unlikely to have occurred by chance), then serious consideration should be given to basing a decision on the subgroup analysis rather than on the overall analysis

Is there indirect evidence in support of the findings?
Indirect evidence is research that has not directly compared the options in which we are interested in the populations in which we are interested, or measured the important outcomes in which we are interested. For differences between subgroups to be convincing, they should be plausible and supported by other external or indirect evidence. For example, research that has measured intermediary outcomes (not the ones in which we are interested) can provide evidence of a plausible mechanism for differential effects. For subgroup analyses for disadvantaged groups, there should be a similarly plausible reason - supported by indirect evidence - to anticipate differential effects

Was the analysis pre-specified or post hoc?
Researchers should state whether subgroup analyses were pre-specified or undertaken after the results of the studies had been compiled (post hoc). Greater reliance may be placed on a subgroup analysis if it formed part of a small number of pre-specified analyses. Performing numerous post hoc subgroup analyses could be seen as data dredging, a process that is inherently unreliable. This is because it is usually possible to find an apparent – but false – explanation for differences in effects when considering many different characteristics

Are analyses looking at within-study or between-study relationships?
Differences in subgroups that are observed within studies are more reliable than analyses of subsets of studies. If such within-study relationships are replicated across studies then this will add confidence to the findings

3. Are there likely to be different baseline conditions across groups or settings such that that the absolute effectiveness of the option would be different, and the problem more or less important, for disadvantaged groups or settings?

If the *relative* effectiveness of a policy or programme is similar in disadvantaged settings, there may still be important differences in the *absolute* effect due to differences in baseline conditions (see Figure 10.3 for an illustration, Table 10.3 for an example, and Table 10.4 for an explanation of relative and absolute effects). Typically, baseline risks are larger in disadvantaged populations and a larger absolute effect could therefore be expected. If the relative effect of improving the delivery of artemisinin combination therapy (ACT) on mortality from malaria is the same for disadvantaged children as it is for other children, for example, the absolute effect would be greater in disadvantaged populations that have a higher mortality rate. Risks may occasionally be lower in disadvantaged populations and, in these instances, the absolute effect will also consequently be less. The baseline risk for coronary artery disease among Filipinos is about one-fifth of the baseline risk in the United States of America. Therefore the number of people it is necessary to treat (and the corresponding cost) in order to prevent one case of coronary artery disease, is five times greater among Filipinos.

Figure 10.3
Absolute versus relative reductions in risk

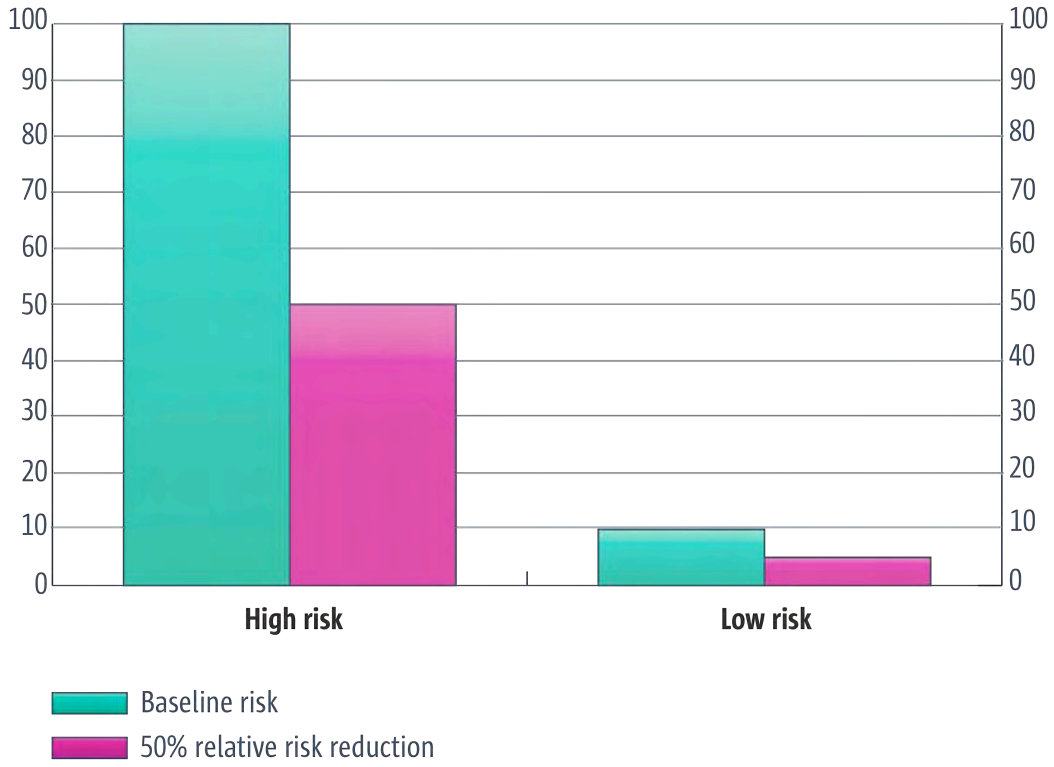

Table 10.3
An example of a difference in baseline conditions leading to a difference in absolute effectiveness

Facility-based births can help to reduce maternal mortality when such facilities are appropriately equipped and staffed by skilled health workers who are able to deliver effective interventions to reduce deaths from the common causes of maternal deaths, such as haemorrhage and eclampsia. Typically, proportions of facility-based births are lower in rural areas than in urban areas due to variations in accessibility. Paying transportation costs to improve access to facilities might reduce inequities. This is because payments may be more effective in rural areas where transportation costs are more of a barrier. It is also due to the lower proportion of facility-based births in rural areas (which thus increases the absolute effect).

Table 10.4
Relative and absolute effects

Relative effects are ratios. For example, a risk ratio (RR) is the ratio between the risk in an intervention group and the risk in a control group. If the risk in an intervention group is 2% (i.e. 20 per 1,000) and the risk in a control group is 2.4% (i.e. 24 per 1,000), the risk ratio (or relative risk) will be 20/24 or 83%. 'Relative risk reduction' is another way of expressing relative effects. This is the proportional or percentage reduction in risk, and is equal to 1-RR which, in this case, is 17% (1 - 0.83 = 0.17).

If the RR value is exactly 1.0, this means that there is no difference between the occurrence of the outcome in the intervention group and the control group. But the significance of this value being above or below 1.0 depends on whether the outcome being measured is judged to be good or bad. If the RR value is greater than 1.0, the intervention increases the risk of the outcome. If the desired outcome is considered to be good (for example, the birth of a healthy baby), an RR greater than 1.0 indicates a desirable effect for the intervention. Conversely, if the outcome is bad (for example, death) an RR value greater than 1.0 would indicate an undesirable effect. If the RR value is less than 1.0, the intervention decreases the risk of the outcome. This then indicates a desirable effect, if it is a bad outcome (for example, death) and an undesirable effect if it is a good outcome (for example, the birth of a healthy baby)

Absolute effects are differences. For example, absolute risk reduction (ARR) is the difference between the risk *with* the intervention and the risk *without* the intervention. In this example, the ARR is 2.0% (20 per 1,000) minus 2.4% (24 per 1,000) i.e. 0.4% (4 per 1,000) fewer deaths from bowel cancer.

Usually the absolute effect is different for high-risk groups (such as those who are disadvantaged) and low-risk groups, whereas the relative effect is often the same. When relevant, it is therefore important to consider whether different groups have different levels of risk. This is illustrated in Figure 10.3, where a 50% relative reduction in risk is shown to result in an absolute reduction of 50 events per 1,000 in the high risk group (from 100 to 50) and an absolute reduction of only 5 per 1,000 in the low risk group (from 10 to 5)

4. Are there important considerations that should be made when implementing the option in order to ensure that inequities are reduced, if possible, and that they are not increased?

Disadvantaged populations generally have poorer access to care and often receive poorer quality care. This is particularly true for hard-to-reach populations, such as illegal immigrants. Consequently, programmes to improve access and the quality of care will often require implementation strategies tailored to address factors that limit access or quality in disadvantaged settings or groups (see Table 10.5, for example). Such methods may include different delivery, financial and governance strategies, or the investment of additional resources. They may also include the provision of additional technical support to implement non-tailored strategies for such groups.

Table 10.5
An example of important considerations regarding implementation

There is a greater likelihood that disadvantaged children compared to more advantaged children will be exposed to greater health risks, have less resistance to disease, and will therefore have higher mortality rates. These inequities are compounded by reduced access to health services. Even public subsidies for health frequently benefit rich people more than poor people. Implementing interventions to reduce child mortality will not necessarily reduce these inequities and may, in some cases, even increase them. Consideration should thus be given to strategies designed to reduce inequities, such as the provision of more affordable and accessible health services [29]. These strategies may target poor people or they may be implemented universally. Situations in which targeting or universal coverage might be more appropriate include [29]:

Targeting more likely to be appropriate	**Universal coverage more likely to be appropriate**
• High risk groups easy to identify	• High risk groups hard to identify
• Intervention only needed by children at risk	• Intervention needed by everyone
• Intervention only protects those who receive it	• Intervention has a spill-over effect
• Intervention is widely provided through the public sector	• Intervention is widely provided through the private sector
• Spontaneous demand for the intervention is low	• Spontaneous demand for the intervention is high
• Health services are unable to cover the whole population	• Health services are able to cover the whole population

Universal coverage may be a more appropriate strategy for vaccines, which are needed by everyone and which have spill-over effects (decreasing the risk of infection for both those who are vaccinated and others). However, in order to also reduce inequities in coverage, additional targeted strategies may be needed such as those that address problems with regard to differences in health service accessibility or to a lack of demand for vaccinations in disadvantaged populations

Conclusion

Policymakers can expect to find limited evidence of the impacts of most health policies on inequities. When they are presented with subgroup analyses that explore whether there are different impacts on specific disadvantaged groups or settings, they should recognise that

these analyses may be misleading. Many policies or programmes may, in fact, have similar relative effects in disadvantaged settings and elsewhere. Nonetheless, differences in absolute effects (due to differences in baseline risks or needs) and differences in barriers to implementing them, are likely to be common. The evidence for such differences should be considered and taken into account when making policy decisions. Because the evidence is often limited, it is important to ensure that the monitoring and evaluations of impacts on equity are as rigorous as possible to ensure that intended effects are achieved and that unintended adverse effects are avoided.

To monitor or evaluate the extent to which implementing policies or programmes differentially affects disadvantaged populations, policymakers should ensure that appropriate indicators of social gradients and measures of change are used. When the reduction of inequities is a priority for policymakers, they should look beyond considerations related to the impacts of health system arrangements on disadvantaged populations. They may also want to consider potential strategies for addressing the social determinants of health and the evidence supporting those strategies [30].

Resources

Useful documents and further reading

- Oxman AD, Fretheim A, Schünemann for SURE. Improving the use of research evidence in guideline development: 2. Incorporating considerations of equity. Health Res Policy Syst 2006; 4:24. www.health-policy-systems.com/content/4/1/12 – This article reviews the literature on incorporating considerations of equity in guidelines and recommendations

- Dans AM, Dans L, Oxman AD, Robinson V, Acuin J, Tugwell P, Dennis R, Kang D. Assessing equity in clinical practice guidelines. J Clin Epidemiol. 2007; 60:540-6. www.ncbi.nlm.nih.gov/pubmed/17493507 – This article discusses criteria for users to evaluate how well clinical practice guidelines address issues of equity

- Braveman PA and Gruskin S. Defining equity in health. J Epidemiol Community Health 2003; 57:254-8. http://jech.bmj.com/cgi/content/full/57/4/254

- Whitehead M. The concepts and principles of equity and health. Int J Health Serv 1992; 22:429-45. www.ncbi.nlm.nih.gov/pubmed/1644507

- Tugwell P, de Savigny D, Hawker G, Robinson V. Applying clinical epidemiological methods to health equity: the equity effectiveness loop. BMJ 2006; 332:358-61. www.bmj.com/cgi/content/full/332/7537/358

Links to websites

Although the focus of this chapter (and others in this book) is on policies within the health sector, we have included links to websites that also focus more broadly on the determinants of health. These are relevant to evidence-informed policymaking both within and outside the health sector.

- *Archives of equidad@listserv.paho.org* – This is the archive of the Pan American Health Organization's (PAHO's) EQUIDAD list. Messages sent to the list cover a broad range of

material, both in published and grey literature, and address all aspects of equity in health as well as other health systems topics

- *Cochrane Health Equity Field:* http://equity.cochrane.org/en/index.html – The Cochrane Health Equity Field forms part of the Cochrane Collaboration (www.cochrane.org). It is co-registered with the Campbell Collaboration (www.campbellcollaboration.org) as the Campbell Equity Methods Group. This Field encourages and supports the authors of systematic reviews to include explicit descriptions of the effects of interventions on the disadvantaged and the ability of interventions to reduce inequalities

- *European Portal for Action on Health Equity:* www.health-inequalities.eu – This portal is a tool to promote health equity amongst different socio-economic groups in the European Union. It provides information on policies and interventions to promote health equity within and between the countries of Europe

- *WHO – Commission on Social Determinants of Health:* www.who.int/social_determinants/en – The final reports on the WHO Commission on Social Determinants of Health are available here. They are intended to support countries and global health partners to address the social factors leading to ill health and inequities. These reports draw attention to the social determinants of health that are known to be among the worst causes of poor health and inequalities between and within countries. The determinants include unemployment, unsafe workplaces, urban slums, globalisation and a lack of access to health systems

- *World Bank – Multi-Country Projects in Equity, Poverty, and Health:* http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTHEALTHNUTRITIONANDPOPULATION/EXTPAH/0,,contentMDK:20219025~menuPK:460198~pagePK:148956~piPK:216618~theSitePK:400476~isCURL:Y,00.html – Recent increases in concern related to the health of the poor have given rise to a large number of inter-country research projects on poverty, equity and health. This website provides links to other resources for information on equity, poverty and health

- *EQUINET Africa:* www.equinetafrica.org – EQUINET, the Regional Network on Equity in Health in Southern Africa, is a network of professionals, civil society members, policymakers, state officials and others within the region who have come together as an equity catalyst, to promote and realise shared values of equity and social justice in health

- *Global Equity Gauge Alliance:* www.gega.org.za – The Global Equity Gauge Alliance was created to support an active approach to monitoring health inequalities and to promote equity within and between societies. The Alliance currently includes 11 member-teams, called Equity Gauges, located in 10 countries in the Americas, Africa and Asia

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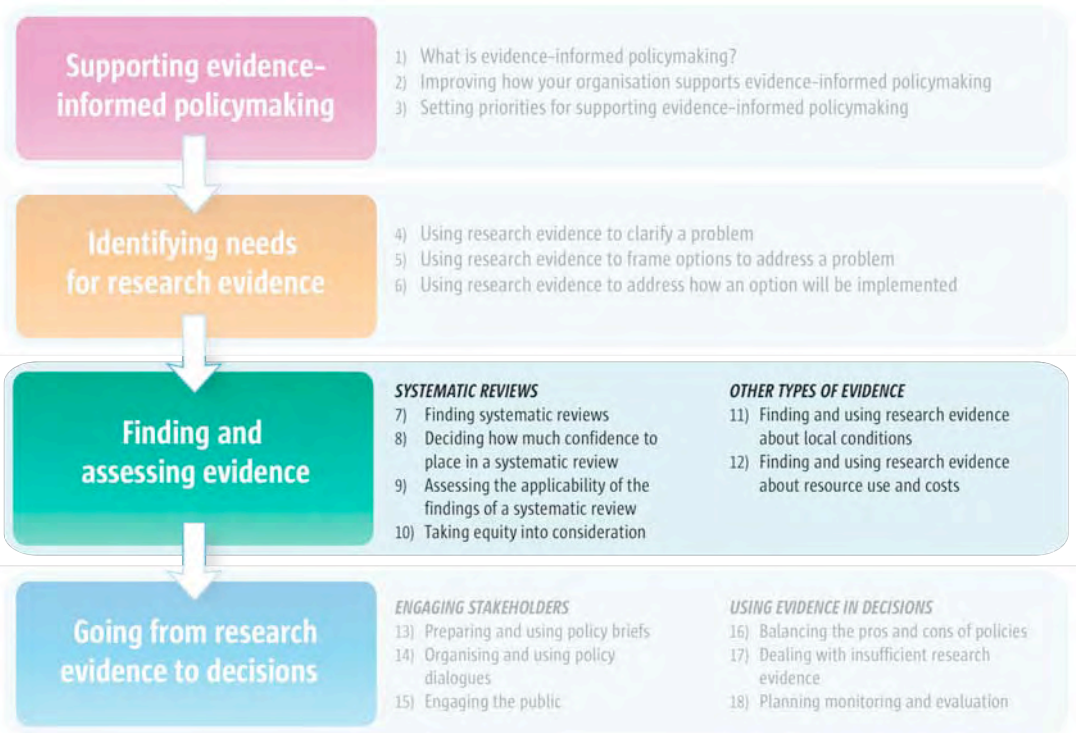
Chapters 11 and 12
Finding and assessing other types of evidence



11. Finding and using evidence about local conditions

Simon Lewin, Andrew D Oxman, John N Lavis, Atle Fretheim, Sebastian Garcia Marti, Susan Munabi-Babigumira

Summary

Evidence about local conditions is evidence that is available from the specific setting(s) in which a decision or action on a policy or programme option will be taken. Such evidence is always needed, together with other forms of evidence, in order to inform decisions about options. *Global evidence* is the best starting point for judgements about effects, factors that modify those effects, and insights into ways to approach and address problems. But local evidence is needed for most other judgements about what decisions and actions should be taken. In this chapter, we suggest five questions that can help to identify and appraise the local evidence that is needed to inform a decision about policy or programme options. These are:

1. What local evidence is needed to inform a decision about options?
2. How can the necessary local evidence be found?
3. How should the quality of the available local evidence be assessed?
4. Are there important variations in the availability, quality or results of local evidence?
5. How should local evidence be incorporated with other information?

Scenarios

Scenario 1: *You are a senior civil servant and have responsibility for putting forward a proposal for a new health reform. You want to ensure that the proposal clearly states the number of people likely to benefit from the health reform as well as the views of stakeholder groups regarding the new initiative*

Scenario 2: *You work in the Ministry of Health and the Minister has decided on a new health reform. You have been instructed to write a background document for the reform and need to find information on the availability of resources to implement the planned changes and possible barriers to implementation*

Scenario 3: *You work in an independent unit that supports the Ministry of Health in its use of evidence in policymaking. You have been commissioned to write a background document for a new health reform that may affect access to care. You need to find information on access to care for the elderly and for those with low incomes in your setting*

Background

This chapter suggests a number of questions that decision makers (Scenario 1) might ask their staff to consider regarding the finding and use of evidence on local conditions to inform health policy or programme options.

The chapter also suggests a number of questions that those who support decision makers (Scenarios 2 and 3) should consider both when guiding the identification and appraisal of

evidence from their local setting to inform a decision on health policy or programme options, and when incorporating this evidence into health policymaking.

Options should always be informed by evidence about local conditions (hereafter referred to as local evidence) together with other forms of evidence. *Global evidence* – the best evidence from around the world – is the best starting point for judgements about the effects of options and factors that modify those effects [1], and for developing insight into ways in which problems can be approached and addressed. *Local evidence* is needed for most other judgements about what decisions and actions should be taken.

Local evidence is evidence that is available from the specific setting(s) in which a decision or action on an option will be taken. The word 'local' in this instance can refer to district, regional or national levels, depending on the nature of the policy issue being considered. Such evidence might include information on the presence of factors that modify the impacts of a policy (the *modifying factors*). Such modifying factors might include: the characteristics of an area and those who live or work in it; the need for services (prevalence, baseline risk or status); views and experiences; costs; political traditions; institutional capacity; and the availability of resources such as staff, equipment and drugs.

Local evidence may be obtained from a range of sources including: routine data (e.g. on the prevalence of diseases, healthcare utilisation, or service costs); survey data (e.g. on household conditions, health and demographics); and data from one-off studies (e.g. trials conducted locally, studies of consumers' views regarding a particular health issue, and cost-effectiveness evaluations). However, local evidence is often assessed only informally or not at all as part of policymaking processes. In some settings, such information may be difficult to locate or may be of poor quality. This chapter provides a systematic approach to finding, assessing, and incorporating local evidence into policymaking.

There are a number of ways in which local evidence may be useful (see Table 11.1 for a list of some of these). For example, policymakers may need local evidence on the prevalence or magnitude of a health issue in order to contextualise (and make relevant) the evidence available from global reviews or studies conducted elsewhere [2]. (See Table 11.2 for a discussion of this issue in the context of malaria treatment in Tanzania and Brazil.) Evidence based on information from the global, regional or national levels may not adequately describe a local situation. Local evidence may also be useful as part of a process of priority-setting for the development of evidence-informed policy and programme options [3]. Information on local delivery, financial or governance arrangements for healthcare may be needed to inform such decisions. The views and experiences of local stakeholders, such as health professionals or consumers, regarding a particular option constitutes another important form of local evidence [4,5]. (See Table 11.3 for examples of how local evidence has been used in Australia for assessing needs regarding general practice, and in South Africa regarding views about the use of insecticide-treated nets.) Finally, information on the local costs of an option and the availability of resources is essential in taking decisions regarding implementation and in planning the delivery of options [6-8]. (See Tables 11.4 and 11.5 for examples related to this issue in South Africa, Chile and the United States of America.)

Table 11.1
Uses of local evidence in informing decisions on options

Local evidence can be used to

- Estimate the magnitude of the problem or issue that the policy aims to address
- Diagnose the likely causes of the problem [9]
- Contextualise, and make relevant, evidence from global reviews of the effects of interventions (e.g. by providing comparative information on the range and outcomes of interventions implemented locally)
- Help select priorities for the development of evidence-informed policies and programmes
- Describe local delivery, financial, or governance arrangements for healthcare
- Inform assessments of the likely impacts of policy options (i.e. due to the existence of modifying factors)
- Inform judgements about values and preferences regarding policy options (i.e. the relative importance that those affected attach to possible impacts of policy options) and views regarding these options
- Estimate the costs (and savings) of policy options
- Assess the availability of resources (including human resources, technical capacity, infrastructure, equipment) needed to implement an intervention
- Identify barriers to implementing policy options
- Monitor the sustainability of programme effects over time
- Examine the effects of a policy option on particular local groups
- Examine the equity impacts of a programme following implementation

Table 11.2
Using local evidence to estimate the magnitude of the problem or issue that an option aims to address

A number of countries have amended their malaria policies to replace chloroquine with sulfadoxine-pyrimethamine as the first-line drug for malaria treatment, due to the growing levels of parasite resistance to chloroquine. In Tanzania, the impetus to amend treatment policies was based in part on evidence of a cure rate of approximately 40% for chloroquine, compared to 85-90% for sulfadoxine-pyrimethamine. This local evidence of the magnitude of the problem was drawn from sentinel sites across the country and linked to the growing burden of malaria morbidity and mortality observed in the country [10].

In some Latin American countries, there is concern regarding the extent to which the pneumococcal vaccine includes the serotypes that are common in the region. In order to estimate the size of this potential problem, information from local sentinel sites has been used to evaluate the match between the serotypes included in the vaccine and those prevalent in the region. In Brazil, for example, it was estimated that 67.5% of the cases of invasive disease in children under 5 years of age were produced by serotypes included in the seven valent pneumococcal conjugate vaccine [11]

Table 11.3
Using local evidence to inform judgements about values and views regarding options

The importance of involving consumers and communities in decisions regarding their healthcare is recognised widely. In Australia, the Consumers' Health Forum undertook consultations with consumers and consumer organisations to explore their needs and expectations regarding general practice. This evidence was gathered to inform policy development for the delivery of general practice services and the improvement of relations between key stakeholders. The evidence was fed into a number of Australian policy processes, including the government's General Practice Reform Strategy, the General Practice Strategy Review, and the development of co-ordinated care as proposed by the Council of Australian Governments [12].

The local acceptability of community-based malaria control interventions provides another example of consumer and community involvement. Indoor residual spraying (IRS) and insecticide-treated

nets – the two principal strategies for malaria prevention – are similar in cost and efficacy. The acceptability of these interventions varies across settings. In South Africa, both research and routine programme monitoring have highlighted community dissatisfaction with the IRS insecticide, DDT. This is due to the residue that DDT leaves on house walls and because it stimulates nuisance insects such as bedbugs. In certain areas of Mozambique, there are concerns that specific sleeping habits – for example, people sleeping outside due to the heat – might also negatively influence the uptake of nets [13,14]

Table 11.4
Using local evidence to estimate the costs (and savings) of options

WHO policy recommends the use of direct observation of treatment (DOT) for treatment delivery for tuberculosis (TB). DOT can be delivered in a number of ways, including through primary healthcare clinics and in the community. An alternative policy option is for patients with TB to self-supervise their own treatment. A study was done in Cape Town, South Africa to assess the costs associated with each of the clinic, community and self-supervised options for treatment delivery. Local data were used to assess the resource input requirements of these three alternative options over a six month period of treatment. These data were then used to estimate the cost per patient treated for each of the three supervision approaches. The results indicated that the cost (in South African Rands) per patient was R3,600 for clinic supervision, R1,080 for self supervision, and R720 for community supervision. The authors concluded that community-based DOT by a volunteer lay health worker may be less costly to the health services than either clinic-based or self supervision [15]. This cost information influenced the city's decision to expand the delivery of DOT using community-based lay health workers.

Policymakers in a Latin American country needed information on the costs of cochlear implants in order to assess the potential costs and savings of interventions to treat hearing loss. A search for local literature using Google identified a report from the Ministry of Health of Chile in which the costs were outlined for the replacement of various components needed for cochlear implants. These data were used to estimate the likely total cost of cochlear implants in the local setting. (The report can be found at: www.minsal.cl/ici/rehabilitacion/consentimiento_informado.pdf)

Table 11.5
Using local evidence to assess the availability of resources with a view to informing a decision regarding options

An increasing number of countries are adding the new human papillomavirus (HPV) vaccine to routine immunisation schedules, or are considering doing so. The vaccine is highly effective against the strains of the virus responsible for approximately 70% of cervical cancers, and has been recommended for routine immunisation in adolescent girls in the United States of America. However, implementation across the country is thought to be uneven. A study was undertaken in an area of North Carolina which had high rates of cervical cancer. The study explored barriers to vaccine delivery and uptake as perceived by healthcare providers. Medical practices noted a number of key concerns, including: inadequate reimbursement by insurance companies of the vaccination costs, the high cost of the vaccine (given that many consumers who needed it did not have adequate health insurance), the burden on practices in ascertaining the availability of insurance cover for each patient (given the varying policies of different insurers), and the high up-front cost to practices of purchasing and storing the vaccine. The study authors note that these resource concerns may act as barriers to the implementation of the national vaccination policy [16]

Local evidence may inform all stages of the policy process. For example, local evidence may place an issue on the policy agenda and so help to set policy goals. Local evidence may also be used by different stakeholders and interest groups to lobby for particular options. The Shack Dwellers Federation of Namibia, for example, provides support to local shack dweller associations for the collection of information on the socio-economic status of their members and other residents, and on the availability of local essential services. This information has been used to help identify local needs and also to provide local groups with a voice in government policy debates. Local groups are also able to use this information to lobby municipal officials and politicians in order to improve the quality of service provision in their areas and to make more land for housing accessible [17].

In addition to informing decisions about options directly, local evidence may be useful in monitoring the effects of a programme or policy over time in order to assess whether the anticipated impacts continue to be delivered [18]. (See Table 11.6 for a discussion of the use of local evidence in monitoring and evaluation in the context of antiretroviral treatment in South Africa.) Where data are collected routinely, some level of retrospective analysis may be possible and this can provide a baseline against which new programmes can be evaluated. Local evidence may also be useful in demonstrating trends in the effects of a programme across small geographic areas, such as neighbourhoods and districts, and in highlighting differences in implementation or uptake. Policymakers may also be concerned with the impacts of a programme on particular groups, such as vulnerable populations or minority groups. Local evidence may be useful in examining whether programme resources have been distributed equitably and if a programme is being implemented in ways that promote equity (see, for example, reference [19]).

Table 11.6
Using local evidence to monitor and evaluate policies

A national programme for the rollout of comprehensive HIV and AIDS care, including antiretroviral treatment (ART), has been implemented in South Africa. The Joint Civil Society Monitoring Forum – a local forum including a number of NGOs, research institutes and other stakeholders – was established to assist government with the effective and efficient implementation of the programme. A briefing document outlining the lessons from this process notes that: "Democracy may be portrayed by the public's ability to contribute to and influence the state's decisions and programmes. With regard to [ART] rollout, it has been reported that access to information has been a major challenge. Reportedly not all provinces have been willing to provide information in this regard. This has made monitoring and development of appropriate resolutions difficult" ([20] p3-4). The report also highlights difficulties with obtaining disaggregated data on HIV and AIDS expenditure. It notes how these difficulties, in turn, create problems with monitoring how global HIV/AIDS budgets are being spent, particularly with regard to relative spending on treatment versus prevention, care and support [20]. This example highlights the need for local evidence to effectively monitor the implementation of a key health programme

Policymakers should be cautious about using local evidence alone to assess the likely impacts of policy or programme options. Local evidence may be more directly relevant than studies conducted elsewhere, but it may also be less reliable due to important limitations in the studies that were done locally. In addition, even when reliable local evaluations are available, they may be misleading because of random errors. Judgements about whether to base a conclusion on a subset of the relevant evaluations (which happen to have been undertaken locally) or on the global evidence (including relevant studies undertaken in other settings) are better informed if made in the context of a systematic review of *all* of the relevant evaluations [1].

When a systematic review is unavailable and it is not feasible to conduct or commission one, local evidence alone may be used to inform decisions about options [21]. In these circumstances, policymakers should be aware of the risks of doing this, particularly if the local evaluation has important limitations (risk of bias) or is small (and therefore the results are imprecise). However, in (the relatively uncommon) circumstances where rigorous, directly relevant and large local impact evaluations are available [22], such evidence may be optimal for informing decisions.

Like all other forms of evidence, the reliability of local evidence needs to be appraised. In this paper we suggest five questions that can help to identify and appraise local evidence that is needed to inform a decision about options.

Questions to consider

The following five questions can be used to guide policymakers and others in identifying potential policy and programme options and finding related evidence.

1. What local evidence is needed to inform a decision about options?
2. How can the necessary local evidence be found?
3. How should the quality of the available local evidence be assessed?
4. Are there important variations in the availability, quality or results of local evidence?
5. How should local evidence be incorporated with other information?

The relationship between these questions is shown in Figure 11.1

1. What local evidence is needed to inform a decision about options?

A range of local evidence may be needed to inform a decision about options (see Tables 11.1 to 11.8 for examples of the use of local evidence at different stages of the policy process). The evidence needed will depend on the nature of the option or question under consideration, the context, and the availability of different forms of local evidence.

Figure 11.1
Finding and using evidence about local conditions to inform decisions about policy or programme options

Table 11.7
Using local evidence to diagnose the likely causes of a health issue

An Australian study of the factors affecting recreational physical activity found that while people living in disadvantaged areas had similar levels of access to public open space as those in wealthier locations, the equipment and space available in the disadvantaged areas were of lower quality. The study suggested that this may explain lower levels of use of these spaces in disadvantaged areas [23].

A province in Argentina detected an increase in maternal mortality. When looking for explanatory reasons, a recent local study was identified in which the causes of maternal mortality were assessed. The report also evaluated those aspects of healthcare that needed to be modified in order to decrease mortality. This local study suggested that abortion was the most common cause of maternal death.

(The report is available at: observatorio.msal.gov.ar/textos/37.pdf)

Table 11.8
Using local evidence to assess the likely impacts of options (i.e. the existence of modifying factors) and to identify barriers to implementing options

In Argentina, an evaluation was conducted of a regulation related to payments for obesity treatments, such as bariatric surgery. A national survey of cardiovascular risk factors was used to assess the extent to which obesity was a national problem. This survey provided data on the proportion of people who were overweight or obese and could therefore be used to assess the likely impacts of making different forms of obesity treatment available.
(This survey is available at: www.msal.gov.ar/htm/Site/enfr/resultados_completos.asp)

Canadian stakeholders participating in a deliberative dialogue about how to improve access to primary healthcare in Canada considered a variety of options. All of these included some form of transition from care which was physician-led to care which was team-led. An evidence brief, drawing on local evidence, was prepared to inform the dialogue. This identified four potential barriers to the implementation of the options:

1. Initial wariness among some patients of potential disruptions to their relationship with their primary healthcare physician
2. Wariness on the part of physicians of potential infringements on their professional and commercial autonomy, in the light of the private delivery component of the 'private delivery/public payment' arrangement with physicians
3. A potential lack of viability in terms of organisational scale in many rural and remote communities, and
4. Government willingness to extend public payment to other healthcare providers and teams while at the same time maintaining the existing public payment to physicians, as part of the 'private delivery/public payment' arrangement with physicians. This was considered to be a particular concern during a recession [24]

2. How can the necessary local evidence be found?

Local evidence may be obtained from routine health information systems, from larger surveys or studies that can be disaggregated, or from specific studies that have collected or analysed data on a local level. We discuss each of these in more detail below.

Like those processes related to global evidence of effects [25], the processes of searching for local evidence and making judgements regarding its inclusion and assessment should be systematic (i.e. systematic processes should be used to ensure that relevant research is identified, appraised and used appropriately) and should also be reported transparently. The selective use of local evidence (sometimes referred to as 'cherry picking') to demonstrate the

usefulness of a particular option, should be avoided as it may result in important data or information being omitted or overlooked during the decision making process. For example, including only the largest estimates of the size of a problem, such as the proportion of children who do not complete their vaccination schedule, will result in a poor understanding of a problem such as incomplete vaccination. It may also result in scarce resources being allocated to interventions that are not needed, that do not respond to local needs, or that may not be needed at the extent to which they are provided. Using the largest estimates of the proportion of children who do not complete their vaccination schedule to inform a decision regarding options, for example, may result in more resources being allocated to the vaccination programme than are actually needed. Similarly, relying only on data on average immunisation coverage across a large population to inform policy may be inadequate. Such evidence may conceal large inequities in coverage across specific areas or groups.

While a wide range of sources of local evidence may be available, this evidence may not be available in a form that addresses the policy question under consideration. For example, data may be available from a survey on household access to different forms of sanitation, such as flush toilets or pit latrines. However, these data may not have been analysed at the level of aggregation needed, such as a specific health district or region, and may not indicate whether the sanitation facilities were operational. It may therefore be necessary to undertake further analysis of available data or to make assumptions regarding the applicability of the data to a particular policy question. We discuss this further in Questions 4 and 5 below.

Local collected data obtained from the routine health information system:

National, district, or other local health authorities (or other organisations in the health system) often collect data routinely on a wide range of issues, including [26]:

- Risk factors: such as nutrition and blood pressure
- Mortality and burden of disease: this includes health outcomes such as child mortality, TB treatment outcomes, peri-operative deaths, infectious disease and cancer notifications
- Health service coverage
  - Coverage for clinical interventions or services such as childhood vaccinations or cervical screening rates
  - Health service utilisation information such as length of hospital stay, number of outpatient visits for specific health conditions, and prescription drugs dispensed
  - Routine surveys of patient satisfaction with care
- Health systems resources
  - Healthcare expenditures according to various cost centres and programmes
  - Human resource data such as numbers and grades of staff in different facilities and programmes, staff development programmes delivered, and staff absenteeism
  - Clinical performance data such as post-surgical infection rates, time to treatment for people with myocardial infarctions
  - Guidelines used for care delivery
  - Adherence to guidelines for care delivery
- Inequities in healthcare and health outcomes

For some of these sources, it may be possible to disaggregate data by specific groups, such as gender or age, or by specific local area, such as a neighbourhood or town [1]. Data from routine health information systems may not have been analysed systematically and considerable resources may be needed to undertake such analysis.

Good starting points for identifying local sources of routine data include the Health Information Departments of Ministries of Health, National Statistics Offices, and local health authorities. Increasingly, these departments publish lists of the range of data that they capture and analyse on the Internet. Many also regularly produce summary statistics. The City of Cape Town Health Department in South Africa, for example, publishes information on their website by sub-district for a small range of health indicators, such as number of live births, number of infant deaths, infant mortality rates, TB case loads and treatment outcomes (see: www.capetown.gov.za/en/cityhealth/Pages/CityHealth.aspx). The Association of Public Health Observatories also provides data on key health indicators for each local authority in England (see: www.apho.org.uk/default.aspx?QN=P_HEALTH_PROFILES). Local research institutions, health non-governmental organisations (NGOs), or the offices of bilateral or multi-lateral agencies, such as WHO country offices, may also be able to advise on local sources of routinely collected data. Some commercial databases may include useful local evidence, for example, related to local prices for drugs, their availability, and the use of other technologies. In general, local health authorities should maintain an overview of local sources of routinely collected data. Policymakers may want to familiarise themselves with these.

Data from larger surveys or studies that can be disaggregated to local level

Important data sources include large surveys or studies such as national censuses, regional surveys of access to basic facilities, and national demographic and health surveys. For some of these sources, disaggregation to the provincial or city level may be possible or may already have been conducted. For example, the Neighbourhood Statistics site of the United Kingdom Office for National Statistics (see: www.neighbourhood.statistics.gov.uk/Dissemination) allows users to find statistics for an area by entering its name or postcode. Data on a wide range of topics are available, including access to services, crime and safety, general health, and teenage pregnancies. Similarly, the website of Statistics South Africa includes information on a wide range of topics disaggregated to a provincial level. For example, this includes information, based on data from a national household survey, on health insurance coverage and health service consultations by province (see: www.statssa.gov.za).

For other datasets, analysis to the appropriate local level may not be conducted routinely. This may be feasible, though, if data are tagged by geographic area. The agency that conducted the survey or the agency housing these data should be able to advise on whether further disaggregation to the local level is possible. The process of further analysis is more complex and statistical support is therefore generally recommended. Some health data, such as the use of treatment services for sexually transmitted infections and HIV/AIDS, may be considered sensitive in nature. It may therefore not be possible to obtain data disaggregated to a local level if the agencies housing these data need to ensure that specific individuals cannot be identified from information placed in the public domain.

Specific studies that have collected and analysed data on a local area

Large numbers of research studies collect, analyse and report data focused on a local area such as a province of a country or a city. These studies may use a wide range of data collection and analysis methods. Studies that present data on a local area can be located in several ways:

- By searching (ideally with the help of an information specialist) global databases of published research papers, such as PubMed, the Cochrane Library or the WHO regional databases (e.g. the Latin American and Caribbean Health Sciences Database [LILACS]), using geographic terms such as ‘Caracas’ or ‘Buenos Aires’. PubMed includes a *hedge*, or

validated search strategy, that allows users to search for administrative databases studies, community surveys and qualitative studies (these may be helpful in providing information on utilisation patterns and on views and experiences, for example). This is available at: www.nlm.nih.gov/nichsr/hedges/search.html

- By searching (ideally with the help of an information specialist) sources of 'grey' or unpublished literature, such as Google Scholar, the WHO Library Information System (http://dosei.who.int/uhtbin/cgisirsi/Mon+May++4+21:00:46+MEST+2009/0/49), and OpenSIGLE (System for Information on Grey Literature in Europe: http://opensigle.inist.fr). Many local studies, such as operational research on health services, are published as reports on the web but may not be published in research journals. Grey literature is therefore a good source of such evidence
- By contacting local researchers in universities, research institutes or health departments or local research networks for relevant information, including unpublished study reports
- By contacting or searching the resources of health observatories such as the European Observatory on Health Care Systems (www.euro.who.int/observatory), the International Observatory on Mental Health Systems (www.cimh.unimelb.edu.au/iomhs), or the Africa Health Workforce Observatory (www.afro.who.int/hrh-observatory)

3. How should the quality of the available local evidence be assessed?

Like all other forms of evidence, the *quality* of local evidence needs to be assessed. Where data quality is poor, interpretation can be difficult and there is a danger that faulty conclusions may be drawn. When considering local evidence, it may be useful to differentiate between *data* (i.e. the raw product of measurements or observations) and *information* (i.e. data that are organised or analysed in relation to a specific question or issue and are therefore more useful for decision making [27]). Some of the potential problems with local evidence relate to data (e.g. the ways in which measurement was done). Others relate to *how* these data are converted into information (e.g. as part of the analysis process).

A number of factors may compromise the quality of routinely-collected local data. Healthcare workers who collate and enter data, for example, may be poorly trained in this task. Similarly, if they do not receive timely feedback, they may not understand the usefulness of the data to informing service delivery. Data entry may also compete with a large number of other care tasks in clinics or hospitals and central quality control may be inadequate [28]. Problems related to the quality of data may be difficult to rectify once data have been collected. In contrast, it may be easier to rectify inadequacies in information by re-running an analysis. Systems for the collection of local data should ideally be designed to provide useful and timely feedback of information to those who collect such data.

Most local evidence that is used to inform decisions about options is *descriptive* (i.e. it includes simple summaries of the sample and measures or outcomes included in the data) rather than *comparative* (i.e. based on the comparison of one set of data with another, for example by area or over time). There are some exceptions, such as evidence about inequities which relies on comparisons.

The descriptive nature of most local evidence has implications for assessing its quality. In the case of comparative studies, the assessment of quality is focused primarily on the risk of bias (i.e. the risk of "a systematic error, or deviation from the truth, in results or inferences" [29]). In contrast, key questions in assessing the quality of local evidence include the following (adapted from [18]. Also see Table 11.9 for a summary of questions that can be used to guide assessments of the quality of local evidence):

Table 11.9
Questions to guide assessment of the quality of local evidence

Main quality criteria	Sub-questions	Example of the assessment of the quality of local evidence: routinely collected data on TB treatment outcomes from TB Registers
Is the evidence representative?	• Is there a clear description of the source of the evidence? • If the evidence is drawn from a sample of the population of interest, is there a clear description of how the sampling was conducted? • Was the sampling approach appropriate (where applicable)? • Is there a description of how any inferences or generalisations were made to the wider population?	• TB Registers should routinely record information on each patient diagnosed with TB. The information is not based on a sample of the population of interest. It should therefore be representative of the demographics and treatment outcomes for people with TB in a particular setting, provided that it is completed for each person with TB
Is the evidence accurate?	• Is there a clear description of who collected the data? • Were the data collectors appropriately trained and supported in this task? • What tools were used for data collection? • Were appropriate tools used? • When were the data collected? • Was the quality of the data collected monitored and was the quality shown to be adequate? • How were the data analysed? • Was the method of analysis reported clearly? • Were any data limitations discussed?	• Most health authorities provide a manual, based on WHO guidance, for completion of the TB Register. This generally specifies what information should be collected and by whom. In using these data, policymakers need to check whether there is clear guidance on completion of the Register, whether TB programme staff have been trained in its use, whether there are mechanisms in place to check the quality of the data at clinic and district levels, and whether data compilation was done appropriately
Are appropriate outcomes reported?	• Is there a clear description of the outcome/s measured? • Is the outcome measure reliable? • Were these outcomes measured appropriately? • Do these outcomes provide a reasonable assessment of the health issue?	• A standard range of measures is generally included in TB Registers, based on WHO guidance. These are designed to assess the functioning of the TB programme. However, the data do not generally provide direct measures of issues such as patient satisfaction with the care provided by TB programme staff

- *Is the evidence representative?* This question focuses on whether the evidence correctly represents the wider population from which it is drawn or to which the findings are generalised. There are several components to this question: firstly, is there a clear description of the source of the evidence? Secondly, if the evidence is drawn from a sample of the population of interest, is there a clear description of how the sampling was conducted, and was the sampling approach that was used appropriate? Thirdly, is there a description of how any inferences or generalisations were made to the wider population?

- *Is the evidence accurate?* This question is concerned with whether the available data match, or are likely to match, the actual value of the outcome measured. When addressing this question, the user may want to consider whether there are clear descriptions of the processes through which the data were collected. Issues that should be addressed include: who collected the data and were they appropriately trained and supported in this task, what tools were used for data collection, when were the data collected, was the quality of the collected data monitored, how was the analysis done (were the methods of analysis reported clearly), and were any data limitations discussed

- *Are appropriate outcomes reported?* This question focuses on whether the measures reported in the data (such as treatment outcomes or health utilisation measures) are suitable for addressing the question for which the data will be used. When addressing this question, the user may want to consider whether there is a clear description of the outcome or outcomes measured, whether they are reliable, and whether these outcomes will provide a reasonable assessment of the health issue. If policymakers are considering, for example, how to improve the quality of care for people with TB, routinely-reported TB treatment outcomes may be a useful measure. This is because the completion of TB treatment is likely to be related to the quality of care received by patients

4. Are there important variations in the availability, quality or results of local evidence?

When assessing and using local evidence, it is important to be aware of variations in its availability, quality or results. Each of these issues is discussed below.

Availability: large variations always occur in the range or depth of available local evidence across geographic areas, jurisdictions or population groups. In many instances, this variation may simply reflect differences in the policies or capacity of health authorities or other agencies across different jurisdictions or areas. In some cases, however, variations in the availability of local evidence across groups or areas may reflect other underlying inequities. These may include the poor access that certain groups have to health facilities, or the failure of surveys to include 'hard to reach' groups such as migrant populations, those speaking other languages, or those living in remote or poorly serviced areas. Groups that are stigmatised on the basis of ethnicity or sexual orientation, for example, or because they are viewed as illegal migrants, may also be reluctant to identify themselves as belonging to these groups for the purposes of data collection [30,31]. There may therefore be little available local evidence related to these groups and collecting such data may be very challenging. Those using local data need to explore the reasons for variations in its availability and consider such factors in the decision making process.

Availability may be limited in other ways. Firstly, evidence may be available from only one source, making it difficult to cross-check the information's reliability. Secondly, information may be available for a large area that includes the area of policy interest but in a form that does not allow this local area information to be separated from the wider dataset. Thirdly,

policymakers may have access to good quality data from a neighbouring area and may then have to assess the extent to which these data can be generalised to the area of interest. Finally, local evidence may be available only for an indicator assessing a related health issue. For example, policymakers in Colombia required data on the number of hospitalisations for meningitis but this information was not available routinely. However, the number of deaths due to meningitis in Columbia was available from the WHOSIS information system (http://apps.who.int/whosis/database/mort/table1.cfm). In addition, data on meningitis mortality rates were available from a local source (www.scielo.br/pdf/rsap/v8s1/v8s1a04.pdf). From these two sets of data, it is possible to estimate the total number of meningitis cases in the country.

Quality and results: different sources of local evidence may differ in quality. In addition, the quality of local evidence may differ from that of other forms of evidence used in decision making. For example, a study of routine malaria data in Mozambique compared paper-based district records of adult inpatient malaria cases and deaths with digital data captured at the provincial level. Large discrepancies between these sources of data were identified (a 62% difference for cases and a 48% difference for deaths). The authors suggested that these variations may be related to errors in the data entry process at the provincial level [32]. Such differences in data quality should be considered explicitly in the decision making process.

Variations in the results of local evidence on a particular health issue across sources of local evidence may occur for a number of reasons, including:

- Differences in the way in which the issue was defined and measured across the sources
- Differences between the individuals, groups or other entities about whom data were collected across the sources
- Differences in the comparators used
- Differences (where applicable) in the interventions delivered
- Differences in the ways in which data were collected and analysed across the sources

When considering such variations, users of these data should explore the following questions:

- Is the variation potentially important from a clinical or policy perspective?
- If the variation is important, is a reasonable explanation clear from the data sources, or can a reasonable explanation be hypothesised (e.g. differences in recruitment, measurement, analysis etc.)?
- Are there other sources of information against which the local evidence can be compared?

Users of data should document any decisions they take regarding the interpretation of the evidence and should note any uncertainties, as discussed below.

5. How should local evidence be incorporated with other information?

Policy decisions require a combination of *global evidence* (the best available evidence from around the world) – ideally from systematic reviews – and different types of *local evidence*, assumptions and judgements. When local evidence is key to a policy decision (i.e. it might influence a decision in one direction or another) it is important to:

- Describe the approach used to *identify* the local evidence. Ideally a systematic approach to accessing this evidence should be used
- Describe the approach used to *assess* the local evidence. As noted earlier, a systematic approach to assessing evidence is recommended. When shortcuts are necessary, or it is necessary to make assumptions or use informal observations, these should be made transparent

- Describe clearly what local evidence is used and from where the evidence is obtained. This should include detail related to the specific groups or communities from which the evidence is drawn. As far as possible, documents and other sources should be cited and made available to others involved in the decision making process
- Describe any important gaps or uncertainties in the evidence due to the lack of local information or its poor quality. A study of the use of data available from the national Australian Childhood Immunisation Register, for example, found that there were challenges in using the Register to adequately measure immunisation rates and outcomes in specific populations, such as remote indigenous groups [21]. Similar uncertainties have been reported from LMICs [33,34]. There may also be uncertainties in evidence due to conflicting findings between different sets of local evidence. For example, hospital mortality rates, complication rates, or duration of stay in intensive care may all be used to assess the quality of surgical care. Studies have found a poor correlation between these different indicators [28,35,36]. Consequently, it may be difficult to decide which set of data best reflects the 'real' quality of surgical services in a hospital or region and therefore which dataset should be used to inform policymaking. The applicability of local evidence to particular population subgroups may also be uncertain. For example, local evidence on teenage pregnancy rates may be available for the general population but not available by population subgroups (e.g. by ethnicity or language)
- Finally, it is important to identify and discuss any differences between the findings obtained from *global* evidence and those obtained from *local* evidence. For example, global evidence suggests that lay health workers can be effective in improving the uptake of immunisation in children [37]. However, local evidence might suggest otherwise if there are strong local views that lay people are inadequately qualified to provide health advice. In this instance, the promotion of this cadre would be less effective locally. Such local evidence might lead to less confidence (i.e. greater uncertainty) about the applicability of global evidence on lay health workers for immunisation uptake, even though the global review would still be seen as providing the best available estimate of effectiveness. Caution also needs to be used in applying economic evidence from other settings to a particular jurisdiction as the relative costs of some inputs may vary greatly across settings. For example, human resource costs generally vary locally while pharmaceutical costs may be similar across settings

A good understanding of the local context and conditions may be helpful in interpreting both local and global evidence [38]. Key elements of context that should be considered include: the physical context (such as health facilities, supply chains, banking systems, etc.), human resources, knowledge (including the skills to implement a policy or intervention), the socio-cultural context (including issues such as belief systems, values, corruption, etc.), and the political context. Tools such as political mapping may be useful in developing an understanding of political context [39,40].

Approaches such as rapid appraisal can be used to bring together the range of different data available at the local and global levels to address a specific policy question. For example, this approach has been used to draw together data related to the management of diabetes care in Georgia and in Kyrgyzstan [41,42]. Local evidence, together with an appraisal of its reliability, may also be incorporated into policy briefs and a range of other documents that are used to inform policy processes. We discuss the use of policy briefs in more detail elsewhere [43].

Conclusion

Local evidence may inform all stages of the policy process – from influencing the policy agenda through to shaping programme choices and monitoring programme sustainability (see Table 11.10 for examples of the types of local evidence that might be relevant to specific policy questions). Such evidence may be obtained from routine health information systems, from surveys or studies that can be disaggregated, or from studies in which data have been collected or analysed on a local level. Both the evidence needed and the evidence available will depend on the nature of the policy question under consideration and the context.

In many settings, steps need to be taken to improve the quality and use of data about local conditions. These may include motivating data collectors by ensuring that such information is useful to them and fed back in a timely way. It may also be necessary to ensure that policymakers and those who support them are aware of the sources of data about local conditions. As with other forms of evidence, the quality of local evidence needs to be assessed. Policymakers should be cautious about using local evidence alone to assess the likely impacts of policy or programme options. Local evidence may be more directly relevant than studies conducted elsewhere. But it may also be less reliable due to the important limitations of studies that are undertaken locally.

Table 11.10. Types of local evidence to address specific policy questions

Stage of the policy cycle	Use of local evidence	Types of local evidence that might be relevant
Diagnosing the problem or goal	To estimate the magnitude of the problem or issue that the policy aims to address and stakeholders' views on it	• Vital statistics data from routine sources, surveys such as the national DHS • Morbidity data from routine sources at national, sub-national or institutional (e.g. hospital) level • Local studies of stakeholder views and experiences
	To diagnose the likely causes of the problem	• Local studies of stakeholder views and experiences • Data on risk factors from surveys
	To describe local delivery, financial or governance arrangements for healthcare	• Ministry of Health and Ministry of Finance policies, guidelines and records • Regulations of professional organisations
Assessing policy options	To contextualise evidence from global reviews of the effects of interventions and to make this evidence relevant	• Data from local health delivery agencies on the range of interventions currently implemented (for a particular health problem) and their outcomes, which can be compared with the programmes evaluated in global reviews • Data from local health delivery agencies on local coverage of these interventions
	To inform assessments of the likely impacts of policy options (e.g. due to the existence of modifying factors)	• Local studies of similar programmes
	To inform judgements about values and preferences regarding policy options (i.e. the relative importance that those affected attach to	• Local studies of stakeholder views • Information from stakeholder organisations, e.g. organisations representing the public and specific consumer groups, such as those living with particular health problems

	possible impacts of policy options) and views regarding these options	• Information from deliberative dialogues with stakeholders
	To estimate the costs (and savings) of the policy options	• Local studies of programme costs and savings • Cost data held by health departments or programmes or by non-governmental delivery agencies
	Examine the effects of a policy option on particular local groups	• Routinely collected programme data • Local studies focusing on the group/s of interest
Exploring implement-tation strategies for a policy option	To assess the availability of resources (including human resources, technical capacity, infrastructure, and equipment)	• Resource data held by health departments or programmes or by non-governmental delivery agencies • Local studies of resource use by similar programmes
	To identify barriers to implementing policy options	• Local studies of stakeholder views • Information from stakeholder organisations, e.g. organisations representing the public and specific consumer groups, such as those living with particular health problems • Information from deliberative dialogues with stakeholders • Local barrier studies
Monitoring the effects of a policy option	Monitor the sustainability of programme effects over time	• Routinely collected programme data
	Examine the equity impacts of a programme following implementation	• Data that can be disaggregated by gender, age, area of residence, etc.

Resources

Useful documents and further reading

- WHO. World Health Statistics. Indicator compendium (Interim version). Geneva: World Health Organisation. 2009. www.who.int/whosis/indicators/WHS09_IndicatorCompendium_20090521.pdf

- The 'Creating Excellence' network in the United Kingdom has produced a short local evidence guide and a toolkit on gathering and analysing local level data. www.creatingexcellence.org.uk/regeneration-renewal-news262.html

- Department for Education and Skills. Using local evidence. A leaflet for service managers, planners and commissioners. www.dcsf.gov.uk/everychildmatters/_download/?id=5728

Links to websites

- *WHO Statistical Information System (WHOSIS):*
  www.who.int/whosis/en – This is an interactive database bringing together core health statistics for the 193 WHO Member States. It comprises more than 100 indicators, which can be accessed by way of a quick search, by major categories, or through user-defined tables

- *African Index Medicus:*
  http://indexmedicus.afro.who.int – An international index to African health literature and information sources produced by the WHO in collaboration with the Association for Health Information and Libraries in Africa. It provides access to health information published in, or related to, Africa and can be searched at no cost

- *The Cochrane Library:*
  www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME –
  The Cochrane Library contains high-quality, independent evidence to inform healthcare decision making. It includes reliable evidence from Cochrane and other systematic reviews and clinical trials. Cochrane reviews provide the combined results of the world's best medical research studies and are recognised as the gold standard in evidence-based healthcare

- *PubMed:*
  www.ncbi.nlm.nih.gov/pubmed – The PubMed database contains more than 19 million citations for biomedical articles from a wide range of indexed journals and can be searched at no cost

- *Health Metrics Network:*
  www.who.int/healthmetrics/en – A global partnership on health information system strengthening. The website provides a range of tools and information to support health information system strengthening

- *Demographic and health survey data:*
  www.measuredhs.com – The demographic and health surveys programme has collected, analysed and disseminated data on population, health, HIV and nutrition through more than 200 surveys in over 75 countries. The website provides a range of freely available data from these surveys

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12. Finding and using research evidence about resource use and costs

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Summary

In this chapter, we address considerations about resource use and costs. The consequences of a policy or programme option for resource use differ from other impacts (both in terms of benefits and harms) in several ways. However, considerations of the consequences of options for resource use are similar to considerations related to other impacts in that policymakers and their staff need to identify important impacts on resource use, acquire and appraise the best available evidence regarding those impacts, and ensure that appropriate monetary values have been applied. We suggest four questions that can be considered when assessing resource use and the cost consequences of an option. These are:

1. What are the most important impacts on resource use?
2. What evidence is there for important impacts on resource use?
3. How confident is it possible to be in the evidence for impacts on resource use?
4. Have the impacts on resource use been valued appropriately in terms of their true costs?

Scenario

You work in the Ministry of Health and the Minister of Health has asked you to brief her on the costs of options being considered as part of a healthcare reform programme

Background

In this chapter, we present four questions that policymakers and those who support them can ask when assessing the costs of a policy or programme option. Such questions could be applied, for instance, in the scenario outlined above. Our focus is on finding and using evidence related to resource use and the costs of a policy or programme option, rather than on cost-effectiveness analysis or other types of economic analysis.

Policymakers want to ensure that policies represent good value for money, as do those affected by them. To do this it is essential to consider the costs of options as well as their health and other impacts. Option costs differ from other impacts in a number of key ways [1]:

- *Healthcare costs are typically shared.* For most impacts other than costs, it is usually clear who will be advantaged and who will be disadvantaged, though this may not be the case for all outcomes. An entire community will benefit from a vaccination programme because of the herd effect (the reduced transmission of the disease once most community members are vaccinated). Similarly, in the case of the widespread use of antibiotics to treat individual infections, downstream adverse consequences of drug resistance may occur for the wider community. These are exceptions for health outcomes. On the other hand, healthcare costs are typically shared by the government, private insurers, employers and patients. And within a society, how costs are shared may differ still

further depending on patient age (e.g. whether they are under or over 65) or circumstance (e.g. whether the patient is receiving social assistance)

- *Unit costs tend to vary widely across jurisdictions.* For instance, the cost per unit of drugs is largely unrelated to the actual costs of production but is instead more closely related to marketing decisions and national policies. Thus, for example, most medicines under patent cost substantially more in the United States of America than in Canada [2]. Further, costs may vary widely even within jurisdictions. Hospitals or health maintenance organisations may be able to negotiate special arrangements with pharmaceutical companies for substantially lower prices than those available to patients or other providers. Unit costs also vary over time due to inflation, but may vary over time due to factors relating to demand, too (e.g. when a drug is indicated for use in an increased range of clinical applications), and supply (e.g. when a drug comes off patent)

- *Resource use is likely to vary across jurisdictions*. In addition to unit costs, the amount of resources used may vary. This is due to a range of factors, including professional practices (e.g. the extent to which a diagnostic test is requested by clinicians for a particular health problem), service settings (e.g. the balance between primary and secondary care), levels of patient adherence, and reimbursement policies

- *Resource implications vary widely across jurisdictions*. Even when resource use remains constant, resource implications may vary widely across jurisdictions. A year's supply of a very expensive drug may pay one nurse's salary in the United States of America, six nurses' salaries in Eastern Europe, and 30 nurses' salaries in Africa. What one can buy with the resources saved if one foregoes the purchase of a drug, vaccine or procedure – and the health benefits achievable with those expenditures – may thus differ significantly [3]

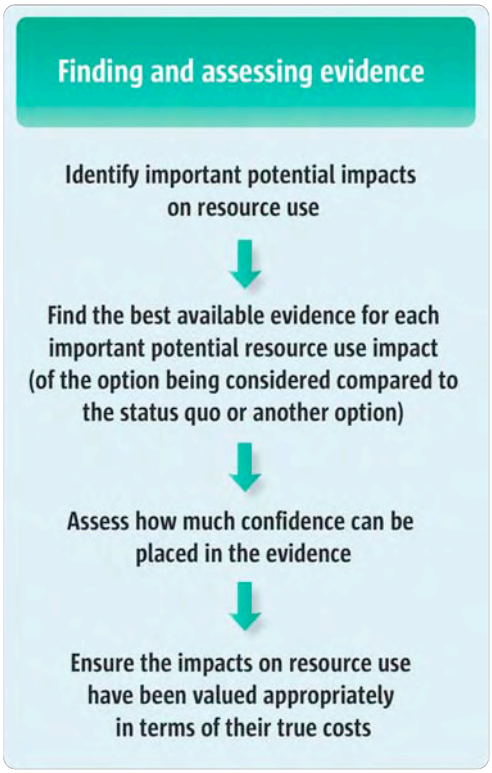
- *Stakeholders have different perspectives regarding the budgetary envelope in which they are considering resource implications*. Individual patients may only be interested in their out-of-pocket costs or may have varying views about risk sharing or who should bear the costs of healthcare. Hospital or district managers who are operating within fixed budgets may consider the cost of an option relative to other possible uses for the same money. Or they may examine the opportunities available to them to shift resources from one use to another. Similarly, a Minister of Health may be interested primarily in healthcare costs and the healthcare budget. Other policymakers, such as those in a Ministry of Finance, may apply a broader perspective and consider the overall government budget, including non-healthcare expenditures and tax increases or reductions

- *Conflicting interests related to costs are common*. For example, the economic interests of health professionals or industry executives (who typically want to earn as much as possible) may often be in conflict with the interests of society or governments (which typically want to get as much as they can for as little as possible)

Despite these differences, cost considerations are similar in many ways to considerations related to other consequences. This is because policymakers and their staff also need to identify important impacts on resource use, and acquire and appraise the best available evidence regarding those consequences to ensure that the resource consequences have been valued appropriately [4-6]. Due to differences between costs and other consequences, a consideration of costs presents special challenges [1,7]. Figure 12.1 shows four steps that are

necessary to identify and incorporate evidence about resource use and costs when considering policy and programme options.

Figure 12.1
Four steps necessary to identify and incorporate evidence of the costs of options



Questions to consider

The following questions can be used to guide assessments of the costs of potential options:

1. What are the most important impacts on resource use?
2. What evidence is there for important impacts on resource use?
3. How confident is it possible to be in the evidence for impacts on resource use?
4. Have the impacts on resource use been valued appropriately in terms of their true costs?

1. What are the most important impacts on resource use?

Health policies and programmes entail the use of resources, particularly human resources such as time. When considering which potential impacts on resource use are important, policymakers should first focus on resource *use* rather than *costs* (see Table 12.1, for example). Examples of potentially important resource consequences that should be considered include changes in the use of healthcare resources, non-healthcare resources, and patient and informal caregiver time (these and others examples are outlined in Table 12.2).

Table 12.1
Example: Identifying potentially important resource consequences for a national programme of outreach visits to improve prescribing for hypertension

Systematic reviews have found that educational outreach visits (i.e. personal visits to healthcare professionals in their own settings by trained outreach visitors) have relatively consistent and small, but potentially worthwhile, effects on prescribing [8]. In a randomised trial in Norway, these visits were found to increase the use of thiazides, in adherence with clinical practice guidelines, from 11% to 17% among patients with newly diagnosed hypertension [9]. To determine whether this improvement was worthwhile (in relation to the cost of a national outreach programme), the following uses of resources were considered [10]:

- Development of software (used to audit medical records and provide feedback to physicians)
- Training outreach visitors (pharmacists)
- Printed materials
- Travel for the pharmacists doing the outreach visits
- Pharmacists' time
- Administrative time (e.g. making appointments for the outreach visits)
- Physicians' time (for the outreach visits)
- Technical support
- Drug expenditure
- Patient visits
- Laboratory tests

Table 12.2
Examples of potentially important resource consequences*

** Adapted from Luce and colleagues [11]*

1. Changes in use of healthcare resources

• Policy or programme delivery
  – Human resources/time
  – Consumable supplies
  – Land, buildings, equipment
• Additional (or fewer) hospitalisations, outpatient visits or home visits
• Additional (or less) use of laboratory tests or examinations
• Paid transportation (e.g. emergency transportation)

2. Changes in use of non-healthcare resources
• Transportation to healthcare facilities • Special diets • Social services (e.g. housing, home assistance, occupational training) • Home adaptation • Crime (such as theft, fraud, violence, police investigation, court costs), for example, in relation to options targeted at drug or alcohol abuse
3. Changes in use of patient and informal caregiver time
• Outpatient visits • Hospital admissions • Time of family or other informal caregivers
4. Changes in productivity
• We suggest that changes in productivity and the intrinsic value of changes in health status should be captured in terms of the value or importance attached to health outcomes and should not be included as resource consequences

When considering which impacts on resource use are important it is essential to consider both the resources used to implement the option (i.e. resource inputs such as drugs, equipment and care) *and* subsequent resource use arising from the impacts of the option on health or other outcomes (e.g. increases or decreases in healthcare utilisation due to the impacts of the option). Incentives to patients to improve adherence to tuberculosis treatment, for example, require substantial resource inputs. These may be offset by subsequent savings if there is a reduction in failed treatment and less spread of the disease

(and therefore less subsequent resource use for retreatment and the treatment of others who become infected).

Changes in the productivity of patients may also be important. People with AIDS, for instance, may place a high value on being able to work and earn money, but the process of measuring and valuing actual changes in productivity is controversial [12]. Like others [1,7,11], we suggest that such changes in productivity should be considered as components of the intrinsic value of changes in health status, and should not be included as resource consequences.

On the other hand, some outcomes such as hospitalisations or days in hospital can be considered as important in their own right and also as a component of resource use.

When deciding which resource consequences are potentially important it is necessary to specify the viewpoint from which recommendations are made. One option is to adopt a societal perspective: this is a broad viewpoint that includes all important healthcare and non-healthcare resources [1]. This option has the advantage of ensuring that the issue of who pays does not determine whether resource use is included.

Policymakers may sometimes have a remit to make decisions about the use of resources within a healthcare system. In such instances, costs or savings outside of the healthcare system would not be included. This exclusion would not preclude a consideration of the impacts of an option on issues such as social services or crime, in addition to health outcomes. But any costs or savings associated with those impacts would not be relevant to the healthcare budget unless there was a transfer of funds (e.g. from criminal justice to health).

It is also necessary to specify the time horizon for a policy decision (i.e. the period of time for which resource use, as well as health outcomes and other impacts, will be considered).

2. What evidence is there for important impacts on resource use?

Evidence must be found for each potentially important resource consequence. Further, an estimate must be provided of the difference in resource use between implementing the policy or programme on one hand, and the comparator (typically the status quo) on the other (see Table 12.3 for examples of resources and data sources used in finding evidence of resource consequences). As with health outcomes and other impacts, a comparison is needed regardless of whether it is made implicitly or explicitly. For instance, when considering the option of scaling up the use of artemisinin combination therapy (ACT) for uncomplicated falciparum malaria, increased expenditures on ACT (and corresponding changes in the use of other anti-malarials) must be compared to current expenditures on ACT and other anti-malarials (the status quo). Other resource consequences of scaling up the use of ACT, such as training or providing incentives to community health workers to deliver ACT must also be compared to the status quo (which may vary from setting to setting). Similarly, any subsequent savings resulting from scaling up the use of ACT (e.g. fewer hospitalisations) must also be compared to the status quo. If two competing options for scaling up the use of ACT are being considered, it will be necessary to compare the resource consequences of *both* of these to each other (either directly or indirectly).

Table 12.3
Example: Finding evidence for resource consequences

The following data sources were used to estimate the differences in resource use between a programme of outreach visits (targeted at all general practitioners in Norway) and no programme (the status quo) [10]. The programme is described further in Table 12.1.

Resources	Data sources
Development of software	Invoices, estimates of time spent
Training of outreach visitors	Estimate of time spent; invoices
Printed materials	Invoice
Travel	Record of travel days, estimate of travel distances
Pharmacists' time	Record of number of visits and days spent on visits
Administrative time	Records and estimates of time expenditure
Physicians' time	Record of length of outreach visit and number of physicians present
Technical support	Records of invoices
Drug expenditure	Medical records
Patient visits	Medical records
Laboratory tests	Medical records

Because data were only collected for one year and from 139 practices (501 physicians, half of whom received outreach visits and half of whom did not) it was necessary to extrapolate the use of resources beyond one year and to the rest of the country.

Systematic reviews, randomised trials and observational studies may provide evidence of the impacts of options on resource use. Such evidence can be published in, or separately from, clinical studies or impact evaluations. The use of resources in specific settings can be retrieved from national or local databases, such as prescription databases for drug use, and hospital databases for information related to hospitalisations [13].

Evidence of resource use may also come from sources other than those used to obtain evidence of health benefits. This may be the case because:

- Trials or impact evaluations (and systematic reviews of these) do not fully report resource use
- Trials and impact evaluations may not fully reflect the circumstances – and thus the resource use – in the setting where a policy decision must be made, and
- The relevant resource use may extend beyond the duration of the trial or impact evaluation

Evidence of resource use should be in natural units, such as visits, hospitalisations or the number of doses of ACT. There are two reasons for this. Firstly, when only total costs are reported (i.e. the number of units of a resource multiplied by the unit cost of the resource), resource use cannot be separated from unit costs, which might vary considerably between settings and over time. Secondly, without information about resource use it is difficult to make judgements about the validity and the applicability of the evidence.

Unfortunately, studies sometimes report costs but do not report the underlying levels of resource use. This was apparent in an economic evaluation of magnesium sulphate for pre-eclampsia which reported the total cost, but not the resource use for magnesium

sulphate, or the resources for administering magnesium sulphate and other hospital resources [14]. Differences in costs could be due to differences in underlying levels of resource use, differences in unit costs, or both.

Often it is not possible to find evidence for components of resource use that are important for policy decisions. A guideline panel convened by WHO to develop recommendations for the prevention of postpartum haemorrhage, for instance, found very limited evidence of resource use for oral misoprostol compared to intramuscular oxytocin [7]. The panel considered hospitalisation, personnel time, and drugs to be potentially important resource consequences but did not find any evidence for the first two types of resources. The resource consequences of these two options for preventing postpartum haemorrhage were therefore very uncertain.

3. How confident is it possible to be in the evidence for impacts on resource use?

The quality of evidence for resource use must be assessed for each important resource consequence (see Table 12.4). This is because the quality of evidence may be better for some consequences (e.g. drug use) than for other consequences (e.g. personnel time). The criteria for assessing the quality of evidence for resource use are largely the same as those for health outcomes [1,6,7,15]. These include: assessing the study design and other study limitations (i.e. the risk of bias), the precision of the estimate, the consistency of the results, the directness of the evidence (see below), and the risk of publication bias. Factors that often lower the quality of resource evidence (i.e. those that result in less confidence in estimates of resource consequences) include:

- The unavailability of data due to resource use not having been measured or reported, or reported only as cost estimates (in other words, without the data upon which those estimates were based)
- Weak (observational) study designs
- Indirectness due to uncertainty about the transferability of resource evidence from one setting to another, and
- Indirectness due to inadequate follow-up periods. This makes it necessary to extrapolate beyond the length of available studies in order to estimate resource consequences

Typically, when estimating the cost-effectiveness of a policy or programme, many assumptions must be made. Economic models that are used to estimate cost-effectiveness are valuable given that they can help to make such assumptions explicit. They also allow for sensitivity analyses that test how robust estimates of cost-effectiveness are in relation to those assumptions. It should be noted however, that the various checklists used to assess the quality of economic analyses in the healthcare literature are not constructed to assess the quality of the evidence upon which the analyses were based [16]. Rather, these checklists tend to focus on the quality of the reporting.

Moreover, although published cost-effectiveness analyses can be helpful, particularly for developing a model, they are often of limited value to policymakers when they are not from a policymaker's own setting. The assumptions made and the unit costs that were used may not be transferable from the setting where the analysis was done to one where a decision must be made. Also, as with any research, cost-effectiveness analyses can be flawed. Without knowledge of the complete model it is difficult to make informed judgements about either the quality of the evidence or its applicability [1,7,17,18].

Table 12.4
Example: Assessing the quality of evidence for resource consequences

The quality of the evidence for the estimates of difference in resource use between a programme of outreach visits (targeted at all general practitioners in Norway) and no programme (the status quo) varied. (See also Tables 12.1 and 12.3.)

Resources	Data sources
Development of software	High quality
Training of outreach visitors	High quality
Printed materials	High quality
Travel	Moderate quality*
Pharmacists' time	Moderate quality*
Administrative time	High quality
Physicians' time	Moderate quality*
Technical support	High quality
Drug expenditure	Moderate to low quality†
Patient visits	Moderate to low quality†
Laboratory tests	Moderate to low quality†

* The evidence for travel, pharmacists' time and physician time was of moderate quality. This was because of uncertainty about the extrapolation of data from practices in the trial to the rest of the country

† The evidence for drug expenditures, patient visits and laboratory tests was of moderate to low quality. This was because of uncertainty about the extrapolation of data from the trial to the rest of the country and, in addition, because of extrapolation beyond one year (the duration of the trial) to estimate the resource consequences over several years for a programme targeted at all general practitioners in the country

4. Have the impacts on resource use been valued appropriately in terms of their true costs?

Attaching appropriate monetary values to resource use can help policymakers to value resource use consistently and appropriately (see Table 12.5 for examples of relevant data sources). In principle, these values should reflect opportunity costs – that is, the benefits foregone by diverting the resources from the next best alternative use [19].

Cost calculations based on reliable databases or data sources in the same jurisdiction are the most reliable sources of data for unit costs [20]. Monetary valuations of resource use should be made with data that are specific to the context where a policy decision must be made using transparent and locally relevant unit costs. If this is not possible, purchasing power parity (PPP), exchange rates and inflation factors could be used to assist interpretation of monetary valuations from other settings or times [21]. In a study estimating the cost of cervical cancer screening in five developing countries [22], for example, unit cost data were derived from more than one year. Country-specific deflators were therefore used to adjust all costs to the same price year. Further, to aid cross-country comparability, PPP exchange rates were used to convert costs expressed in local currency units to dollars. Both were measured according to the relevant values in the price year 2000.

Table 12.5
Example: Attaching monetary values to resource consequences

The following data sources were used to estimate the monetary value of differences in resource use between a programme of outreach visits (targeted at all general practitioners in Norway) and no programme (the status quo) [10]. (See also Tables 12.1, 12.3 and 12.4.)

Resources	Data sources for monetary values
Development of software	Invoices, salary payments
Training of outreach visitors	Salary payments
Printed materials	Invoice
Travel	Travel invoices
Pharmacists' time	Salary payments
Administrative time	Salary payments, standard estimates for overheads, office rental figures
Physicians' time	Standard tariff for interdisciplinary meetings
Technical support	Invoices
Drug expenditure	"Felleskatalogen 2003" (a Norwegian list of drugs and prices)
Patient visits	Standard tariff for consultation
Laboratory tests	Standard tariff

Discounting is used in economic evaluations to adjust for social or individual preferences over the timing of costs and health benefits. This means that less weight is given to costs or benefits occurring further in the future than those expected imminently. Recommended discount rates differ between countries and are often varied in sensitivity analyses.

When costs are presented, these should be reported using the appropriate discount rate for the context where the policy decision must be made. Data used to calculate the discounted costs – including quantities of all resource items, unit costs, and the discount rate – should be transparent so that it is possible to assess the validity and applicability or appropriateness of each component.

Conclusion

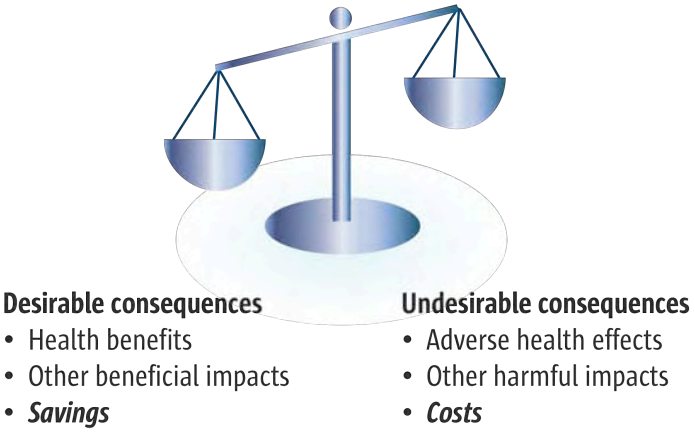


Figure 12.2
Balancing the pros and cons of health policies and programmes, including resource consequences*

* *Resource consequences (the savings or costs of a policy or programme compared to the status quo or other alternative) need to be considered along with health and other impacts when making judgements about the balance between the pros and cons of health policies and programmes*

Policymakers and others are concerned with getting value for money; in other words, that health policies and programmes are cost-effective (efficient). Evidence of resource use and costs is needed to inform judgements about cost-effectiveness. We discuss making judgements about the balance between the pros and cons (including savings and costs) of policies and programmes (as illustrated in Figure 12.2) in Chapter 16 [23].

Evidence of resource use and costs is also needed to inform judgements about equity [24]. In addition to considering the overall costs (and cost-effectiveness) of policies and programmes, policymakers need to consider who will bear particular costs and the impact that this will have on inequities.

In terms of both efficiency and equity it is important to ensure that all potentially important resource consequences are identified. It is also essential that the best available evidence is used, and that important uncertainties about resource (and other) consequences are acknowledged and addressed [25,26].

Resources

Useful documents and further reading

- Guyatt GH, Oxman AD, Kunz R, Jaeschke R, Helfand M, Vist GE, Schunemann HJ, and the GRADE Working Group. Incorporating considerations of resource use. BMJ 2008; 336:1170-3

- Brunetti M, Oxman AD, Pregno S, Lord J, Shemilt I, Vale L, et al. GRADE guidelines: 10. Special challenges – resource use. J Clin Epidemiol. In press

Links to websites

- *Campbell & Cochrane Economics Methods Group:* www.c-cemg.org – The Campbell & Cochrane Economic Methods Group is an international network of individuals with an interest and expertise in approaches to evidence synthesis that combine economics and systematic review methods

- *GRADE Working Group:* www.gradeworkinggroup.org/index.htm – The Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group has developed a system for grading the quality of evidence and the strength of healthcare recommendations. The system includes an approach to the grading of resource use evidence and the incorporation of evidence into recommendations

- *International Health Economics Association:* www.healtheconomics.org – The International Health Economics Association was formed to increase communication among health economists, foster a higher standard of debate in the application of economics to health and healthcare systems, and assist young researchers at the start of their careers

- *Office of Health Economics, United Kingdom:* www.ohe.org/page/index.cfm – The Office of Health Economics provides independent research, advisory and consultancy services on policy implications and economic issues within the pharmaceutical, healthcare and biotechnology sectors

- *CCEMG - EPPI-Centre Cost Converter:* http://eppi.ioe.ac.uk/costconversion/default.aspx – a simple web-based tool that can be used to adjust an estimate of cost expressed in one currency and price year, to a target currency and/or price year

- *NHS Economic Evaluation Database (NHS EED):* www.crd.york.ac.uk/crdweb/Home.aspx?DB=NHS%20EED&SessionID=&SearchID=&E=0&D=0&H=0&SearchFor= – NHS EED contains 24,000 abstracts of health economics papers including over 7,000 quality-assessed economic evaluations. The database aims to assist decision makers by systematically identifying and describing economic evaluations, appraising their quality, and highlighting their relative strengths and weaknesses

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Chapters 13, 14, and 15
Going from research evidence to decisions: engaging stakeholders

13. Preparing and using policy briefs to support evidence-informed policymaking

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Summary

Policy briefs are a relatively new approach to packaging research evidence for policymakers. The first step in a policy brief is to prioritise a policy issue. This is then used to mobilise the full range of research evidence relevant to the various features of the issue. Drawing on available systematic reviews makes the process of mobilising evidence feasible in a way that would not otherwise be possible if individual relevant studies had to be identified and synthesised for every feature of the issue under consideration. In this chapter, we suggest questions that can be used to guide those preparing and using policy briefs to support evidence-informed policymaking. These are:

1. Does the policy brief address a high-priority issue and describe the relevant context of the issue being addressed?
2. Does the policy brief describe the problem, costs and consequences of options to address the problem, and the key implementation considerations?
3. Does the policy brief employ systematic and transparent methods to identify, select, and assess synthesised research evidence?
4. Does the policy brief take quality, local applicability, and equity considerations into account when discussing the synthesised research evidence?
5. Does the policy brief employ a graded-entry format?
6. Was the policy brief reviewed for both scientific quality and system relevance?

Scenarios

Scenario 1: *You are a senior civil servant and have been sent a policy brief that describes the research evidence about an issue that is of growing concern to the Minister. You are responsible for ensuring that the policy brief profiles research evidence in a way that informs different elements of the issue and recognises the importance of drawing on both local and global evidence. You want to ensure that the policy brief won't place the Minister in an awkward position by making a recommendation that is not politically or economically feasible*

Scenario 2: *You work in the Ministry of Health and have been given a few hours to prepare an assessment of a policy brief that has been sent to the Ministry on a high-priority issue. All that you have been told is that this policy brief is different in a number of ways to the type of policy brief that you have produced in the past including the way in which it profiles research evidence about a problem, the options and implementation considerations, and the fact that it does not conclude with a specific recommendation*

Scenario 3: *You work in an independent unit that supports the Ministry of Health in its use of research evidence in policymaking. You are preparing a policy brief for both the Ministry and key stakeholders to profile what is known and not known about a problem, options for addressing it, and implementation considerations. You have been told to prepare the brief in a systematic way and to report the methods and findings in a transparent and readily understandable way, but you want guidance on how to be both thorough and efficient in your work*

Background

For policymakers (Scenario 1), this chapter suggests a number of questions that they might ask themselves or their staff to consider when assessing a policy brief. For those who support policymakers (Scenarios 2 and 3), this chapter suggests a number of questions to guide the assessment of a policy brief or the preparation of one.

Three major shifts have occurred recently in the focus of many efforts to package research evidence for policymakers. Firstly, there has been a shift from packaging single studies to packaging systematic reviews of studies that address typical policy-relevant questions. A number of research groups, including the SUPPORT collaboration (www.support-collaboration.org/), now produce policymaker-friendly summaries of systematic reviews. These summaries always highlight the key messages from the review but some of them, like SUPPORT summaries, also address considerations related to quality, local applicability, and equity [1]. This shift has made it easier for policymakers to scan broadly across large bodies of research evidence. And it has also enabled them to extract what they need to know easily from particular systematic reviews that directly address key features of any policy issue of interest.

Secondly, there have been more recent complementary efforts to package systematic reviews (together with local research evidence) in the form of a new product – the policy brief – which mobilises the best available research evidence on high-priority issues [2]. For policy briefs, the starting point is the issue and *not* the related research evidence that has been produced or identified. Once an issue is prioritised, the focus then turns to mobilising the full range of research evidence addressing the different features of the issue concerned. These include the underlying problem, options to address the problem, and key implementation considerations. Drawing on available systematic reviews makes the process of evidence mobilisation feasible in a way that would not otherwise be possible if single studies had to be identified and synthesised for all the features of the issue. In this chapter, we have restricted our use of the term 'policy brief' to those products matching this description exactly. But the term has also been applied elsewhere to many other types of products prepared by those supporting policymakers. The appropriation of this term by those involved in producing and supporting the use of research evidence reflects perhaps their increasing orientation to the needs and contexts of policymakers.

Evidence-packaging mechanisms and policy briefs in particular have been developed largely as a response to the findings of systematic reviews of factors influencing the use of research evidence in policymaking [3,4]. Three factors in particular have emerged as significant. These are: 1. Timing or timeliness, 2. Accordance between the research evidence and the beliefs, values, interests, or political goals and strategies of policymakers and stakeholders, and 3. Interactions between researchers and policymakers.

Having access to both a stock of the summaries of systematic reviews and policy briefs helps to address the need that policymakers have for timely inputs to policymaking processes [5]. Review summaries and policy briefs can typically be produced in days and weeks rather than the months or years required to prepare a systematic review from scratch. Undertaking primary research (i.e. original studies) can be similarly and often more time intensive. Evidence-packaging mechanisms, and policy briefs in particular, can also make it easier for policymakers and other stakeholders to determine whether and how the available research evidence accords with their own beliefs, values, interests, or political goals and strategies. With a problem clarified, what is known and not known about the options clearly described,

and key implementation considerations clearly flagged, policymakers may be more readily able to identify viable ways forward.

Thirdly, changes have occurred in the purpose for which packaged research evidence has typically been produced. Policy briefs are increasingly used as an input into policy dialogues involving individuals drawn from those who will be involved in, or affected by, decisions about a particular issue. These dialogues provide the opportunity for greater interaction between researchers and policymakers. Dialogues in which research evidence is just one input in a policy discussion form the focus of Chapter 14 [6].

The formats used for evidence-packaging have often been developed in response to the few available empirical studies of the preferences of health policymakers for different kinds of mechanisms (and *not* their usage or effects, which typically have not been evaluated) [3,7]. These studies have revealed a need amongst policymakers to have formats that both provide graded entry to the full details of a review *and* facilitate assessment of decision-relevant information [3]. A graded-entry format of one page of take-home messages, a three-page executive summary that summarises the full report, and a 25-page report (i.e. a 1:3:25 format) has been shown to be particularly promising [8]. Presumably, either the one- or three-page summary should follow a structured format [9]. Structured abstracts have been found to have an effect on intermediate outcomes such as searchability, readability and recall among healthcare providers. However, no studies have compared full text to structured abstracts and no studies have examined the impact of format features on policymakers [10]. Decision-relevant information can include the important impacts (both benefits and harms) and costs (i.e. resources used) of policy and programme options, as well as local applicability and equity considerations [3].

Questions to consider

The following questions can be used to guide the preparation and use of policy briefs to support evidence-informed policymaking:

1. Does the policy brief address a high-priority issue and describe the relevant context of the issue being addressed?
2. Does the policy brief describe the problem, costs and consequences of options to address the problem, and the key implementation considerations?
3. Does the policy brief employ systematic and transparent methods to identify, select, and assess synthesised research evidence?
4. Does the policy brief take quality, local applicability, and equity considerations into account when discussing the research evidence?
5. Does the policy brief employ a graded-entry format?
6. Was the policy brief reviewed for both scientific quality and system relevance?

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

Policy briefs are distinguished most clearly from other packaged evidence summaries by the fact that they begin with the explicit identification of a high-priority issue. In instances where an issue has been on the agenda of key stakeholders for some time, policy briefs may act as a way to spur progress. This is highlighted in the example shown in Table 13.1 of low coverage rates for artemisinin-based combination therapies (ACT) to treat uncomplicated falciparum malaria in sub-Saharan African countries. Alternatively, if the issue is relatively new, the policy brief may play an agenda-setting role. Either way, it is critical that the issue is deemed

a priority by at least some key stakeholders. Ideally the prioritisation process should also be systematic and transparent and Chapter 3 outlines an approach for achieving this [11].

Table 13.1
Outline of a policy brief about supporting the widespread use of a new, highly effective treatment for malaria in an African country

What problem has been identified?
• The overarching problem is one of low coverage rates for artemisinin-based combination therapies (ACT) to treat uncomplicated falciparum malaria in sub-Saharan Africa. Key features of the problem include – A high incidence of, and death rates from, malaria – Existing treatments have much lower cure rates than ACT. However, patients often favour existing treatments because of their past experiences and the higher price of ACT – The national malaria control policy, treatment guidelines, and drug formulary in many countries do not all support the prescription, dispensing and use of ACT – Delivery arrangements for ACT often rely primarily on physicians but not everyone has regular access to them and many are comfortable receiving care from community health workers. Financial arrangements favour existing treatments over ACT (which is much more expensive) yet some patients are sceptical about heavily subsidised medication. Governance arrangements often do not allow community health workers to prescribe ACT and do not protect against counterfeit or substandard drugs
What information do systematic reviews provide about three viable options to address the problem?
• Each of the following three options was assessed in terms of the likely benefits, harms, costs (and cost-effectiveness), key elements of the policy option if it was tried elsewhere, and the views and experiences of relevant stakeholders – Enlarge the scope of practice for community health workers to include the diagnosis of malaria and prescription of ACT (governance arrangements), introduce target payments for achieving a defined coverage rate for ACT treatment (financial arrangements), and provide them with training and supervision for the use of both rapid diagnostic tests and prescribing (delivery arrangements) – Introduce partial subsidies for both rapid diagnostic tests and ACT within the private sector where much care is provided in urban areas (financial arrangements) – Restrict the types of anti-malaria drugs that can be imported and introduce penalties for those found dispensing counterfeit or substandard drugs (governance arrangements) and make changes to the national malaria control policy and drug formulary to ensure that ACT is the recommended first-line treatment • Important uncertainties about each option's benefits and potential harms were flagged in order to give them particular attention as part of any monitoring and evaluation plan put into place
What key implementation considerations need to be borne in mind?
• A number of barriers to implementation were identified, among which were the familiarity of some patients and healthcare providers with existing treatment options and their resistance to change. Systematic reviews about the effects of mass media campaigns, the effects of strategies for changing healthcare provider behaviour generally, and for influencing prescribing and dispensing specifically, all proved helpful in deciding how to address these barriers
Notes about the supporting evidence base
• Six systematic reviews about anti-malarial drugs had been published since the release of the World Health Organization guidelines in 2006, all of which lent further support to ACT as the recommended first-line treatment • Of the systematic reviews identified: two addressed relevant governance arrangements, six

addressed financial arrangements, five addressed specific configurations of human resources for health, and fifteen addressed implementation strategies, many of which could be supplemented by local studies

Table 13.2
Outline of a policy brief about improving access to high quality primary healthcare in Canada

What problem has been identified?

- The problem is limited or inequitable access to sustainable, high-quality community-based primary healthcare in federal, provincial, and territorial publicly-funded health systems in Canada. Key characteristics of the problem include:
  - Chronic diseases represent a significant share of the common conditions that must be prevented or treated by the primary healthcare system
  - Access to cost-effective programmes, services and drugs in Canada is not ideal. This is the case both when Canadians identify their own care needs or (more proactively on the part of healthcare providers) when they have an indication (or need) for prevention or treatment, particularly for chronic disease prevention and treatment
  - Health system arrangements have not always supported the provision of cost-effective programmes, services and drugs. Many Canadians do not:
    1. Have a regular physician or place of care
    2. Receive effective chronic-disease management services, or
    3. Receive care in a primary healthcare practice that uses an electronic health record, faces any financial incentive for quality, or provides nursing services
  - What is more difficult to determine is the proportion of physicians who receive effective continuing professional development for chronic disease management and the proportion of primary healthcare practices that:
    1. Are periodically audited for their performance in chronic disease management
    2. Employ physician-led or collaborative practice models, and
    3. Adhere to a holistic primary healthcare model's (the Chronic Care Model's) key features [14]

What information do systematic reviews provide about three viable options to address the problem?

- Each of the following three options was assessed in terms of its likely benefits, harms, costs (and cost-effectiveness), its key elements if it had been tried elsewhere, and stakeholder views about and experiences with it:
  - Support the expansion of chronic disease management in physician-led care through a combination of electronic health records, target payments, continuing professional development, and auditing of their primary healthcare practices
  - Support the targeted expansion of inter-professional, collaborative practice primary healthcare
  - Support the use of the Chronic Care Model in primary healthcare settings. This model entails the combination of self-management support, decision support, delivery system design, clinical information systems, health system, and community
- Important uncertainties about each option's benefits and potential harms were flagged. This was done in order to give these issues particular attention within any monitoring and evaluation plan put into place

What key implementation considerations need to be borne in mind?
• Little empirical research evidence could be identified about implementation barriers and strategies. Four of the implementation barriers identified were: 1. Initial wariness amongst some patients of potential disruptions to their relationship with their primary healthcare physician 2. Wariness on the part of physicians (particularly older physicians) of potential infringements on their professional and commercial autonomy 3. The organisational scale required for some of the options is not viable in many rural and remote communities, and 4. Hesitancy on the part of governments about broadening the breadth and depth of public payment for primary healthcare, particularly during a recession
Notes about the supporting evidence base
• Dozens of relevant systematic reviews were identified, some of which addressed an option directly and others of which addressed elements of one or more options [13]

A second key feature of policy briefs is that they are typically *context-specific*. Describing the key features of a context in the policy brief is important as a way of creating a level playing field among policy brief readers. Table 13.2 highlights issues related to limited or inequitable access to sustainable, high-quality community-based primary healthcare in Canada. There, as the policy brief explained, the issue could only be understood in the context of the particular features of Canadian primary healthcare and the existence of 'private delivery/public payment' arrangements with physicians. These are of particular importance in this context for they have meant historically that most primary healthcare in Canada is delivered by physicians working in private practice with first-dollar, public (typically fee-for-service) payment [12]. Improving access in creative ways, including the use of collaborative practice models, requires an understanding that: 1. Physicians tend to be wary of potential infringements on their professional and commercial autonomy, 2. No other healthcare providers at this time can secure the public payment required to function independently as primary healthcare providers on a viable scale, and 3. Many forms of care (including prescription drugs and home care services) would still not be covered [13].

2. Does the policy brief describe the problem, costs and consequences of options to address the problem, and the key implementation considerations?

A policy brief would ideally describe different features of a problem, what is known (and not known) about the costs and consequences of options for addressing the problem, and key implementation considerations. As outlined in Chapter 4, a problem can be understood in one or more of the following terms [15]:

1. The nature and burden of the actual common diseases and injuries that the healthcare system must prevent or treat
2. The cost-effective programmes, services and drugs that are needed for prevention and treatment, and
3. The broader health system arrangements that determine access to, and the use of, cost-effective programmes, services and drugs, including how they affect particular groups.

A policy brief would help to clarify the problem by diagnosing it in one or more of these terms.

Ideally, the number of options described in a brief that is to be presented to senior policymakers would conform to local document conventions. Three-option models, for instance, are familiar to many policymakers. But regardless of the number selected, each option in the policy brief can be characterised in terms of:

- The benefits of each option
- The harms of each option
- The costs of each option or their relative cost-effectiveness (if possible)
- The degree of uncertainty related to these costs and consequences (so that monitoring and evaluation can focus on particular areas of uncertainty if any given option is pursued)
- Key elements of the policy option if it has been tried elsewhere and adaptation is being considered, and
- Stakeholder views about and experiences with each option

A policy brief would help to make clear the trade-offs involved in selecting one option over others. If the options are not designed to be mutually exclusive, a policy brief would also help to make clear the benefits of combining particular elements of the different options and which *combination* of options might bring about positive synergies. Alternatively, the elements from one or more individual options could be presented first, followed by 'bundles' of options combining different elements in various ways.

Barriers to implementation (outlined in further detail in Chapter 6) are located at different levels, ranging from the consumer (citizen or healthcare recipient) level through to healthcare providers, organisations, and broader systems [16]. Policy briefs would help to identify these barriers and describe what can reasonably be expected (again, in terms of benefits, harms, and costs) as a result of pursuing alternative implementation strategies to address these barriers. A policy brief could also identify considerations related to the preparation of a monitoring and evaluation plan. Table 13.3 provides a possible outline for a policy brief.

Table 13.3 (next page): Possible outline of a policy brief

Title *(possibly in the form of a compelling question)*

Key messages *(possibly as bullet points)*

- **What is the problem?**
- **What do we know (and not know) about viable options to address the problem?**
- **What implementation considerations need to be borne in mind?**

Report

- Introduction that describes the issue and the context in which it will be addressed
- Definition of the problem such that its features can be understood in one or more of the following terms:
  1. The nature and burden of common diseases and injuries that the healthcare system must prevent or treat
  2. The cost-effective programmes, services and drugs that are needed for prevention and treatment, and
  3. The health system arrangements that determine access to and use of cost-effective programmes, services and drugs, including how they affect particular groups
- Options for addressing the problem, with each one assessed in a table (an example is shown below)

	Category of finding	Nature of findings from systematic reviews and other available research evidence
	Benefits	
	Harms	
	Costs and cost-effectiveness	
	Uncertainty regarding benefits and potential harms	
	Key elements of the option (how and why it works)	
	Stakeholders' views and experiences	

- Implementation considerations, with potential barriers to implementing the options assessed in a table (please see example below), each viable implementation strategy also assessed in table (please see example above), and suggestions for a monitoring and evaluation plan

	Levels	Option 1	Option 2	Option 3
	Consumer			
	Healthcare provider			
	Organisation			
	System			

Additional content that could appear on a cover page or in an appendix:

- A list of authors and their affiliations
- A list of those involved in establishing the terms of reference for the policy brief and their affiliations
- A list of key informants who were contacted to gain additional perspectives on the issue and to identify relevant data and research evidence, and their affiliations
- A list of funders (for the organisation producing the policy brief and for the policy brief itself)
- A statement about conflicts of interest among authors

Additional content that could appear in boxes or in an appendix

- Methods used to identify, select, and assess synthesised research evidence (including assessments of quality, local applicability and equity considerations)
- Review process used to ensure the scientific quality and system relevance of the policy brief

3. Does the policy brief employ systematic and transparent methods to identify, select, and assess synthesised research evidence?

Policymakers and a wide range of stakeholders who will be involved in or affected by a decision, are the main audience of a policy brief. Research language should therefore be kept to a minimum as most people will be unfamiliar with it. A policy brief, nevertheless, should still ideally describe how synthesised research evidence was identified, selected and assessed in ways that are easily understood. This objective can be achieved by using techniques such as explanatory 'boxes' within the brief to clarify or highlight particular concepts, or through the inclusion of additional appendices. The methods, too, should be systematic in nature and reported in a transparent yet understandable way. For example, users could be provided with a description of how systematic reviews addressing the benefits and harms of particular health system arrangements were identified through a search of continuously updated databases containing reviews in particular domains. This could provide significant reassurance to readers that most, if not all, key reviews had been found and that few, if any, key reviews had been missed.

4. Does the policy brief take quality, local applicability, and equity considerations into account when discussing the research evidence?

Systematic reviews may be of high or low quality, their findings may be highly applicable to a given policymaker's setting or of very limited applicability, and they may or may not give consideration to the impacts an option is likely to have on disadvantaged groups, and on equity in a specific setting. Ideally, a policy brief would flag such variations for policymakers and other readers. As outlined in Chapter 8, explicit criteria are available to assist with quality assessments [17]. Importantly, some databases of systematic reviews, such as Rx for Change (www.rxforchange.ca), provide quality ratings for all reviews contained in the database. If possible, a policy brief would provide a quality review for all systematic reviews from
which key messages have been extracted. Explicit criteria are also available to assist with local applicability assessments and these are outlined in further detail in Chapter 9 [18]. Given that policy briefs are typically context-specific, a policy brief would also ideally comment on the local applicability of the findings of any systematic reviews that are critical to an understanding of the impacts of any options being considered. Equity considerations can also be addressed using explicit criteria (see Chapter 10) [19]. A policy brief should also note in its introduction whether any groups have been given particular attention in the brief. Group-specific key messages could be added to the overall key messages in each section.

5. Does the policy brief employ a graded-entry format?

A policy brief would ideally allow busy policymakers and other readers to scan the key messages quickly in order to determine whether these corresponded sufficiently closely to their key issue of concern and context to warrant reading the entire document. A graded-entry format could take a number of forms. These could be achieved, for example, through a 1:3:25 format – i.e. *one* page of take-home messages, a *three*-page executive summary, and a *25*-page report [8]. Or a brief may take the form of a 1:12 format, with one page of take-home messages followed by a 12-page report. Whatever form is chosen, the minimum that a policy brief should contain is a list of key messages, a report, and a reference list for those who wish to read more. The key messages would range from the identification of the problem through what is known about the options, and the key considerations for implementation.

A number of other features of a policy brief could engage potential readers and facilitate assessments of who was involved in preparing, informing and funding it. The title of a policy brief could be worded in a way that would engage policymakers and other stakeholders. This could be achieved, for example, by using a compelling question as a title. The cover and/or the acknowledgements section of a policy brief could provide a list of authors and their affiliations. It could also include a list of those involved in establishing the terms of reference of the policy brief, a list of the key informants contacted for additional perspectives on the issue and to identify relevant data and research evidence, and their affiliations. A list of funders for both the organisation producing the policy brief and the policy brief itself, and a statement about any conflicts of interest among authors could also form part of the policy brief document.

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

Policy briefs need to meet two standards: scientific quality and system relevance. To ensure this, the review process could involve at least one policymaker, at least one other stakeholder, and at least one researcher. This so-called *merit review* process differs from a typical *peer review* process that would typically only involve researchers in the review process, and hence focus primarily on scientific quality. Involving policymakers and other stakeholders can help to ensure the brief's relevance to the health system.

Conclusion

Policy briefs are a new approach to supporting evidence-informed policymaking. Their preparation and use continues to evolve through practical experience. Evaluations of this new approach are needed in order to improve our understanding of which particular design features are well received for particular types of issues and in particular contexts. Describing the different features of a problem may, for example, be perceived as being particularly important for highly politicised topics where the very nature of the problem is contentious. Taking equity considerations into account through a focus on only one group may be perceived as inappropriate in political systems that may have a long tradition of either addressing all major ethnocultural groups in policy documents or perhaps of focusing on no groups in particular. Evaluations are also necessary as a way of improving our understanding of whether, and how, policy briefs influence policymaking. Table 13.4 provides a description of one approach to the formative evaluation of policy briefs.

Table 13.4
An example of an approach to the formative evaluation of a policy briefs series

The McMaster Health Forum surveys those to whom it sends a policy brief, with the long-term goal of identifying which design features work best for particular types of issues, and in which particular health system contexts. Participation is voluntary, confidentiality assured, and anonymity safeguarded

- **Twelve features of the policy briefs series are the focus of questions in the formative evaluation survey**
  - Describes the context of the issue being addressed
  - Describes different features of the problem, including (where possible) how it affects particular groups
  - Describes three options for addressing the problem
  - Describes key implementation considerations
  - Employs systematic and transparent methods to identify, select, and assess synthesised research evidence
  - Takes quality considerations into account when discussing the research evidence
  - Takes local applicability considerations into account when discussing the research evidence
  - Takes equity considerations into account when discussing the research evidence
  - Does not conclude with particular recommendations
  - Employs a graded-entry format (i.e. a list of key messages and a full report)
  - Includes a reference list for those who want to read more about a particular systematic review or research study, and
  - Is subject to a review by at least one policymaker, at least one stakeholder, and at least one researcher. This process is termed a *merit* review to distinguish it from a standard *peer* review which would typically only involve researchers in the review process
- **For each design feature, the survey asks**
  - How useful did they find this approach (on a scale from 1 = Worthless to 7 = Useful)?
  - Are there any additional comments or suggestions for improvement?
- **The survey also asks**
  - How well did the policy brief achieve its purpose, namely to present the available research evidence on a high-priority issue in order to inform a policy dialogue where research evidence would be just one input to the discussion (on a scale from 1 = Failed to 7 = Achieved)?
  - What features of the policy brief should be retained in future?
  - What features of the policy brief should be changed in future?
  - What key stakeholders can do better or differently to address the high-priority issue and what they personally can do better or differently?
  - Their role and background (so that the McMaster Health Forum can determine if different groups have different views and experiences related to policy briefs)

The Evidence-Informed Policy Networks (EVIPNet) operating in Africa, Asia and the Americas plan to use a similar approach in the formative evaluation of their policy briefs

Resources

Useful documents and further reading

- Research Matters. Knowledge Translation: A 'Research Matters' Toolkit. Ottawa, Canada: International Development Research Centre: www.idrc.ca/research-matters/ev-128908-201-1-DO_TOPIC.html – Source of additional examples of policy briefs (Chapter 8) and, most importantly, guidance about effective communication (Chapters 6 and 7)

- Canadian Health Services Research Foundation. Communication Notes: Reader-Friendly Writing - 1:3:25. Ottawa, Canada: Canadian Health Services Research Foundation: www.chsrf.ca/knowledge_transfer/pdf/cn-1325_e.pdf – Source of advice about writing for an audience of policymakers and other stakeholders

- Lavis JN, Boyko JA: *Evidence Brief: Improving Access to Primary Healthcare in Canada*. Hamilton, Canada: - McMaster Health Forum; 2009 [13] – Example of a policy brief for a specific country (Canada)

- Oxman AD, Bjorndal A, Flottorp SA, Lewin S, Lindahl AK: *Integrated Health Care for People with Chronic Conditions*. Oslo, Norway: Norwegian Knowledge Centre for the Health Services; 2008 [20]: www.kunnskapssenteret.no/Publikasjoner/5114.cms?threepage=1 – Example of a policy brief that provides an exhaustive review of the potential elements of policy options before bundling them together into three viable options for a specific country (Norway)

Links to websites

- *Health Evidence Network/European Observatory on Health Systems and Policies:* www.euro.who.int/hen/policybriefs/20070327_1 – Source of policy briefs targeted at policymakers in the World Health Organization's European Region

- *Program in Policy Decision-Making (PPD)/Canadian Cochrane Network and Centre (CCNC) database:* www.researchtopolicy.ca/search/reviews.aspx – Source of policy briefs as well as systematic reviews and overviews of systematic reviews (with links to policymaker-friendly summaries of systematic reviews and overviews of systematic reviews)

- *SUPPORT Collaboration:* www.support-collaboration.org – Example of a source of policymaker-friendly summaries of systematic reviews relevant to low- and middle-income countries

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14. Organising and using policy dialogues to support evidence-informed policymaking

John N Lavis, Jennifer Boyko, Andrew D Oxman, Simon Lewin, Atle Fretheim

Summary

Policy dialogues allow research evidence to be considered together with the views, experiences and tacit knowledge of those who will be involved in, or affected by, future decisions about a high-priority issue. Increasing interest in the use of policy dialogues has been fuelled by a number of factors: 1. The recognition of the need for locally contextualised 'decision support' for policymakers and other stakeholders 2. The recognition that research evidence is only one input into the decision-making processes of policymakers and other stakeholders 3. The recognition that many stakeholders can add significant value to these processes, and 4. The recognition that many stakeholders can take action to address high-priority issues, and not just policymakers. In this chapter, we suggest questions to guide those organising and using policy dialogues to support evidence-informed policymaking. These are:

1. Does the dialogue address a high-priority issue?
2. Does the dialogue provide opportunities to discuss the problem, options to address the problem, and key implementation considerations?
3. 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?
4. Does the dialogue ensure fair representation among those who will be involved in, or affected by, future decisions related to the issue?
5. Does the dialogue engage a facilitator, follow a rule about not attributing comments to individuals, and *not* aim for consensus?
6. Are outputs produced and follow-up activities undertaken to support action?

Scenarios

Scenario 1: *You are a senior civil servant and have been invited to a policy dialogue about an issue that is of growing interest to the Minister. You are concerned about whether the policy dialogue is being organised in way that will inform different elements of the issue, and recognises the importance of drawing on both research evidence and stakeholder views and experiences. You also want to ensure that the policy dialogue does not conclude with a recommendation that is politically or economically unfeasible and hence potentially awkward for the Minister concerned*

Scenario 2: *You work in the Ministry of Health and have been given a few hours to prepare an assessment of a planning document for a policy dialogue that will address a high-priority issue for the Ministry. All that you have been told is that this policy dialogue is different in a number of ways from the type of stakeholder engagement processes that you have organised in the past for the Ministry, including how it will be informed by a pre-circulated summary of the best available research evidence on the problem, options to address it, and implementation considerations*

Scenario 3: *You work in an independent unit that supports the Ministry of Health in its use of*

research evidence in policymaking. You are organising a policy dialogue for senior Ministry officials and key stakeholders to deliberate about a problem, options to address it, and implementation considerations. You have been told to organise the policy dialogue in a way that is likely to enhance its potential impact, but you want guidance on how to do so

Background

For policymakers (Scenario 1), this chapter suggests a number of questions that they might ask their staff to consider when deciding whether to participate in a policy dialogue or how to maximise the value of a policy dialogue that they are sponsoring. For those who support policymakers (Scenarios 2 and 3), this chapter suggests a number of questions to guide their assessment of a plan for a policy dialogue or their organisation of one.

There has been growing interest in identifying interactive knowledge-sharing mechanisms that allow research evidence to be brought together with the views, experiences and tacit knowledge of those who will be involved in, or affected by, future decisions about high-priority issues [1,2]. This interest has been fuelled by a number of developments:

1. The recognition of the need for locally contextualised 'decision support' for policymakers and other stakeholders [3,4]
2. The recognition that research evidence is only one input into the decision-making processes of policymakers and other stakeholders [5,6]
3. The recognition that many stakeholders can add significant value to these processes [7,8], and
4. The recognition that many stakeholders can take action to address high-priority issues – not just policymakers

Policy dialogues constitute a promising 'interactive knowledge-sharing mechanism'. The development of these dialogues has been informed, at least in part, by findings from two systematic reviews of the factors influencing the use of research evidence in policymaking [9,10]. While the reviews identified that research in this field was not extensive, rigorous or consistent, a few factors did emerge consistently:

- Higher levels of interaction between researchers and policymakers increased the likelihood of research evidence being used (particularly when the interactions were based on informal relationships). Conversely, a lack of interaction decreased the likelihood of research evidence being used
- Timeliness increased the likelihood of research evidence being used in policymaking, while a lack of timeliness decreased this likelihood
- The likelihood of research evidence being used in policymaking increased when available research evidence accorded with the beliefs, values, interests or political goals and strategies of politicians, civil servants and stakeholders (or when particular political stances had not yet been decided). Conversely, a lack of accord decreased the probability of research evidence being used.

Policy dialogues have the potential to improve the use of research by shaping the factors listed above. This potential can be realised through support related directly to:

1. Interactions between researchers and policymakers (and among a wider range of stakeholders who are able to take action)
2. The timely identification and interpretation of the available research evidence (when a policy dialogue is organised urgently to address a high-priority issue), and
3. The 'real time' identification of accord between research evidence and the beliefs, values,

interests or political goals and strategies of policymakers and stakeholders.

Table 14.1 provides a simple framework for distinguishing the differences between 'dialogue' and 'debate'. While *dialogue* is the goal of policy dialogues, *debate* does not typically offer suitable opportunities for the support of constructive interaction and the identification of shared ground. This does not mean that debate does not have a critical and complementary role in policymaking. Indeed, forums are also needed to enable contesting value positions to be articulated. In these, the extent and quality of the research evidence supporting alternative problem definitions, options, and implementation strategies (supported by very different value positions) can be publicly presented and debated.

Table 14.1
Differences between dialogue and debate

Dialogue	Debate
Collaborative	Oppositional
Common ground	Winning
Enlarges perspectives	Affirms perspectives
Searches for agreement	Searches for differences
Causes introspection	Causes critique
Looks for strengths	Looks for weaknesses
Re-evaluates assumptions	Defends assumptions
Listens for meaning	Listens for countering
Remains open-ended	Implies a conclusion

Source: Adapted from the Co-Intelligence Institute and appearing in Jones CM, Mittelmark MB. The IUHPE Blueprint for Directed and Sustained Dialogue for Partnership Initiatives

Models for policy dialogues can be distinguished in three ways both from each other and from other stakeholder engagement processes in terms of their:

- Goals – which can include information sharing, networking, discussion, consensus statement development, and action planning about related goals and/or processes
- Group composition, and
- Group processes – which can include pre- and post-circulated materials and format (e.g. concurrent deliberations in several groups or sequential deliberations in a single group, and rules)

Considerable attention has been paid to these distinctions (and their implications) in public engagement initiatives [11,12] and in clinical practice guideline development [13-15]. For example, researchers have developed an evidence base to inform choices about the design of guideline development processes. This includes approaches to panel composition, the format of pre-circulated evidence summaries, and consensus rules [16].

Far less attention has been given to the benefits, harms and costs of alternative approaches to policy dialogues that seek to support evidence-informed policymaking, or to support other types of evidence-informed action related to health systems. A systematic review found no rigorous evaluations of the effects of policy dialogues [2]. However, the review did identify a variety of policy dialogue characteristics that appear promising, including consultation with all parties affected by an outcome, the fair representation of scientists and stakeholders, high-quality syntheses of the scientific evidence, and skilful chairing [1,2]. Our own

formative evaluation of a policy dialogue that involved policymakers, civil society groups and researchers from 20 low- and middle-income countries found that pre-circulated evidence summaries, skilled facilitation, the application of the Chatham House Rule (prohibiting the attribution of particular comments), and a lack of emphasis on achieving consensus, were among the highly-valued design features [17].

Questions to consider

The following questions can guide how to organise and use policy dialogues to support evidence-informed policymaking:

1. Does the dialogue address a high-priority issue?
2. Does the dialogue provide opportunities to discuss the problem, options to address the problem, and key implementation considerations?
3. 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?
4. Does the dialogue ensure fair representation among those who will be involved in, or affected by, future decisions related to the issue?
5. Does the dialogue engage a facilitator, follow a rule about not attributing comments to individuals, and *not* aim for consensus?
6. Are outputs produced and follow-up activities undertaken to support action?

1. Does the dialogue address a high-priority issue?

Policy dialogues should ideally address an issue considered high priority by some or all stakeholders. If a particular issue has been on the agenda of key stakeholders for some time, then policy dialogues, like policy briefs (discussed further in Chapter 13), may act as a way to spur action [18]. The Evidence-Informed Policy Network (EVIPNet) in both Burkina Faso and Cameroon, for example, convened a national policy dialogue to address the long-standing challenge of low coverage rates for artemisinin-based combination therapies (ACT) to treat uncomplicated falciparum malaria. If an issue in a policy brief is relatively new, then the associated policy dialogue may potentially play an agenda-setting role. But irrespective of whether it does so or not, the focus of a policy dialogue would always ideally be an issue deemed to be a priority by at least some key stakeholders.

The process of obtaining consensus on the selection of a priority issue for a policy dialogue, however, may leave organisers hostage to policymakers and stakeholders who support the status quo or are seeking to avoid change. Issues related to obtaining consensus on how a problem can best be clarified or options best framed, may also privilege those seeking to avoid change. Such groups may be also be privileged by the choice of dialogue invitees or facilitator, and decisions related to follow-up activities to support action. (These concerns form the focus of Questions 2 to 6 below). While our focus in this chapter is primarily on policy dialogues organised with the active engagement of existing political regimes, other policy dialogue scenarios are possible. These may include dialogues organised by those working with opposition leaders, ‘shadow’ health ministers, and others who might not share the prevailing orthodoxy about what constitutes a high-priority issue or a feasible set of approaches to addressing it.

Because of the way in which priorities change, the timing of policy dialogues is also often critical. In order to address issues when they are considered a high priority and ‘windows of opportunity’ for change are evident, it may be necessary to organise policy dialogues rapidly.

2. Does the dialogue provide opportunities to discuss the problem, options to address the problem, and key implementation considerations?

Policy dialogues, like policy briefs, focus on:

1. Different features of a problem, including (where possible) how it affects particular groups
2. Options to address the problem, and
3. Key implementation considerations

During policy dialogues, participants may conclude that none of the options are optimal. In these instances, they may advocate 'borrowing' additional features from other options in order to create a new hybrid (or 'bundled') option. Dialogues may also be convened at different stages of the policymaking process, giving greater focus to *problem* definition earlier in the process and to *implementation* later.

Policy *briefs* present the best available synthesised research evidence. But (as described in Chapter 13 in the book) they do not speak explicitly to potential actions based on that evidence. Policy *dialogues*, in contrast, can do this. The focus, in these instances, could be on working through what actions can be taken *individually* (by a politician, for example) and *collectively* (by a coalition, for instance, of health professional associations). The fact that this may be done 'collectively', however, does not imply that everyone will be included. It may instead mean that only several of the groups whose members are participating in a policy dialogue will move forward collectively. And as we discuss below, consensus on the type of collective action chosen is usually not actively sought.

3. 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?

A policy brief, as described in Chapter 13, is a highly efficient way of introducing global *and* local research evidence about a problem [18]. It also provides options to address a problem, as well as introducing key implementation considerations to dialogue participants. The goal of a policy dialogue is to support the full discussion of relevant considerations (including research evidence) about a high-priority issue in order to inform policymaking and other types of action. Dialogues provide a vehicle for harnessing many types of information and creating locally contextualised knowledge that can inform policymaking and other types of action.

To ensure that key relevant research evidence is taken into account, it is important to have policy briefs pre-circulated. This is also critical because policy briefs provide common ground from which discussions about the issues can be launched. At the start of each set of deliberations (about a problem, options and implementation considerations, respectively), highlights from the corresponding section of a policy brief may be introduced informally. These final highlights would ideally be informally presented and discussed. The alternative of a more formal method of presentation may give some participants the impression that research evidence constitutes the sole focus of the deliberations, or takes precedence over other considerations. A final round of deliberations focusing on who may be able to support the implementation of possible actions has no corresponding written section in a policy brief.

While research evidence can be codified in the form of a policy brief, it is perhaps the views,

experiences and tacit knowledge of those who will be involved in, or affected by, future decisions about a high-priority issue that can best emerge spontaneously in the course of a policy dialogue. Dialogue participants would ideally be invited to introduce their own understanding about factors that need to be considered. These include on-the-ground realities and constraints, the values and beliefs of citizens and communities, the power dynamics among interest groups, institutional constraints, and considerations related to 'external' factors (such as the broader economy or, in the case of low- and middle-income countries, the strategic priorities of donors). These understandings are particularly important given that they shape participant approaches to a problem, the options they may choose to address the problem, the implementation of the options, and future decisions related to who should undertake particular actions.

4. Does the dialogue ensure fair representation among those who will be involved in or affected by future decisions related to the issue?

A policy dialogue would ideally bring together the many parties involved in, or affected by, future decisions related to a high-priority issue in order to ensure fair representation. As a first step, this requires the careful mapping of the full range of stakeholders associated with the issue at hand. Stakeholder mapping may be achieved by creating an inventory of role categories specific to the issue. Those involved could include:

- Policymakers (including elected officials, political staff or civil servants) in the national government and/or in sub-national governments if independent public policymaking authority related to the issue exists at the sub-national level. These policymakers may be drawn from many different departments, and not just health or finance departments
- Managers in districts/regions, healthcare institutions (e.g. hospitals), and non-governmental organisations, and other relevant types of organisations
- Staff or members of civil society groups, which could include consumer groups, health professional associations, and industry associations, among others, and
- Researchers in national research institutions, universities, and from other jurisdictions.

In some countries, individuals may play several of these roles concurrently (or have played them sequentially).

As a second step, individuals will need to be carefully selected from the role categories above. Two criteria may be useful:

1. The ability of the individuals to articulate the views and experiences of a particular constituency on the issue, while constructively engaging at the same time with participants drawn from other constituencies and learning from them, and
2. The ability of the individuals to champion the actions that will address the issue within their constituencies

Different political systems will have different traditions relating to which individuals – and how many individuals – will be invited to meetings to discuss high-priority issues. It may or may not be possible, or desirable, to adapt a tradition for a specific policy dialogue. But when determining the number of invitees, a key consideration should be the balanced representation of all key constituencies, on one hand, and the opportunity for all individuals to contribute, on the other hand. A total of between fifteen and twenty participants might achieve such a balance for some issues and in some contexts. A group twice this size might be needed for other issues and in other contexts. In some French-speaking African countries, for example, EVIPNet teams have organised policy dialogues that were even larger (this is discussed further in Table 14.2). In order to allow all individuals to contribute in these instances, the local organisers included frequent concurrent deliberations among subgroups.

Table 14.2
Policy dialogues about improving malaria treatment

Two EVIPNet teams, one in Burkina Faso and one in Cameroon, convened national policy dialogues to support a full discussion of relevant considerations (including research evidence) about how to support the widespread use of artemisinin-based combination therapy to treat uncomplicated falciparum malaria. The dialogue in Burkina Faso brought together 38 stakeholders in May 2008 to discuss this problem, three options to address it, and key implementation considerations. The insights derived from the policy dialogue directly informed the preparation of the Burkina Faso government's successful application to the Global Fund to Fight AIDS, Tuberculosis and Malaria. Held in January 2009, the dialogue in Cameroon included almost twice the number of stakeholders involved in Burkina Faso, and worked through the particular features of the same problem of malaria treatment in Cameroon, three options appropriate to the problem, as well as related implementation considerations. This group was divided into four smaller 'working groups' for each set of deliberations. The dialogue received significant media attention and increased the likelihood of meaningful action in the following months

Invitation letters to policy dialogues can prove critical to engaging key individuals. The title for a policy dialogue would ideally be worded in a way that will engage invited policymakers and stakeholders and may, for example, take the form of a compelling question. The invitation letter would ideally provide a list of those involved in planning the dialogue and a list of funders (of the organisation convening the dialogue and of the dialogue itself), as well as their affiliations.

5. Does the dialogue engage a facilitator, follow a rule about not attributing comments to individuals, and *not* aim for consensus?

A skilled, knowledgeable and neutral facilitator is required to ensure that a policy dialogue is run well. Skill is needed to keep the deliberations focused on the issue at hand, to ensure that all dialogue participants have a voice in the deliberations, and to challenge constructively any possible misinterpretations of the issue under discussion, and evidence of the other factors that may influence decision making. It is particularly important for the facilitator to guard against the possibility that perceptions about the relative status of participants (whether based on position in an organisation, educational background or other factors) or other considerations such as language barriers, do not privilege some participants in the dialogue over others. An intermediate level of knowledge about the issue at hand *and* the local context is required in order to interpret the contributions of the policy brief and to manage the dynamics during the deliberations. Neutrality is also required in order to ensure that all participants perceive the dialogue as a 'safe harbour' for deliberation and not as a vehicle for facilitators to steer deliberations in a direction that they may prefer.

Arranging such a safe space for deliberation requires some commonly agreed rules to reassure individuals that they may speak frankly and without fear of repercussion in the media – or elsewhere – for having done so. Many policy dialogues follow the Chatham House Rule: "Participants are free to use the information received during the meeting, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed" (www.chathamhouse.org.uk/about/chathamhouserule). This rule ensures that

dialogue participants feel empowered to act on what they have learned while knowing that their contributions will not be used to hurt them in the future.

Not aiming for consensus may seem paradoxical at first. But this is an important provision for many policymakers and stakeholders. Policymakers are ultimately responsible for setting policies. Therefore, while actual policy development typically occurs through a complex set of interactions involving government officials and stakeholders, most policymakers would be very hesitant to commit themselves to one approach after only a single dialogue, or without the opportunity to confer with policymakers in other parts of government or with other stakeholders. Similarly, some stakeholders will need to return to their groups or organisations in order to decide what actions the groups or organisations should take. All of this said, although seeking consensus may not be an appropriate goal in most contexts, consensus can and probably should be embraced if it emerges spontaneously.

6. Are outputs produced and follow-up activities undertaken to support action?

Action to improve health is the preferred outcome for policy dialogues, and therefore mechanisms are needed to equip both dialogue participants and others with the tools to support such action. As a minimum, both the policy brief and a high-level summary of the policy dialogue (i.e. a summary of key points rather than a detailed report) should be actively disseminated. The dialogue summary would need to remain true to the Chatham House Rule that requires comments not to be attributed to identified individuals or to individuals with identified affiliations. Under this same rule, the dialogue summary may not include a list of dialogue participants.

Additional steps can also be taken to support any required action. For example, the McMaster Health Forum, a university-based convenor of policy dialogues:

1. Offers dialogue participants the opportunity to participate in a brief video interview in which they can describe the insights drawn from the dialogue, or the actions they see as critical to addressing a high-priority issue. At the same time, it is made clear to them that their personal choice to relax the way in which the Chatham House Rule applies to them does not alter the way in which the rule applies to others
2. Offers a personalised briefing about the implications of the dialogue to key stakeholder groups in order to support their understanding of what the policy brief and dialogue summary mean for them, and
3. Offers a year-long evidence service that brings to attention newly published or newly identified systematic reviews. This provides added momentum to proposed actions or the need for changes. The video interviews and evidence service updates are all posted on the Forum's website to inspire and inform others.

As with all efforts in this nascent domain, such follow-up activities warrant further evaluation.

Over time, consideration can be given to how policy dialogues might 'fit' with the rest of an evidence-informed policymaking process and whether they can become the norm for important issues.

Conclusion

Policy dialogues represent a new and evolving approach to supporting evidence-informed policymaking. They are one of many forms of political interaction that could usefully be more evidence-informed. The organisation and use of policy dialogues continues to evolve through practical experience. Evaluations of this approach are needed in order to improve our understanding of which particular design features and follow-up activities are well received for particular types of issues and in particular types of contexts. For example, the Chatham House Rule may be perceived as being particularly important for highly politicised topics. Similarly, the objective of *not* aiming for consensus may be perceived as inappropriate in political systems that have a long tradition of civil society engagement in policymaking. Evaluations are also necessary as a way of improving our understanding of whether, and how, policy dialogues and related follow-up activities support evidence-informed policymaking. Table 14.3 provides a description of one approach to the formative evaluation of policy dialogues.

Table 14.3
An example of an approach to the formative evaluation of policy dialogues

The McMaster Health Forum surveys participants in all of the policy dialogues it convenes and has the long-term goal of identifying *which* particular design features work best for *which* particular types of issues and in *which* types of health system contexts. Participation is voluntary, confidentiality is assured, and anonymity safe-guarded

- Dialogues are characterised by twelve features and these are the focus of the questions in the formative evaluation survey. A dialogue:
  - Addresses a high-priority issue
  - Provides an opportunity to discuss different features of the problem, including (where possible) how these affect particular groups
  - Provides an opportunity to discuss three options to address the policy issue
  - Provides an opportunity to discuss key implementation considerations
  - Provides an opportunity to discuss who might take what action
  - Is informed by a pre-circulated evidence brief that mobilises both global and local research evidence about the problem, three options to address the problem, and key implementation considerations
  - Is informed by a discussion about the full range of factors that can inform how to approach the problem, options to address the problem, and the implementation of these options
  - Brings together many parties who would be involved in, or affected by, future decisions related to the issue
  - Ensures fair representation among policymakers, stakeholders, and researchers
  - Engages a facilitator to assist with the deliberations
  - Allows for frank, off-the-record deliberations by following the Chatham House Rule: "Participants are free to use the information received during the meeting, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed", and
  - Does *not* aim for consensus
- For each design feature the survey asks**:**
  - How useful did they find this approach on a scale ranging from 1 (Worthless) to 7 (Useful)?
  - Comments and suggestions for improvement?
- The survey also asks:
  - How well did the policy dialogue achieve its purpose, namely to support a full discussion of relevant considerations (including research evidence) about a high-priority issue in order to inform action on a scale from 1 (Failed) to 7 (Achieved)?

  - What features of the dialogue should be retained in future?
  - What features of the dialogue should be changed in future?
  - What others can do better or differently to address the high-priority issue and what they personally can do better or differently?
  - Their role and background (so that the McMaster Health Forum can determine if different groups have different views about, and experiences with, the dialogues)
- The McMaster Health Forum also plans to conduct brief follow-up surveys six months after a dialogue, with the objective of identifying what, if any, actions have been undertaken by dialogue participants and what, if any, impacts have been achieved. Here again, participation is voluntary, confidentiality is assured, and anonymity safeguarded
- The Evidence-Informed Policy Networks (EVIPNet) operating in Africa, Asia and the Americas plan to use a similar approach in the formative evaluation of their policy dialogues

Resources

Useful documents and further reading

- Lomas J, Culyer T, McCutcheon C, McAuley L, Law S: *Conceptualizing and Combining Evidence for Health System Guidance*. Ottawa, Canada: Canadian Health Services Research Foundation; 2005 [2]
  www.chsrf.ca/other_documents/pdf/evidence_e.pdf

Links to websites

- *Chatham House:*
  www.chathamhouse.org.uk – Source of the 'Chatham House Rule'

- *Evidence-Informed Policy Networks:*
  www.evipnet.org – Network of groups involved in convening national policy dialogues

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14. Fretheim A, Schunemann HJ, Oxman AD: **Improving the use of research evidence in guideline development: 3. Group composition and consultation process.** *Health Research Policy and Systems* 2006, **4.**

15. Fretheim A, Schunemann HJ, Oxman AD: **Improving the use of research evidence in guideline development: 5. Group processes.** *Health Research Policy and Systems* 2006, **4.**

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15. Engaging the public in evidence-informed policymaking

Andrew D Oxman, Simon Lewin, John N Lavis, Atle Fretheim

Summary

In this chapter, we address strategies to inform and engage the public in policy development and implementation. The importance of engaging the public (both patients and citizens) at all levels of health systems is widely recognised. They are the ultimate recipients of the desirable and undesirable impacts of public policies, and many governments and organisations have acknowledged the value of engaging them in evidence-informed policy development. The potential benefits of doing this include the establishment of policies that include their ideas and address their concerns, the improved implementation of policies, improved health services, and better health. Public engagement can also be viewed as a goal in itself by encouraging participative democracy, public accountability and transparency. We suggest three questions that can be considered with regard to public participation strategies. These are:

1. What strategies can be used when working with the mass media to inform the public about policy development and implementation?
2. What strategies can be used when working with civil society groups to inform and engage them in policy development and implementation?
3. What methods can be used to involve consumers in policy development and implementation?

Scenario

The Minister of Health has promised to deliver a new healthcare reform. In declaring her intentions, the Minister has emphasised the importance of engaging stakeholders in the development of the proposal for the reform. You are a member of the team responsible for developing the proposal and for ensuring that key stakeholders are informed about relevant research evidence and engaged effectively in evidence-informed policy development

Background

In this chapter, we present three questions that policymakers and those who support them can ask when considering strategies to inform and engage the public in evidence-informed policy development and implementation, such as in the scenario described above.

Much of the terminology used to describe individuals who come into contact with health systems is problematic [1,2]. Words such as ‘patient’, ‘client’, ‘consumer’ and ‘user’ are commonly used, but may be misleading or considered unacceptable by those they are applied to. Several of these terms, for example, implicitly suggest the existence of a market-based relationship and some people may find this objectionable. Nonetheless, the term ‘consumer’ is commonly used when describing approaches that engage people in decisions about healthcare [3,4].

Healthcare ‘consumers’ can include patients, unpaid carers, parents or guardians of patients, users of health services, disabled people, members of the public who are the potential

recipients of either health promotion or public health programmes, people who believe they have been exposed to potentially harmful products or services, people who believe they have been denied products or services which they believe could have benefited them, as well as those who pay for health services (e.g. as tax payers) [5]. Depending on the context, people can be described as 'lay' people, 'non-experts', 'service users', 'members of the general public' or as 'citizens'. In this chapter, we use the term 'the public' to include people in any of these various roles, and the term 'consumer' when referring to *individuals* in any of these roles.

The importance of engaging the public at all levels of health systems is widely recognised. This is because members of the public are the ultimate recipients of the effects of health policy, both intended and unintended, and many governments and organisations have acknowledged the value of public engagement in policy development. The potential benefits of doing this include the development of policies that include their ideas or address their concerns, the improvement of policy implementation, better health services, and better health outcomes.

Public engagement can also be viewed as a goal in itself by encouraging participative democracy, public accountability and transparency. The World Health Organization's Declaration of Alma Ata, for example, states that "... people have the right and duty to participate individually and collectively in the planning and implementation of their health care" [6].

However, there is little evidence of the effects of engaging the public in health policy [3,4,7-11]. Of the 42 papers identified in a systematic review of public involvement in the planning and development of health care, for instance, 31 of these (74%) were case studies [7]. Often these papers attributed the involvement of the public to changes in services, including attempts to make services more accessible. Changes in the attitudes of organisations to involving the public and positive responses from consumers who took part in initiatives were also reported. Although this evidence suggested that public participation may have contributed to changes in the provision of services, such evidence was limited and came almost entirely from high-income countries.

When considering strategies to inform and engage the public in health policy development and implementation, it may be helpful to consider three broad strategy categories: those for working with the mass media (including the use of interactive information and communication technologies), those for working with civil society groups (organisations representing various interests), and those related to consumer involvement. As illustrated in Figure 15.1, effective engagement of the public in evidence-informed health policymaking is likely to require a combination of these overlapping strategies.

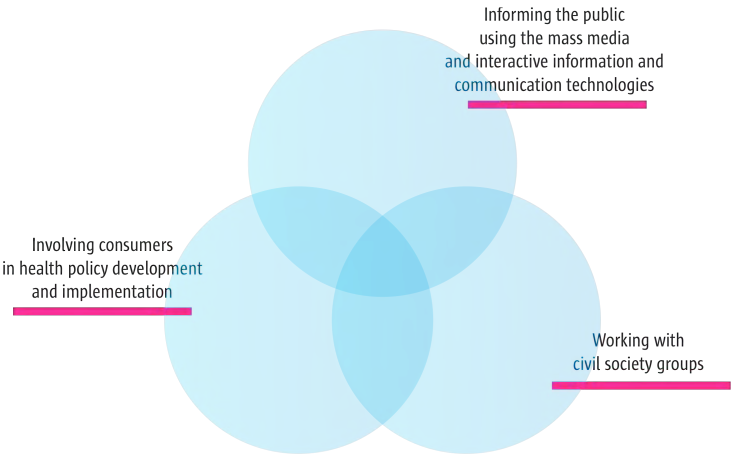

Figure 15.1
Strategies to engage the public in evidence-informed health policymaking

Questions to consider

The following questions can be considered when developing and implementing health policies:

1. What strategies can be used when working with the mass media to inform the public regarding policy development and implementation?
2. What strategies can be used when working with civil society groups to inform and engage them in policy development and implementation?
3. What methods can be used to involve consumers in policy development and implementation?

1. What strategies can be used when working with the mass media to inform the public regarding policy development and implementation?

One way in which the public can be informed about (and potentially engaged in) evidence-informed health policy development is through the use of reports in the mass media. These reports are able to receive wide coverage and are an important source of information for the public, for healthcare professionals, and for policymakers. Although the impact of healthcare reporting is difficult to measure, mass media can influence individual health behaviours, levels of healthcare utilisation, healthcare practices, and health policy [12-15]. Nevertheless, health technology assessment (HTA) agencies, clinical practice guideline developers and units that support the use of research evidence in health policy have, thus far, generally made negligible efforts to communicate evidence to the wider public in this way [16].

Journalists are likely to agree that the accurate reporting of research related to health policy is important. However, many are faced with constraints that may limit their ability to achieve this goal [17,18]. These obstacles may include a lack of time, publishable space (or airtime) and knowledge; competition for audiences; difficulties with understanding and communicating jargon; problems with finding and using sources; problems with editors (who rarely have research training and may inhibit the ability to report research accurately); and commercial pressures (the need for journalists to sell their stories). As a consequence, much health reporting is either inaccurate or incomplete [19-23].

Mutual efforts by researchers and journalists are therefore likely to be needed to address these constraints, and may entail using a variety of strategies, including training, or innovations such as structured press releases [24]. Well-designed press releases could help to address the lack of time, space and knowledge within the mass media, as well as difficulties journalists may have with understanding jargon. It is, however, unclear whether such strategies could result in greater coverage for particular health issues [25]. Understanding the constraints which journalists face may also contribute to the design of more effective communication strategies. These could, for example, reflect recognition of the competing pressures of publishing space and audiences, as well as issues related to finding and using sources, or problems with editorial control. Efforts that do not recognise these constraints in the mass media are unlikely to be effective.

Possible strategies for working with the media to inform the public about the development and implementation of evidence-informed health policies include:

- *Structured press releases*: research press releases do not routinely highlight study limitations, and data are often presented using formats that may exaggerate the

perceived importance of findings [21,25]. Presentations comparable to the format of the structured abstracts used in many journals (which include a section for the contextual description of the results, a section highlighting any limitations, and a statement about potential conflicts of interest) could help to ensure that journalists are given – and are therefore more likely to report – key information related to impact evaluations or other policy-relevant research. Press releases for policy-relevant systematic reviews could help to place research in context and shift the focus of reporting from the latest (but often misleading) single study to a broader understanding of newsworthy research relevant to important policy decisions [26,27]. Structures could also be used that are similar to those provided in the summaries of systematic reviews including, for example, key messages, a summary of key findings, and a description of the basis for the information used [28-31]. Similarly, press releases for policy briefs might use a structure that mirrors the contents of a policy brief, including structured sections with information about how a problem is defined, the relevant policy options and implementation strategies, and summaries of the key messages about the underlying evidence [32]

- *Fact boxes*: information is often not reported about the benefits and harms of clinical interventions and policy options, or it is reported in ways that are uninformative or may be misleading [21,22,25,33]. Standardised tables, similar to a summary of findings tables, that quantify the probability of outcomes together with different treatments or policy options [34,35], could also be used to enhance an understanding of the benefits, harms and costs of different options, and the extent to which we can be confident about those consequences [31,36,37]

- *Press conferences*: providing opportunities to question those involved in policy development and decisions may offer added value to journalists. The effectiveness of press conferences can be maximised by: planning ahead (two to three weeks where possible), timing the conference to achieve maximum coverage (e.g. holding it in the morning for a suitable length of time, ensuring that the conference does not clash with other events), issuing invitations that include all the relevant facts well in advance, ensuring easy access to the press conference, preparing a press kit (including a structured press release, fact boxes, relevant background material, and suitable illustrations), and ensuring that presentations are appropriately simple and have clear messages [38]

- *Providing stories*: it is important for journalists to be able to tell a story that will appeal to their audiences and also be both easily understood and informative. Providing journalists with appropriate anecdotes can facilitate this. These can play a complementary role in research and can facilitate the application of research evidence in health care decisions [39]. Anecdotes can also be vehicles enabling the delivery of research results to policymakers and health professionals, as well as to the public. It is, however, important to ensure that anecdotes are used appropriately to personalise and illustrate research findings and to present information in more meaningful ways. Conversely, it is important to ensure that anecdotes do not conflict with the available evidence

- *Avoiding jargon*: unnecessary jargon should be avoided in order to improve communication with journalists and the public in turn. In instances where terminology is necessary or useful, a glossary or the inclusion of fact boxes can help to explain essential terms and thereby help to improve reporting on important health policy issues. Another strategy is to write about issues in plain language first and then to introduce the relevant technical terms. This allows readers to understand technical concepts more

clearly before seeing complex technical detail. The more common alternative of using the technical term first and providing a definition later, presents a barrier to immediate understanding and interrupts the flow of reading and assimilation of ideas

- *Providing access to experts*: to facilitate good coverage of important health policy issues it is important to identify people with relevant expertise, including researchers who are familiar with the research in question, as well as policymakers, stakeholders and people with a good understanding of relevant research or policy development methods. Briefing experts who are familiar with the media and can guide communication with the media may help to ensure that key information is delivered in ways that are understandable

- *Tip sheets*: providing journalists with simple questions to consider and discuss when they are interviewing experts, or researching or writing up stories, can help to ensure that key questions are asked about health policy issues and options, and that the answers are reported [20,40,41]

- *Training*: workshops or other types of training can help journalists gain greater understanding of evidence-informed health policymaking and to develop skills that may help to improve the quality of health policy reporting [18,42]. As a consequence, the extent to which the public is well-informed and better able to engage in the development and implementation of health policies may be improved

In addition to working with traditional mass media, consideration can be given to using new interactive information and communication technologies (ICTs) – including websites, blogs, and social networking sites – which are becoming more and more important. However, a lack of Internet access in some communities, particularly in low- and middle-income countries, limits access to online public engagement platforms. Infrastructural and cultural contexts vary and require different models and approaches. In addition, although the Internet is an important and increasingly popular source of information, policymakers face the challenge (similar to those in other forms of mass media) of competing with vast amounts of health information, some of which is neither accurate nor complete [34,43]. Harnessing the full potential of ICTs to engage the public in evidence-informed health policymaking therefore requires a mix of old and new technologies and thoughtful planning.

An OECD report on the challenges of online citizen engagement [44] proposes the following 10 strategies to guide online consultation:

1. Start planning early
2. Demonstrate commitment to the online consultation and communicate this clearly
3. Guarantee personal data protection
4. Tailor your approach to fit your target group
5. Integrate online consultation with traditional methods
6. Test and adapt tools (e.g. software, questionnaires)
7. Promote your online consultation
8. Ensure that sufficient time, resources and expertise are available to provide thorough analysis of the input received in the course of the online consultation
9. Publish the results of the online consultation as soon as possible and inform participants of the next steps in the policymaking process. Ensure that participants are informed of how the results were used in reaching decisions
10. Evaluate the consultation process and its impacts

2. What strategies can be used when working with civil society groups to inform and engage them in policy development and implementation?

Civil society can be defined in a number of ways. In this chapter, we use this term to refer to the wide range of organisations outside the state. These may include patient organisations, community groups, coalitions, advocacy groups, faith-based organisations, charities or voluntary organisations, professional associations, trade unions, and business associations.

The National Institute for Health and Clinical Excellence (NICE), based in the United Kingdom, has adopted a comprehensive approach to involving the public and has a programme with dedicated staff responsible for public involvement [45-48]. NICE's efforts to involve stakeholder organisations are far more extensive than that of other clinical guideline developers. We are not aware of similar programmes aimed at engaging stakeholder organisations or civil society in the development or implementation of evidence-informed health policymaking. All of the strategies used by NICE, however, could potentially be applied to the engagement of civil society in evidence-informed health policymaking. Civil society, for example, could potentially be engaged in comparable stages for the development and implementation of health policies, as illustrated in Figure 15.2.

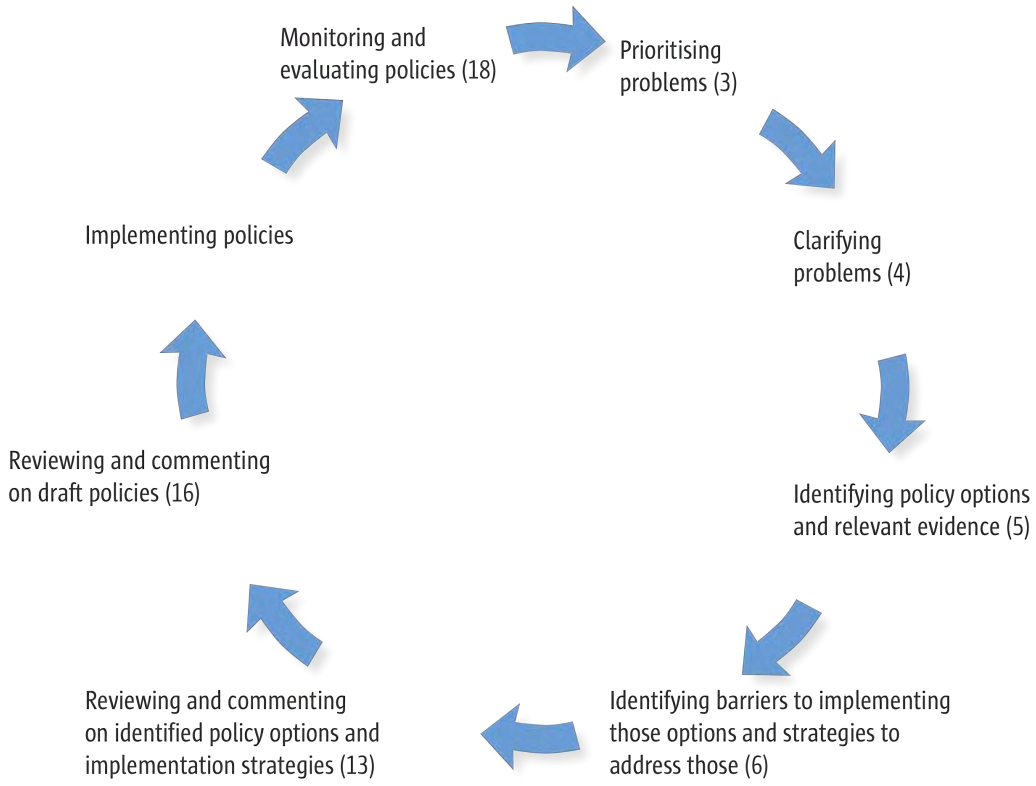

Figure 15.2
Engagement of civil society in stages in the policy development and implementation cycle*

** The numbers shown in brackets refer to the articles in this series (described in the Introduction [1]) which address the use of research evidence to inform each stage in the cycle*

NICE includes the following organisations as stakeholders in its clinical guideline development process [49]:

- National patient and carer organisations that directly or indirectly represent the interests of people whose care is covered by each guideline ('patient and carer stakeholders')
- National organisations that represent healthcare professionals who provide the services described in each guideline ('professional stakeholders')
- Companies that manufacture the medicines or devices used in the clinical area covered by each guideline and whose interests may be significantly affected by each guideline ('commercial stakeholders')

- Providers and commissioners of health services in England, Wales and Northern Ireland
- Statutory organisations including the Department of Health, the Welsh Assembly Government, National Health Service (NHS) Quality Improvement Scotland, the Healthcare Commission, and the National Patient Safety Agency
- Research organisations that have done nationally-recognised research in each relevant area

It may be important to engage a broader list of civil society or stakeholder organisations for those health policies that focus on health systems arrangements including, for example, trade unions and business associations. NICE alerts potential stakeholder organisations in a number of ways and invites them to register their interest. These alerts include the issuing of press releases, listing topics on their website with details of how to register, contacting organisations that have registered for previous guidance to alert them to new topics, and writing to other patient, carer and professional organisations that may have an interest. NICE then contacts registered stakeholders and encourages them to get involved in the development of the different stages of such guidance. These include determining the scope of guidance, submitting evidence, commenting on draft guidance, and checking guidance revisions prior to publication.

Politicians and their constituency offices are likely to be familiar with the potential challenges of working with civil society, including claims that particular groups represent relevant patients or the public. Not all such groups do so adequately. Many patient groups are primarily advocacy groups that focus on obtaining resources for their particular area of interest or on providing peer support, rather than engaging in broader health policy issues [50]. And many patient organisations are funded by industry and may therefore also have conflicting interests [51]. Professional organisations, too, may have similar conflicts of interest. Some, for example, may receive funds from industry and be concerned primarily with the effects of policies on their own members rather than on health or the wider healthcare system.

3. What methods can be used to involve consumers in policy development and implementation?

Useful frameworks for describing and considering approaches to consumer involvement have been developed including, for example, the framework presented by Oliver and colleagues [3,4]. Similarly, Telford and colleagues have also developed a set of principles and indicators for involvement [52]. While both of these approaches have been developed in the context of consumer involvement in research, they provide useful frameworks for considering public engagement in health policy development and implementation.

The framework developed by Oliver and colleagues (Table 15.1) characterises diverse methods for involving consumers based on the degree of involvement, the forum for communication, involvement in decision making, the recruitment of representatives, training, and financial support.

In their framework, the degree of involvement is classified in three ways, namely *consultation*, *collaboration* and *consumer control*. The process of *consultation* entails asking consumers for their views and using these to inform decision making. Policymakers or researchers, for example, may hold one-off meetings with consumers to ascertain their priorities or may write to consumers in accessible terms to invite their views. Consumers' views, in such instances, are not necessarily adopted although they may inform the decisions taken.

Table 15.1
A framework for describing and considering approaches to consumer involvement

** Adapted from Oliver and colleagues [3]*

Characteristics of different approaches	Examples
Degree of consumer involvement	• Consultation • Collaboration • Consumer control
Forum for communication	• Written consultation • Interviews • Focus groups • Consumer panels • Committee membership
Involvement in decision making	• No involvement • Implicit involvement • Explicit involvement
Recruitment	• Targeted, personal invitations • Wide advertising • Use of mass media • Contact by telephone, mail or email
Training and support	• Education (e.g. workshops) • Counselling • Mentoring • Introduction days
Financial support	• No financial support • Reimbursement of expenses • Fee or honoraria

Collaboration entails active, ongoing partnerships with consumers. For example, consumers may be committee members (e.g. on the boards of health service organisations or regulatory committees) or they may collaborate less formally. Again, there is no guarantee that consumers' views will influence decisions, but collaboration offers more opportunities for them to be heard than consultation. Formal methods of decision making may help to ensure appropriate forms of collaboration [53]. Without these it may be difficult to judge whether public involvement has had any influence at all.

Consumer control, the third kind of consumer involvement in the framework, entails consumers developing and advocating or implementing health policies themselves. Professionals are only involved at the invitation of the consumers. In the context of public health systems this might entail, for example, the inclusion of politicians who are elected to represent their constituents.

Within this framework, methods are further distinguished by descriptions of the forum for communication (such as one-to-one interviews, focus groups, citizens' juries, town meetings, committee meetings, and working groups) and methods for decision making (such as informal committee consensus or voting). The presence or absence of transparent descriptions of methods for decision making can distinguish implied involvement in decisions (such as participation in committee meetings) and explicit involvement in decisions. Without transparent decision making there is a risk that consumer involvement may be regarded as tokenism.

Telford and colleagues used a consensus process to identify principles and indicators of successful consumer involvement [52]. Each of the eight principles they identified can be

measured by at least one clear indicator (see Table 15.2). Although developed specifically to address the involvement of consumers in research, these principles and indicators are also relevant to public engagement in policy development and implementation.

Principles	Indicators
• The roles of consumers are agreed	• The roles of consumers were documented
• The cost of consumer involvement is budgeted for	• Consumers were reimbursed for their travel • Consumers were reimbursed for their indirect costs (e.g. carer costs)
• Policymakers respect the differing skills, knowledge and experience of consumers	• The contribution of consumers was reported
• Consumers are offered training and personal support to enable their involvement	• Consumers were provided with training to enable their involvement
• Policymakers ensure that they have the necessary skills to involve consumers effectively	• Policymakers were provided with training to enable them to involve consumers effectively
• Consumers are involved in decision making	• Consumers' advice was documented • Consumers' role in decision making was documented
• Consumer involvement is described in policy briefs	• Consumers' contributions were described and acknowledged in policy briefs
• Policy briefs are available to consumers in formats and languages they can easily understand	• Summaries of policy briefs were disseminated to consumers in appropriate formats

Conclusion

Policymakers, and those who support them, need to tailor strategies for engaging the public in evidence-informed policymaking to fit specific contexts, policies and key target groups. In poor countries, for example, radio may be the most important mass media. The Internet offers new opportunities for the interactive engagement of large numbers of consumers in policy development and decisions, and new ways to keep the public informed. Access to the Internet, however, varies widely. It is therefore important that the use of the Internet as a participation tool should be supplemented with other strategies in order to avoid exacerbating inequities in public engagement.

For the public to be effectively engaged in evidence-informed policymaking – and to avoid accusations of token involvement and consultation – it is important that policymakers and those who support them carefully plan and evaluate the strategies they use.

Resources

Useful documents and further reading

- Organisational self-assessment and planning tool for consumer and community participation: a tool for organisations involved in health policy and education. Version 1.0. 2003.

- Crawford MJ, Rutter D, Manley C, Weaver T, Bhui K, Fulop N, et al. Systematic review of involving patients in the planning and development of health care. BMJ 2002;325:1263–7

- Nilsen ES, Myrhaug HT, Johansen M, Oliver S, Oxman AD. Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material. Cochrane Database of Systematic Reviews 2006, Issue 3

Links to websites

- *International Alliance of Patients' Organizations (IAPO):* www.patientsorganizations.org – A global alliance of patients' organisations working at international, regional, national and local levels to represent and support patients, their families and carers

- *Association of Health Care Journalists (AHCJ):* www.healthjournalism.org/index.php – An independent, non-profit organisation dedicated to advancing public understanding of healthcare issues. Its mission is to improve the quality, accuracy and visibility of healthcare reporting, writing and editing

- ***INVOLVE*** is a national advisory group, funded by the National Institute for Health Research (NIHR): www.invo.org.uk/index.asp – Supports and promotes active public involvement in NHS, public health and social care research

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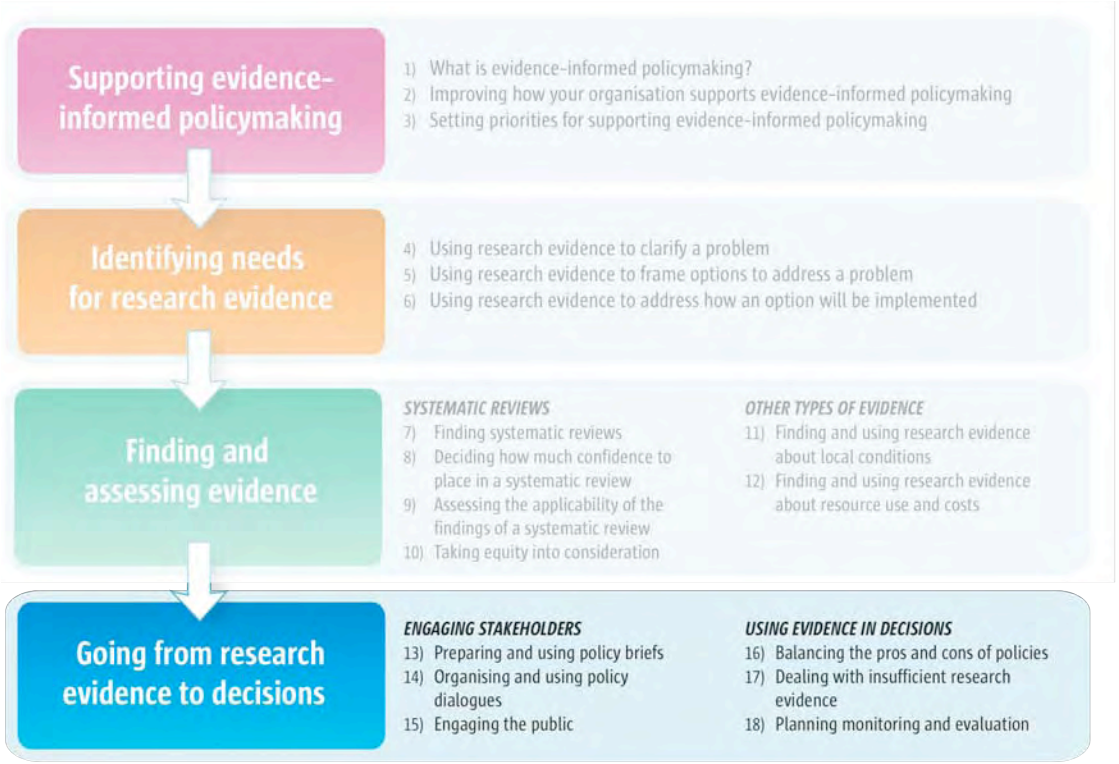

Chapters 16, 17, and 18
Going from research evidence to decisions: using evidence in decisions

16. Using research evidence in balancing the pros and cons of policies

Andrew D Oxman, John N Lavis, Atle Fretheim, Simon Lewin

Summary

In this chapter, we address the use of evidence to inform judgements about the balance between the pros and cons of policy and programme options. We suggest five questions that can be considered when making these judgements. These are:

1. What are the options that are being compared?
2. What are the most important potential outcomes of the options being compared?
3. What is the best estimate of the impact of the options being compared for each important outcome?
4. How confident can policymakers and others be in the estimated impacts?
5. Is a formal economic model likely to facilitate decision making?

Scenario

You work in the Ministry of Health. The Minister of Health has asked you to present a summary of the expected benefits, harms and costs of an important change in health policy that is being considered

Background

In this chapter, we suggest five questions that policymakers and those who support them can ask when considering how to ensure that judgements about the pros and cons of health policy and programme options are well-informed by research evidence. Such questions can be asked, for instance, in scenarios such as the one described above.

Research alone does not make decisions [1]. Judgements are always required, including judgements about what evidence to use, how to interpret that evidence, and our confidence in the evidence. More importantly, decisions about options require judgements about whether the anticipated desirable consequences outweigh the undesirable consequences (see Figure 16.1) [2]. In addition to making judgements about how big the impacts are likely to be, decision-making processes require judgements about how important the impacts are,

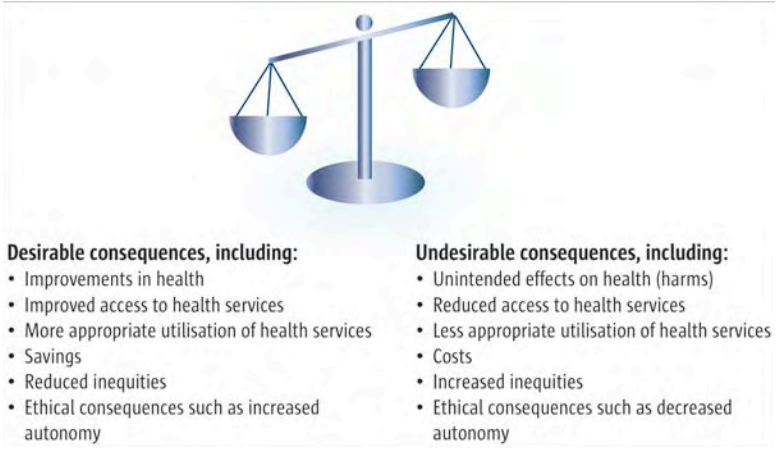

Figure 16.1
Balancing the pros and cons of health policies and programmes*

** Decisions about health policy or programme options require judgements about whether the desirable consequences of an option are worth the undesirable consequences*

the resources that are required to implement the option [3], and the extent to which the option is a priority relative to other ways in which those resources might be used.

It would be simple to make a decision if an option was expected to have large benefits with few downsides and little cost, if we were confident about the evidence and the importance of the benefits, and if the option was a clear priority. Unfortunately, this is rarely the case. More often the expected impacts and costs are uncertain, and complex and difficult judgements must be made.

The questions we propose here do not reduce the need for judgements. However, more systematic considerations and discussions of these questions could help to ensure that important considerations are not overlooked and that judgements are well informed. These could also help to resolve disagreements or at least help to provide clarification. If these judgements are made transparently they could help others to understand the reasoning behind health policy decisions.

Preparing and using a balance sheet (as explained in Table 16.1 and addressed in the first four questions discussed below) can facilitate well-informed decision making. Sometimes using a formal economic model, such as a cost-effectiveness analysis, can also be helpful. This latter issue is addressed in the fifth question discussed in this chapter. The considerations we suggest here are based on the work of the GRADE Working Group [4]. Although the Group's focus has been primarily on clinical practice guidelines, their approach to decisions about clinical interventions can also be applied to policies and programmes [5].

Table 16.1
The pros and cons of balance sheets

A balance sheet is a simple but powerful way to present the advantages and disadvantages of different options, including policy options [6,7]. In this section we describe the evidence and judgements needed to prepare and use a balance sheet such as the one shown in Table 16.2. We also describe the advantages of using a balance sheet compared to the use of non-systematic and non-transparent judgements of experts.

The aim of a balance sheet is to help decision makers develop an accurate understanding of the important consequences of the options being compared. Balance sheets help to achieve this in a number of ways. Firstly, they condense the most important information, thus enabling efficient consideration. Secondly, balance sheets focus attention on the most important outcomes. This increases the likelihood that decision makers will gain an accurate perception of what is known about the impacts of the options being considered and the important consequences. Thirdly, the act of constructing a balance sheet is a helpful mechanism for organising thinking, structuring evidence analysis, and focusing debate. Fourthly, balance sheets can help to develop more explicit judgements about what the most important consequences of policy options are, the underlying evidence, and subsequent judgements about the balance between the relative advantages and disadvantages of the various options. Lastly, balance sheets can provide other decision makers with 'raw information', thereby helping them to apply their own judgements about the trade-offs between desirable and undesirable consequences.

But two important limitations also need to be considered when using balance sheets in decision making. Firstly, when there are complicated trade-offs between multiple outcomes, judgements may require a high level of information processing by policymakers. Secondly, when weighing up different outcomes, the value judgements employed by policymakers could remain implicit. Formal economic modelling may help to address these limitations by making any underlying assumptions (including value judgements) more explicit. This enables the use of sensitivity analyses to explore the effects of both uncertainties and varying assumptions on the results.

Questions to consider

The following five questions can be used to guide the use of evidence to inform judgements about the pros and cons of health policy and programme options:

1. What are the options that are being compared?
2. What are the most important potential outcomes of the options being compared?
3. What is the best estimate of the impact of the options being compared for each important outcome?
4. How confident can policymakers and others be in the estimated impacts?
5. Is a formal economic model likely to facilitate decision making?

The first four questions are intended to guide the use of balance sheets in policy decision making. Answering the final question can help to ensure that the scarce resources used in full economic analyses are applied where they are needed most.

Ideally, balance sheets (and economic models) should be constructed by researchers or technical support staff together with policymakers. They should also be based on systematic reviews for the same reasons described elsewhere that highlight the importance of systematic reviews in general [8]. We will not consider the many detailed judgements that must be made when constructing a balance sheet as these have been addressed elsewhere [9]. Policymakers are rarely, if ever, in a position where they are required to make all such judgements themselves. Yet even in instances where there is competent technical support to prepare a balance sheet, it is important that policymakers know what to look for and what questions to ask. This ensures that balance sheets can be used judiciously to inform the decisions for which policymakers are accountable.

1. What are the options that are being compared?

When using a balance sheet such as the one shown in Table 16.2, the first consideration is the need to identify what options are being compared. Often this is not as straightforward as it sounds (see Table 16.3, for example). Those preparing a balance sheet must decide on both the option being considered *and* the comparative option. Typically, the comparison is the status quo. However, the status quo is likely to vary from setting to setting. Decisions need to be made, therefore, about which characteristics of the status quo are:

- Crucial – such that research with a comparison without those same characteristics would be excluded
- Important but not crucial – such that research with a comparison without those same characteristics would be included, but with less confidence that the results would be the same in the chosen setting, and
- Unimportant – such that we would be confident that the results are likely be the same in the chosen setting

These same judgements also need to be made about the options being considered: which of their characteristics are crucial, important or unimportant in terms of affecting the likely impacts?

Table 16.2
Should the licensing of tobacco retailers be conditional on not selling tobacco to minors?

Should the licensing of tobacco retailers be conditional on not selling tobacco to minors?

Population: Minors (as defined by a legal age limit)
Setting: Europe
Interventions: Licensing of tobacco retailers and compliance checks[1]
Comparison: No licensing or compliance checks

Outcomes	Impact			Number of studies	Quality of the evidence (GRADE) [2]
	Pessimistic	Best guess	Optimistic		
Reduced number of smokers per year	**0**	**?**	**1,650 in the country** (population 4.5 million)	4 studies	⊕◯◯◯ Very low[3]
Life years saved per year	**0**	**?**	**9,240 in the country** (population 4.5 million)	4 studies	⊕◯◯◯ Very low[4]
Cost per year	**€10.5 million** (3 controls per year)	**?**	**€7.2 million** (1 control per year and internal control)	0 studies	⊕◯◯◯ Very low[5]

[1] The proposed licensing law in the European country in question would require retailers to have a licence to sell tobacco. The policy options that were considered included three compliance checks per year, and one per year together with internal control. Compliance checks (by a teenager attempting to purchase tobacco) are done to ensure that tobacco is not being sold to minors. The penalty for non-compliance is the loss of a retail licence. Internal control requires the retailers themselves to have routines for controlling the sale of tobacco to minors

[2] See Table 16.8

[3] The systematic review used as a basis for this summary (which was not used in the expert report to which we refer in subsequent tables) included one relevant randomised trial and three controlled before-after studies with important limitations. There was a high risk of bias for the estimated impacts on smoking prevalence. Important inconsistencies in the results lacked a compelling explanation. The studies in the review were based in the United States of America (2), the United Kingdom (1) and Australia (1), with differences in the interventions and uncertainty about whether similar results would be expected in the country where this policy was being considered. Two studies found an effect in lower age groups that was not sustained in one study; two studies did not find a change in smoking behaviour. It is difficult to estimate, based on these studies, what the best estimate would be of the impact of licensing of tobacco retailers with compliance checks on reducing the number of people who smoke. A lower estimate would be that there would be no impact from this intervention. The upper estimate is taken from an expert report (see Tables 16.3-16.5)

[4] The upper estimate of life years saved, which is taken from the same expert report, has the same limitations as the estimate of the impact on smoking behaviour, since it is based on that estimate. In addition, it is based on assumptions about what would happen long beyond the length of the studies that had evaluated impacts on smoking behaviour as well, and assumptions about the impact of the changes in smoking behaviour on mortality

[5] The estimates of the cost of the policy are taken from the expert report (described in subsequent tables in this chapter). These are based on an estimate of how many retailers sold tobacco, an assumption about what it would cost to process each licence, and an assumption about the costs of each compliance check

Table 16.3.
What is being compared? Case example: The licensing of tobacco retailers

The reduction of teenage smoking was a priority for a Minister of Health in a European country. A report of policy options to achieve this was commissioned by the government concerned and a report was prepared by leading public health experts. One of the policy options considered in the report was the licensing of tobacco retailers. The loss of such a license was proposed as a penalty for the illegal selling of tobacco to minors. This option was compared in the report to the status quo, namely the absence of licensing for tobacco retailers. The public health experts did not undertake or use a systematic review, nor did they specify which characteristics of the policy option (or comparator) they considered to be crucial or important.

A number of important issues were not considered in the report. Important differences, for example, might have existed between the status quo of the areas where the policymakers considered implementing the policy and those where the studies were done. Such considerations may have included other policies already in place to reduce the sales of tobacco to minors. It is possible that existing legislation may already have made the sale of tobacco to minors illegal, or contained other methods by which legislation could be enforced (e.g. through fines or other penalties for the illegal sale of tobacco, face-to-face education of retailers (informing them about the legal requirements), or media campaigns (to raise community awareness). There might also have been differences in the ease with which minors could obtain tobacco from other sources (e.g. from parents and friends or through theft).

The experts explicitly considered two policy options for the licensing of tobacco retailers, namely three compliance checks per year (by a teenager attempting to purchase tobacco) to make sure that retailers were not selling tobacco to minors, and one compliance check per year together with internal control (requiring retailers themselves to control that tobacco is not being sold to minors). The penalty for non-compliance in both cases was the loss of the relevant licence. Other ways of enforcing licensing are possible, some of which have been evaluated in other studies. The experts writing this report did not explicitly address whether differences in approaches to licensing enforcement were likely to result in important differences in the effectiveness of the policy.

2. What are the most important potential outcomes of the options being compared?

Policymakers, in general, are motivated by the desire to serve the people they represent and should be interested primarily in the impacts of policy and programme options on outcomes that are important to those affected (see, for example, Table 16.4). These include health outcomes, access to – or utilisation of – health services, unintended effects (harms), and resource use (costs or savings) (see Figure 16.1). Other often important consequences include the distribution and equity of benefits and costs [10], and spillover effects to other sectors. Ethical consequences such as those related to a reduction in people's autonomy, may also be important.

Being explicit about which outcomes are important can help to ensure that the important consequences of an option are not overlooked. It can also help to ensure that unimportant consequences are not given undue weight. This is particularly important for surrogate outcomes – i.e. outcomes that are not important in and of themselves. They are considered important because they are believed to reflect important outcomes. For example, people do not typically regard their blood pressure as an important concern. What makes the issue of blood pressure important is its association with strokes, heart attacks and death, all of which *are* very much of importance to people. So when considering options targeted at

hypertension (or other cardiovascular risk factors), decisions should be based on the impacts of these options on important outcomes (cardiovascular disease). Evidence of impacts on blood pressure alone is only a form of indirect evidence of the impacts on cardiovascular disease.

Table 16.4
What are the most important outcomes? Case example: The licensing of tobacco retailers

The primary outcome considered by the expert report commissioned by the government concerned was the prevalence of smoking. This was recognised to be a surrogate outcome for the consequences of smoking. The impact on life years saved was estimated based on the estimated impact on the prevalence of smoking and on epidemiological data linking smoking to mortality. Impacts on morbidity were not considered. Other impacts that were explicitly considered by the experts were administrative costs, political acceptability and public acceptability. There are a number of other outcomes that the expert report could have considered, including:

- Costs to retailers and potential harms (e.g. increased theft or cross-border shopping)
- Who would pay the administrative costs of such schemes
- The potential differences in the impacts of the policy on different populations (e.g. socio-economically disadvantaged minors or those living close to the country's border who could potentially cross over into a neighbouring country to purchase tobacco)
- Ethical consequences (e.g. those related to the use of a minor or person pretending to be a minor for compliance checks, or the fairness of the policy in relation to the potentially different impacts on different groups of minors and different retailers)

3. What is the best estimate of the impact of the options being compared for each important outcome?

Deciding whether the desirable impacts of an option are worth the undesirable impacts requires an estimate of how large these different impacts (and their economic consequences) will be. Ideally, this should take the form of a comparison between what could be expected for every important outcome if an option *were* to be implemented, and what could be expected if it *were not* – or what could be expected if a different option were implemented instead (see Table 16.5, for example). It is also useful to know how precise each estimate is – i.e. what the 'confidence interval' is for each estimate (this is explained further in Table 16.6).

Table 16.5
What are the best estimates of the impacts? Case example: The licensing of tobacco retailers

The expert report on policies to reduce teenage smoking commissioned by the government concerned estimated that licensing tobacco retailers would result in a 10% relative reduction in the number of smokers. Using the current prevalence of smokers as a reference, the absolute effect of the policy was estimated to be a reduction of 1,650 smokers per year. Based on epidemiological models of the increased risk of dying due to smoking, the experts estimated that this policy would save 9,240 lives per year. No confidence intervals were provided, although it was noted that the actual effect was very uncertain and a range of estimates was used to calculate the cost-effectiveness of licensing tobacco retailers. Administrative costs were estimated, based on an estimate of how many retailers sold tobacco, an assumption about what it would cost to process each licence, and an assumption about what each inspection would cost (to check compliance with the requirement not to sell tobacco to minors).

Using these different assumptions, the total estimated cost was between €7.2 million and €10.5 million per year

It is important that decision makers recognise the difference between estimates of effect that are presented as *relative* effects, and those that are presented as *absolute* effects. Patients, health professionals, and people making decisions about health policies and programmes are more likely to decide to use an intervention if its effects are reported as relative effects than if they are reported as absolute effects [11]. For example, a study reported that 61% of a sample of health professionals in Australia agreed to implement a colorectal cancer screening programme that would reduce the rate of deaths from bowel cancer by 17% (the relative risk reduction). In comparison, only 24% of the health professionals agreed to implement a programme that produced an absolute reduction in deaths from bowel cancer of 0.4% (the absolute risk reduction) [12]. Both estimates were, in fact, from the same programme (for an explanation of the difference between relative and absolute effects see Table 10.4 in Chapter 10 [10]).

4. How confident can policymakers and others be in the estimated impacts?

Six factors can lower our confidence in estimates of the impacts of a policy or programme [13]:

- A weak study design
- Other study limitations
- Imprecision
- Inconsistent results
- Indirectness of the evidence
- Publication bias

An assessment of these factors is inevitably technical. Policymakers do not need to have a detailed understanding of these factors or how they are assessed. But both policymakers and their technical support staff can still benefit from understanding why it is important to consider these factors.

Studies in which a programme is randomly assigned reduce the risk of unknown or unmeasured differences between the groups being compared. This gives greater confidence that impacts are attributable to the programme and not some other factor [14-16]. Study designs that do not use random assignment can account only for differences that are measured. For example, a study in which communities are randomly assigned to a programme or policy option, such as the licensing of tobacco retailers, would provide more compelling evidence of the impacts of an option than a study would if it compared communities that had decided themselves whether to implement a particular option. This is because communities that decide to implement an option are likely to differ from those that do not in ways that could have an impact on the outcomes of interest (in this case, smoking prevalence). It would therefore be impossible to know whether the differences in outcomes were due to the policy or programme option or due to those other differences between the communities.

Other study limitations can affect both randomised and non-randomised impact evaluations. Incomplete data or the unreliable measurement of outcomes, for instance, may increase the risk of an estimate being biased, and therefore lower confidence in the derived estimates.

Imprecision (as indicated by a wide confidence interval) also lowers the confidence with which chance can be ruled out as a factor shaping any observed differences in outcomes between compared groups, and consequently our confidence in an estimated effect. (Table 16.6 explains the concept of confidence intervals in further detail)

If different studies of the same policy or programme option have inconsistent results and there is no compelling explanation for such differences, there will also be less confidence in knowing the expected impacts arising from implementing the option.

Table 16.6
Confidence intervals

A confidence interval (CI) is the range around an estimate which conveys how precise the estimate is. The confidence interval is a guide that represents how sure it is possible to be about the quantity we are interested in (e.g. the effect of a policy option on an outcome of interest). The narrower the range between the upper and lower numbers of the confidence interval the more precise the estimate is, and the more confident it is possible to be about the true value. The wider the range, the less certain it is possible to be. The width, or range, of the confidence interval reflects the extent to which chance may be responsible for an observed estimate (wider intervals reflect the greater likelihood of chance being a factor). A 95% CI means that we can be 95% confident that the true size of an effect is between the lower and upper confidence limit. Conversely, there is a 5% chance that the true effect is outside this range

There are several ways in which studies might not be directly relevant to a particular question, and therefore result in less confidence in the results. As noted above, if an indirectly relevant outcome (such as blood pressure) is measured in place of an important outcome (cardiovascular disease), there will be less confidence in the impacts on the important outcome (for which the indirect outcome is a surrogate). If only *indirect* comparisons are provided, confidence will also be lower. We would be less confident in studies of an option that lacked head-to-head comparisons, for example, between the option compared to a control (with no intervention) and studies of a different option compared to a control. Other ways in which evidence can be indirect include differences between a study and the setting of interest in:

- The characteristics of the population
- The option being considered, or
- The status quo or comparison option

Studies that find statistically significant effects are often more likely to be published than those that do not [17]. When such 'publication bias' appears likely, confidence in estimates from published studies alone may also be lowered. Publication bias should be considered in instances where there are a number of small studies, especially if these are industry-sponsored, or if the investigators are known to share other similar conflicts of interest.

In summary, assessments of the 'quality' or robustness of evidence, and confidence in estimates of the likely impacts of options, depend on a consideration of *all* of the factors noted above. Although there are no fixed rules for assessing these factors, judgements related to the quality of evidence that explicitly address each factor help to reduce the likelihood of important factors being overlooked. They also help to reduce the probability of biased assessments of the evidence (see Table 16.7, for example). Using a systematic and transparent approach, such as the GRADE approach (see Table 16.8), makes it easier to inspect the judgements made [4].

Table 16.7
How confident are we in the estimated impacts? Case example: The licensing of tobacco retailers

The expert report commissioned by the government concerned concluded that the empirical basis for the licensing of tobacco retailers was "robust" but the basis for this judgement was unclear. The experts did not conduct, or cite, the systematic review that is referenced in Table 16.3, or any other systematic review as the basis for their estimates, even though a systematic review was available [18]. In contrast to the experts' unexplained judgement, an assessment of the evidence summarised

in the systematic review using the GRADE approach, suggests that the quality of the evidence was very low for all the important outcomes (see Table 16.8 for further information related to the GRADE assessment system). Table 16.1 summarises the findings of the experts' report in the form of a balance sheet for this policy decision and shows an assessment of the quality of the evidence for the three estimates using the GRADE approach.
The authors of the systematic review (which included a broader range of interventions and study designs) concluded: "Interventions with retailers can lead to large decreases in the number of outlets selling tobacco to youths. However, few of the communities studied in this review achieved sustained levels of high compliance. This may explain why there is limited evidence for an effect of the intervention on youth perceptions about ease of access to tobacco, and on smoking behaviour." The 'pessimistic' estimates of the benefits in Table 16.1 are consistent with the findings of the systematic review and were not considered in the expert report

Table 16.8
The GRADE system for assessing the quality of evidence

Evaluating the quality of evidence requires judgements about the extent to which one can be confident that an estimate of effect is correct. GRADE provides a systematic and transparent approach to making these judgements for each outcome important to a decision [13]. The judgements are based on the type of study design (randomised trials versus observational studies), the risk of bias (study limitations), the consistency of the results across studies, and the precision of the overall estimate across studies. Based on these considerations for each outcome, the quality of the evidence is rated as high, moderate, low, or very low, using the following definitions:	
⊕⊕⊕⊕ High	Confident that the true effect lies close to that of the estimate of the effect
⊕⊕⊕◯ Moderate	The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
⊕⊕◯◯ Low	The true effect may be substantially different from the estimate of the effect
⊕◯◯◯ Very low	Very uncertain about the estimate

5. Is a formal economic model likely to facilitate decision making?

Formal economic models, such as cost-effectiveness analyses and cost-utility analyses, can help to inform judgements about the balance between the desirable and undesirable consequences of an option [7]. Economic models can be valuable for complex decision making and for testing how sensitive a decision is to key estimates or assumptions. A model, though, is only as good as the data on which it is based. When estimates of benefits, harms or resource use come from low-quality evidence, the results will necessarily be highly speculative (an example is provided in Table 16.9).

A full economic model is more likely to help to inform a decision when there is:
- A large difference in the resources consumed between the compared options
- Large capital investments are required, such as the construction of new facilities
- Uncertainty about whether the net benefits are worth the incremental costs
- Good quality evidence regarding resource consumption

An economic model can also be used to clarify information needs by exploring the sensitivity of an analysis to a range of plausible estimates.

Table 16.9
Is a formal economic model likely to help? Case example: The licensing of tobacco retailers

The expert report commissioned by the government concerned included an economic analysis. This concluded that the cost per life year saved by licensing tobacco retailers and conducting compliance checks, was between approximately €900 and €92,000, with a best estimate of €8,000. The authors noted that there was substantial uncertainty about their estimates and suggested focusing on the range of estimates rather than the best estimate. Nevertheless, they reported exact estimates (based on the assumptions they made) and concluded that the empirical basis for recommending licensing tobacco retailers was robust. As a result, policymakers who failed to read this report critically could conclude (wrongly, in our opinion) that the report provided high-quality evidence that the licensing of tobacco retailers was as cost-effective as (or more cost-effective than) a wide range of clinical preventive services paid for by the government. A more systematic review of the underlying evidence [18], and a summary of the findings that included more systematic and transparent judgements of the quality of the evidence (as shown in Table 16.1), would have provided a better basis for decision making

Unfortunately, published cost-effectiveness analyses, particularly those undertaken for drugs, have a high probability of being flawed or biased. They are also specific to a particular setting which may differ in important ways from the setting of interest [19]. Policymakers may thus consider developing their own formal economic models. To do this, they must have the necessary expertise and resources.

Conclusion

Policy decisions are informed by assessments of the balance between the pros and cons of options. As we have recommended, these should be done systematically and transparently. When the net benefit (i.e. the difference between the desirable and undesirable consequences) is large in relation to the costs, we are more confident about a decision. When the net benefit is small in relation to the costs, we are less confident.

Generally, the less confident we are about the likely impacts of an option, the less confident we will be when deciding what to do. There are exceptions to this: firstly, we may have so little confidence about the impacts of something that it is easy to decide not to do it.

Secondly, even if there is little confidence in the benefits of a particular option it may be easy to decide to do something simply because there is little or no risk of harm, it doesn't cost much, and it might do some good. Many types of health information could be categorised as such. Policymakers, though, should be cautious about assuming that seemingly harmless polices and programmes *cannot* do harm [20]. Even something as simple as providing health information can, in fact, be deadly [21]. This is demonstrated by the advice given to mothers in many countries for nearly 50 years, namely that babies should sleep on their front. This seemingly harmless advice caused tens of thousands of deaths from sudden infant death syndrome [22].

Finally, despite important uncertainty about the likely impacts of a policy or programme, it may be easy to come to a decision that something that is promising should only be done in the context of a well-designed evaluation of its impacts [23].

Even when we are confident about the impacts of a policy or programme, it may not be a priority to implement it. The extent to which we are confident is a critical factor for deciding on what to do and the extent to which doing something is a priority. Other additional factors (such as those described in Table 16.10) may also determine whether policy or programme implementation is a priority or not.

Table 16.10
Factors that can determine the importance of implementing health policies and programmes

The following factors may sometimes be considered independently (or in combination) as criteria for setting priorities for implementing health policies and programmes:

- How serious the problem is – the more serious a problem is, the more likely it is that a policy or programme that addresses the problem will be a priority
- The number of people that are affected by the problem – the more people who are affected, the more likely it is that a policy or programme that addresses the problem will be a priority
- Benefits – the larger the benefit, the more likely it is that a policy or programme will be a priority
- Adverse effects – the greater the risk of undesirable effects, the less likely it is that a policy or programme will be a priority
- Resource use (costs) – the greater the cost, the less likely it is that a policy or programme will be a priority
- Cost-effectiveness – the lower the cost per unit of benefit, the more likely it is that a policy or programme will be a priority
- Impacts on equity – policies or programmes that reduce inequities may be more of a priority than ones that do not (or ones that increase inequities)

Decisions about priorities should rest on shared criteria or reasoning such as the ideas shown above. They should also be open to inspection and it should be possible to appeal these in light of considerations that stakeholders may raise. Regulation should ensure that these three conditions are met [24]. When criteria such as the above are used implicitly rather than explicitly, it is difficult to judge whether the criteria or the decisions were appropriate [25]

Resources

Useful documents and further reading

- Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, Schunemann HJ, and the GRADE Working Group. GRADE: An emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008; 336:924-6.

- Guyatt GH, Oxman AD, Kunz R, Vist GE, Falck-Ytter Y, Schunemann HJ, and the GRADE Working Group. What is 'quality of evidence' and why is it important to clinicians? BMJ 2008; 336:995-8.

- Guyatt GH, Oxman AD, Kunz R, Jaeschke R, Helfand M, Vist GE, Schunemann HJ, and the GRADE Working Group. Incorporating considerations of resource use. BMJ 2008; 336:1170-3.

Links to websites

- *SUPPORT Summaries:* www.support-collaboration.org/index.htm – Concise summaries of the pros and cons of health policies and programmes for low- and middle-income countries based on systematic reviews

- *GRADE Working Group:* www.gradeworkinggroup.org – The Grading of Recommendations Assessment, Development and Evaluation (or GRADE) Working Group has developed an approach to grading the quality of evidence and the strength of healthcare recommendations

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9. Guyatt G, Oxman A, Kunz R, Vist G, Brozek J, Norris S, *et al*: *GRADE guidelines: 1. Introduction – GRADE evidence profiles and Summary of Findings tables*. J Clin Epidemiol. 2009.
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13. Guyatt GH, Oxman AD, Kunz R, Vist GE, Falck-Ytter Y, Schunemann HJ: **What is "quality of evidence" and why is it important to clinicians?** *BMJ* 2008, **336:**995-8.
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17. Dealing with insufficient research evidence

Andrew D Oxman, John N Lavis, Atle Fretheim, Simon Lewin

Summary

In this chapter, we address the issue of decision making in situations in which there is insufficient evidence at hand. Policymakers often have insufficient evidence to know with certainty what the impacts of a health policy or programme option will be, but they must still make decisions. We suggest four questions that can be considered when there may be insufficient evidence to be confident about the impacts of implementing an option. These are:

1. Is there a systematic review of the impacts of the option?
2. Has inconclusive evidence been misinterpreted as evidence of no effect?
3. Is it possible to be confident about a decision despite a lack of evidence?
4. Is the option potentially harmful, ineffective or not worth the cost?

Scenario

The Ministry of Health is considering strategies to recruit and retain health professionals in underserved rural areas. You have been asked to advise the Minister of Health about these strategies. You have found many articles describing strategies that have been used in other settings but no reliable evaluations of the impacts of such strategies [1]

Background

In this chapter, we present five questions that policymakers and those who support them can ask when considering scenarios in which there may be insufficient evidence to inform judgements about the impacts of policy and programme options.

It is unrealistic to assume that one can predict the impacts of a health policy or programme with certainty. Many governance, financial and delivery arrangements have not been rigorously evaluated. Neither have many of the programmes, services and drugs that these arrangements support. But policymakers must still make decisions regardless of the availability (or paucity) of evidence to inform such decisions.

In this chapter, we focus on decision making undertaken in instances in which there is insufficient evidence available to be able to know whether an option will have the impacts intended, or whether it may have unintended (and undesirable) impacts. Common mistakes made when there is insufficient evidence at hand include making assumptions about the evidence without a systematic review, confusing a lack of evidence with evidence of no effect, assuming that insufficient evidence necessarily implies uncertainty about a decision, and the assumption that it is politically expedient to feign certainty. We present four questions in this chapter that can help to avoid these.

Questions to consider

If there is insufficient evidence at hand to allow one to be confident about the impacts of implementing a policy or programme option, the following questions can be considered:

1. Is there a systematic review of the impacts of the option?
2. Has inconclusive evidence been misinterpreted as evidence of no effect?
3. Is it possible to be confident about a decision despite a lack of evidence?
4. Is the option potentially harmful, ineffective or not worth the cost?

1. Is there a systematic review of the impacts of the option?

The first step in addressing a perceived lack of evidence is to find out what evidence *is* available. It is risky to make assumptions about the availability of evidence without referring to systematic reviews. Considerations related to finding and critically appraising systematic reviews are addressed in Chapters 5 and 6 [2,3].

For many questions related to health systems it is not possible to find relevant and up-to-date systematic reviews. There is widespread recognition, for example, that health workers are critical to achieving the Millennium Development Goals (MDGs) and other health goals. Yet despite this, an overview of systematic reviews of options to address human resources for health found only a small amount of high-quality, synthesised research evidence regarding the effects of a few options for the improvement of human resources for health [4]. Other overviews of reviews have found similar gaps [e.g. 5]. A lack of systematic reviews may not necessarily reflect a lack of evidence. But under such circumstances it is difficult for policymakers to know what evidence is available (see Table 17.1, for example).

Table 17.1
An independent inquiry into inequalities in health – an example of the need for up-to-date systematic reviews to know what evidence there is

In 1997, the incoming British Labour government was keen to reduce inequalities in health. To do this, it set about obtaining advice from the public health community about how to reduce inequalities, but clear limits were set about what advice it would find acceptable. The government wanted the advice quickly but stipulated that the advice had to be backed by evidence, in keeping with the government's expressed desire that public policy should be based on evidence [6]. The public health and other communities responded enthusiastically. A considerable amount of material was produced by, and for, the inquiry and many recommendations were made [7].

Subsequent reviews of the recommendations, however, found little evidence for the likely or actual effectiveness of many of the recommendations [7]. There was also a striking lack of adequate searches for relevant evidence or attempts to avoid bias in the way information was identified, appraised, and used.

This is not to suggest that governments cannot develop or implement policies that lack the support of unequivocal evidence. A lack of evidence does make it difficult, however, for them to decide on priorities. The readiness of researchers to recommend policies while knowing little about the likely effectiveness makes this more difficult still.

The task of this particular inquiry in the United Kingdom would have been easier if up-to-date systematic reviews had been available. Further, a system to ensure that the inquiry's recommendations would be reviewed regularly as new information and evidence emerged from updated systematic reviews, would have helped to ensure that adjustments in policies could have

been made. This could also have helped to avoid similar future difficulties when similar inquiries were undertaken or similar policies considered in other jurisdictions. International networks such as The Cochrane Collaboration (www.cochrane.org) (which focuses on healthcare) and the Campbell Collaboration (www.campbellcollaboration.org) (which focuses on education, crime and justice, and social welfare) have structures for preparing and keeping systematic reviews up-to-date, and these can facilitate the more effective use of evidence.

The investment of public resources in primary research has been substantial and remains so. But the returns remain far less than might otherwise have been expected, and the results scattered rather than synthesised. People faced with tasks and timescales similar to those of the British inquiry would be assisted greatly if up-to-date systematic reviews were more readily available. In terms of developing health policies and programmes, there are no unequivocal answers to the question "What works?" A systematic review is the best starting point for finding out what is known.

Rapid assessments may need to be undertaken when time or resources are limited. These assessments should be transparent about the methods used, as well as any important methodological limitations or related uncertainties. They should also address the need for, and urgency of, undertaking a full systematic review at a later date [8]. Consideration should also be given to commissioning a new review whenever a relevant, up-to-date review of good quality is unavailable. Appropriate processes should be used, including setting priorities for systematic reviews [9]. Building and strengthening international collaborations, such as the Cochrane Collaboration (www.cochrane.org), can help to avoid unnecessary duplications of effort involved in producing systematic reviews and help to ensure that up-to-date reviews are more readily available.

2. Has inconclusive evidence been misinterpreted as evidence of no effect?

Another common mistake made in instances when evidence is inconclusive is the confusion of a lack of evidence of an effect with 'evidence of no effect' [10]. It is wrong to claim that inconclusive evidence shows that a policy or programme has had 'no effect'. 'Statistical significance' should *not* be confused with importance.

When results are not 'statistically significant' it cannot be assumed that there was no impact. Typically a cut-off of 5% is used to indicate statistical significance. This means that the results are considered to be 'statistically non-significant' if the analysis shows that differences as large as (or larger than) the observed difference would be expected to occur by chance *more* than one out of twenty times ($p \geq 0.05$). There are, however, two problems with this assumption. Firstly, the cut-off point of 5% is arbitrary. Secondly, 'statistically non-significant' results (often mislabelled as 'negative'), might or might not be inconclusive. Table 17.2 contains a further discussion of this point and Figure 17.1 illustrates how the use of the term 'statistically non-significant' or 'negative' can be misleading.

Trends that are 'positive' (i.e. in favour of an option) but 'statistically non-significant' are often described as 'promising' and this can also be misleading. 'Negative' trends of the same magnitude, in contrast, are not typically described as 'warning signs'.

Policymakers should be aware that researchers commonly make these mistakes. To avoid being misled, they should be watchful for misinterpretations of statistical significance.

Figure 17.1
Two problems with classifying results as 'statistically non-significant' or 'negative'

The blue dots in this figure indicate the estimated effect for each study and the horizontal lines indicate the 95% confidence intervals. A 95% confidence interval means that we can be 95 % confident that the true size of the effect is between the lower and upper confidence limit (the two ends of the horizontal lines). Conversely, there is a 5% chance that the true effect is outside this range.

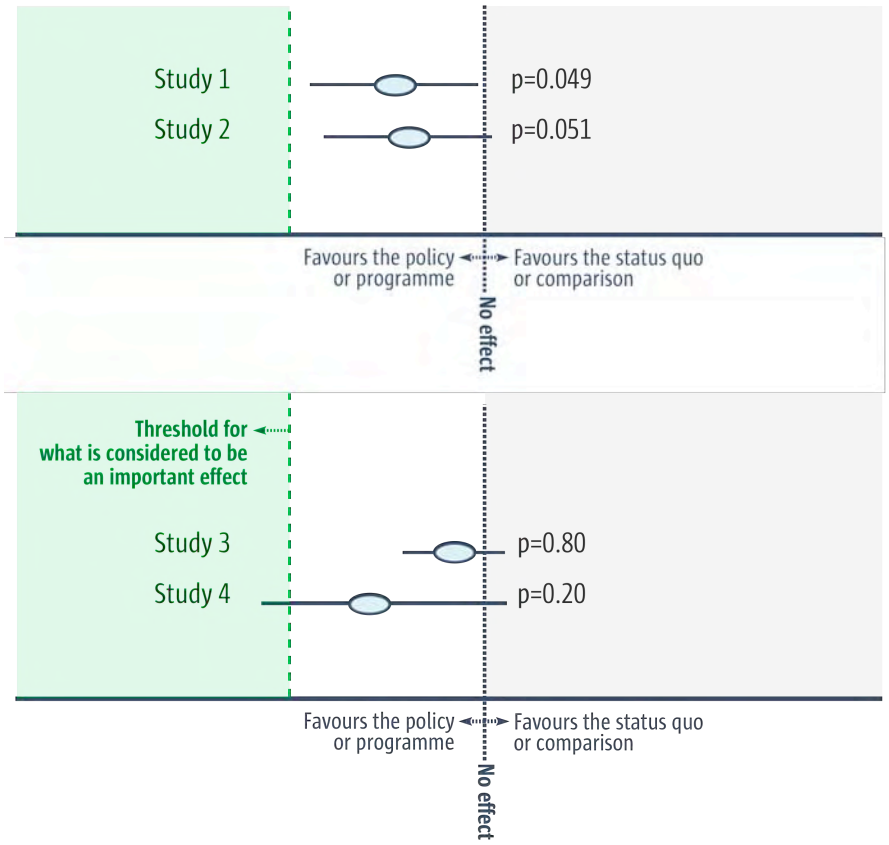

Table 17. 2
'Statistical non-significance'

Figure 17.1 illustrates two problems that arise when results are classified as 'statistically non-significant' or 'negative':

1. *The classification is based on an arbitrary cut-off.* The results of Study 1, for example, are marginally different from the results of Study 2. But by using the conventional cut-off of P < 0.05, the results of Study 1 are ranked as 'statistically significant' and the results of Study 2 as 'statistically non-significant'

2. *'Statistically non-significant' results may or may not be inconclusive.* If the short green vertical line in the figure below indicates the smallest effect considered important, the results for Study 3 would be conclusive, since an important impact is highly unlikely. The results for Study 4 would be categorised as 'inconclusive' since it is not unlikely that there would be an important impact (the 95% confidence interval crosses the threshold for what is considered to be an important effect). Both results, however, might be regarded as 'statistically non-significant' or 'negative'

3. Is it possible to be confident about a decision despite a lack of evidence?

Some policymakers may agree with Charlie Brown, who claimed: "I am always certain if it is a matter of opinion". But most would agree that high-quality evidence provides a better basis for being confident about decisions. Nevertheless, there may be good reasons for being confident about a decision even when there is a lack of evidence. There is very low-quality evidence, for example, that giving aspirin to children with influenza or chicken pox may cause Reye's syndrome (a rare but deadly condition) [11]. Despite the limitations of this

evidence, the US Surgeon General and others have confidently advised against the use of aspirin in these circumstances. This is because of the availability of paracetamol (acetaminophen) as an equally effective and inexpensive alternative which allows children not to be put at risk, even if there is uncertainty about the actual level of the risk itself. Conversely, it may be reasonable to be confident that policies or programmes with high costs and potentially serious adverse effects should *not* be rolled out without a rigorous impact evaluation.

4. Is the option potentially harmful, ineffective or not worth the cost?

"Professional good intentions and plausible theories are insufficient for selecting policies and practices for protecting, promoting and restoring health. Humility and uncertainty are preconditions for unbiased assessments of the effects of the prescriptions and proscriptions of policy makers and practitioners for other people. We will serve the public more responsibly and ethically when research designed to reduce the likelihood that we will be misled by bias and the play of chance has become an expected element of professional and policy making practice, not an optional add-on." (Iain Chalmers, Editor, the James Lind Library, presentation at the Norwegian Directorate for Health and Social Welfare, 1 September 2003. For a more detailed discussion of these comments see Reference [12])

It is risky not to acknowledge uncertainty for the sake of political expediency. As we noted in Chapter 1 [13], acknowledging that there is imperfect information to inform policies can reduce political risk because it allows policymakers to set in motion ways to alter course if policies do not work as expected.

As the quote above suggests, good intentions and plausible theories are insufficient when selecting policies and practices. This is true for health systems as well as clinical interventions. Examples of clinical interventions found to be relatively ineffective or harmful after initially being believed to be beneficial and widely used, include:

- High instead of low osmolar rehydration solutions for children with diarrhoea [14]
- Diazepam or phenytoin instead of magnesium sulphate for women with eclampsia [15,16]
- Six or more antenatal care visits instead of four [17]
- Corticosteroids for patients with severe head trauma [18]
- Albumin instead of salt water for resuscitation in critically ill patients [19]
- Hormone replacement therapy to reduce the risk of coronary heart disease and stroke in women [20]
- Electronic mosquito repellents for preventing mosquito bites and malaria infection [21]

All the above interventions were based on underlying theories, indirect evidence, surrogate outcomes, and observational studies: randomised trials subsequently disproved all the underlying assumptions. This supports the assertion (quoted above) that by making rigorous evaluations an *expectation* rather than an *option* for informing decisions about the provision of clinical interventions, the public can be more responsibly and ethically served.

These same concerns apply to health systems and public health interventions. Examples of health systems and public health interventions that have been widely used and advocated, but which may be ineffective and do more harm than good, include the following:

- Educational and community interventions to reduce the risk of teenage pregnancy [22]
- Directly observed therapy for tuberculosis [23]
- User fees for essential medicines [24]
- For-profit instead of not-for-profit private hospitals [25]

- Reducing maldistribution by requiring doctors to spend a minimum number of years in an underserved area before allowing them to specialise [1]
- Some forms of results-based financing or pay-for-performance [26]
- Contracting with the private sector to provide health services [27]

Substantial caution is required before investing scarce resources in policies or programme options requiring large investments that cannot be recouped [28]. If there is important uncertainty about the impacts of such options, a rigorous evaluation (such as a pilot study, for example), can prevent the potential for resource wastage. And while such undertakings may appear to present unnecessary delays, Julio Frenk, the former Minister of Health from Mexico, has noted: "Both politically, in terms of being accountable to those who fund the system, and also ethically, in terms of making sure that you make the best use possible of available resources, evaluation is absolutely critical" [29]. Decisions both in support of an option and those against, may be equally likely to have undesirable consequences if there is insufficient evidence (see Table 17.3 for an example and further explanation). Informing policymaking by testing a proposed option within a well-designed impact evaluation offers a better approach.

Table 17.3
The consequences of saying "no" or "yes" instead of "only in the context of an evaluation"

All countries face resource constraints. For this reason, in the United Kingdom for example, the National Institute for Health and Clinical Excellence (NICE) officially recognises the principle of recommending that when important uncertainties exist about an intervention's effects, such interventions should only be used in the context of research [28]. Sixteen (approximately 4%) of NICE's technology appraisal recommendations published between 1999 and early 2007 advised the use of a technology only in the context of research. The consequences of getting decisions wrong by either saying "no" or "yes" to a technology without doing so, are summarised below (see Reference [28] for further details).

The consequence of saying "no" instead of "only in research"

- Patients are denied access to promising and potentially effective technologies
- There are delays in building the evidence base in key areas, with a resulting negative overall impact on health outcomes

The consequences of saying "yes" instead of "only in research"

- Access to unproven and potentially harmful or ineffective interventions is promoted
- Any ongoing or future research in the field is severely hindered. Important questions on effectiveness and cost-effectiveness may never be answered
- Limited resources are wasted
- Having to reverse a "yes" decision in the light of any future evidence compromises credibility and is difficult to implement

When judgements about the effects of options are based on theories, surrogate outcomes, limited observational studies, inadequate impact evaluations, anecdotal experience or analogies, policymakers should be cautious about implementing them (see example in Table 17.4) [30].

Table 17.4
An example of a potentially ineffective or harmful intervention that has been widely promoted based on insufficient evidence

Effective drugs for tuberculosis have been available since the 1940s. Despite this, two million people continue to die from the disease each year, mostly in low-income countries. People with tuberculosis require treatment that lasts between six to eight months. Many find it difficult to complete their course of treatment and this serves as a major constraint to eradicating the disease.

Poor adherence to treatment can lead to prolonged infectiousness, drug resistance, relapses, or even death. Incomplete treatment thus poses a serious risk both to the individual and to communities as a whole.

Directly observed therapy (DOT) seeks to improve the adherence of people to tuberculosis treatment by using health workers, family members, or community members to directly observe patients taking their anti-tuberculosis drugs. DOT is potentially advantageous because adherence may improve when people are closely monitored and there is a social process involving peer pressure. Potential disadvantages include the fact that this treatment moves away from adherence models of communication, with their emphasis on cooperation between patient and provider, back to a traditional medical approach where the patient is a passive recipient of advice and treatment. Also, resource implications for such a policy are substantial, particularly in low- and middle-income countries where the case load may be high. DOT may also make adherence worse if it is rigidly applied in an authoritarian setting, or where people are expected to travel considerable distances to have their treatment supervised.

The World Health Organization (WHO) and others have actively promoted DOT since the 1980s, generally as part of a comprehensive tuberculosis management programme known as DOTS (directly observed therapy, short course), a five-element strategy for the control of tuberculosis. Although the strategy as a whole appears sound, there is substantial uncertainty about DOT as a key element of DOTS. When DOTS was originally launched, the evidence for the effectiveness of DOT came entirely from observational studies and no randomised impact evaluations of DOT had been undertaken. Subsequently, 11 randomised trials have compared DOT with self-administration and found that DOT did not improve adherence, despite the substantial resources required and its other disadvantages [23]

And even if there is little uncertainty about the benefits of an option, there may still be important uncertainty about *other* potentially important consequences, including unintended effects (harms) and costs (see example in Table 17.5). Policies or programmes with compelling rationales can, in fact, cause harm.

For an option that is promising, but for which there is insufficient evidence to be confident about whether it is potentially harmful, ineffective, or not worth the cost, consideration should be given to requiring a well-designed impact evaluation. This can be undertaken either prior to rolling out the policy or programme, or integrated as part of the rollout. We address further considerations regarding monitoring and evaluation in Chapter 18 [30].

Conclusion

Most health policies and programmes are complex and they are likely to have multiple effects. Some evidence will almost always be available based on experience with similar policies or programmes in other settings. However, as addressed in Chapters 8 and 9, it is important for policymakers to consider how much confidence to place in such evidence and to assess the applicability of the findings to their own setting [3,31]. Typically, there will be uncertainty about the impacts of policies and programmes on important outcomes. When there is important uncertainty, common mistakes such as those described in this chapter should be avoided.

Table 17.5
An example of important uncertainties about potentially important harms

Although there is little doubt that financial incentives, if they are large enough, can change behaviours, they can also cause unintended behaviours. The costs of both the incentives and their administration can also be substantial [26]. Unintended effects of paying for performance (the provision of payment for the attainment of well-defined results) that have been observed include:	
Unintended behaviours	Conditional cash transfers (CCT) have caused some mothers to keep their children malnourished in order to retain eligibility. An increase in fertility of between 2% and 4%, noted in another study, may have been due to the fact that only pregnant women were eligible for a CCT subsidy
Distortions	Financial incentives may cause recipients to ignore other important tasks
Gaming	Financial incentives can result in gaming (changes in reporting rather than desired changes in practice)
Corruption	Financial incentives may be stolen or misused, if not adequately managed
Cherry-picking	Performance incentives for providers can influence whether healthcare is accessible to patients by altering how willing healthcare workers or organisations are to care for sicker patients, more disadvantaged populations, or more difficult patients
Widening the resource gap between rich and poor	Performance incentives for providers may widen the resource gap that exists between organisations that serve disadvantaged patients and those that do not
Dependency on financial incentives	Relying on incentives may foster dependency on them. If provider behaviours are not ingrained, they may decline or disappear when the incentives end or new incentives are introduced
Demoralisation	Financial incentives may cause feelings of injustice and demoralisation in instances where, for example, professionals on short-term contracts receive more financial incentives than those who have established long-term practices, or where favouritism is perceived
Bureaucratisation	Results-based financing schemes may have substantial administrative costs associated with monitoring performance and managing disbursement of the financial incentives

Resources

Useful documents and further reading

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18. Planning monitoring and evaluation of policies

Atle Fretheim, Andrew D Oxman, John N Lavis, Simon Lewin

Summary

The term *monitoring* is commonly used to describe the process of systematically collecting data to inform policymakers, managers and other stakeholders whether a new policy or programme is being implemented in accordance with their expectations. Indicators are used for monitoring purposes to judge, for example, if objectives are being achieved, or if allocated funds are being spent appropriately. Sometimes the term *evaluation* is used interchangeably with the term *monitoring*, but the former usually suggests a stronger focus on the achievement of results. When the term *impact evaluation* is used, this usually implies that there is a specific attempt to try to determine whether the observed changes in outcomes can be attributed to a particular policy or programme. In this chapter, we suggest four questions that can be used to guide the monitoring and evaluation of policy or programme options. These are:

1. Is monitoring necessary?
2. What should be measured?
3. Should an impact evaluation be conducted?
4. How should the impact evaluation be done?

Scenarios

Scenario 1: *You are a senior civil servant with overall responsibility for several healthcare programmes. You wish to ensure that you have the information necessary to assess how various programmes are performing and the impact they are having*

Scenario 2: *You work in the Ministry of Health and have been instructed to prepare a memo on various issues that should be taken into consideration when the national vaccination programme is evaluated*

Scenario 3: *You work in a unit supporting the government in its use of evidence in policymaking. You are preparing a monitoring and evaluation plan for the national tuberculosis control programme*

Background

For policymakers (Scenario 1), this chapter suggests a number of questions that their staff might be asked when planning the monitoring and evaluation of a new policy.

For those who support policymakers (Scenarios 2 and 3), this chapter suggests a number of questions to consider when planning how to monitor the implementation of policies and programmes, and the evaluation of their impacts.

Policymakers and other stakeholders will often need to know whether a new policy or programme has been implemented in accordance with their expectations. Is the programme rollout progressing as planned? Are the objectives being achieved, and are the allocated funds being spent appropriately? *Monitoring* is the term commonly used to describe the process of systematically collecting data to provide answers to such questions [1]. The term *performance monitoring* is often used when the main focus of an evaluation is comparing "how well a project, program, or policy is being implemented against expected results" [1].

Indicators are frequently used as part of the monitoring process. An indicator has been defined as a "quantitative or qualitative factor or variable that provides a simple and reliable means to measure achievement, to reflect the changes connected to an intervention, or to help assess the performance" [1]. An indicator can be a simple count of events, e.g. the number of vaccinations conducted within a set period of time, or a construct based on various data sources, e.g. the proportion of all children being fully immunised before their first birthday.

The term *evaluation* is sometimes used interchangeably with *monitoring*, but the former usually suggests a stronger focus on the achievement of results. These terms are not used consistently and may mean different things to different people. The term *impact evaluation* is frequently used when an attempt is made to evaluate whether observed changes in outcomes (or 'impacts') can be attributed to a particular policy or programme.

Questions to consider

1. Is monitoring necessary?
2. What should be measured?
3. Should an impact evaluation be conducted?
4. How should the impact evaluation be done?

1. Is monitoring necessary?

The importance of monitoring depends on the perceived need among relevant stakeholders to know more about what is happening 'on the ground'.

Determining whether a system for monitoring a policy or programme should be established may depend on several factors, including:

- Whether a monitoring system is already in place that includes the desired indicators, or if a new set of indicators is required
- The likely costs of establishing the system required. For example, could a few new items be added to data collection procedures already in place, or is it necessary to conduct additional large-scale household surveys or to develop a completely new tool?
- Whether the findings are likely to be useful. What actions should be taken if monitoring reveals that things are not going as planned?

Monitoring is not worthwhile if data remain unused. Data are particularly useful if corrective action is undertaken when a gap is identified between expected and actual results. Such findings may result in expectations being reconsidered. This may take the form of assessments, for example, of whether the initial plans were too ambitious, or whether a new policy has failed to work as effectively as expected.

See Table 18.1 for two illustrative examples of monitoring systems that have been put in place within health systems [2,3].

Table 18.1
Examples of monitoring systems in the healthcare system

Scaling up provision of antiretroviral therapy (ART) in Malawi [2]
When Malawian health authorities decided to make ART available to a large proportion of the HIV-positive population, a system was put in place to monitor the implementation of this new policy. The principles of the system are based on the WHO's approach to the monitoring of national tuberculosis programmes. Each patient who starts on ART is given an identity card with a unique identity number, and this is kept at the clinic. The information collected from new patients includes their name, address, age, height, the name of their guardian, and the reason for starting ART. Patients are asked to attend each month to collect their medication. During their visit, their weight is recorded and they are asked about their general health, ambulatory status, work, and any drug side effects. Pill counts are also undertaken and recorded as a way of ensuring drug adherence. In addition, the following standardised monthly outcomes are recorded using the following categories:

- *Alive*: Patient is alive and has collected his/her own 30-day supply of drugs
- *Dead*: Patient has died while on ART
- *Defaulted*: Patient has not been seen at all for a period of 3 months
- *Stopped*: Patient has stopped treatment completely either due to side effects or for other reasons
- *Transfer-out*: Patient has transferred out permanently to another treatment

Data collected as part of the Malawian monitoring system of the ART rollout may be analysed and used in a variety of ways. Comparisons can be made between treatment outcomes for patients who were recruited at different times. If, for example, the rate of switching from first- to second-line regimens increases, or rates of mortality do likewise, an increase in drug resistance to the first-line regimen could be the cause. If the rate of deaths or defaulters declines, this could indicate that the management of the ART treatment programme is improving. If outcomes are particularly poor in certain geographic areas or clinics, action may need to be taken to address this.

Lung cancer surgery in Denmark [3]
Danish authorities issued national clinical practice guidelines for the management of lung cancer prompted by poor outcomes for patients who underwent lung cancer surgery. To monitor the implementation of the guidelines, a register of lung cancer patients was established which included specific information about those patients undergoing surgery. Indicators selected by the Danish Lung Cancer Registry include the extent (or 'stage') of cancer in the body, the surgical procedure used, any complications that occurred, and the survival outcome.

Data from the Danish Lung Cancer Registry are used, among other purposes, to monitor whether national recommendations for lung cancer surgery are being followed. Local, regional, and national audits are performed with the purpose of identifying problems or barriers that may impede adherence to the national guidelines. Based on these findings, specific strategies are proposed for quality improvement.

2. What should be measured?

Indicators that focus on various parts of the 'results chain' (i.e. on inputs, activities, outputs, outcomes or impacts – see Figure 18.1) are typically used to monitor the implementation of a programme or policy option. In some circumstances it may be seen as sufficient to monitor inputs (i.e. the provision of resources such as personnel and equipment). In others it may be important to monitor the activities of the programme or its outcomes (such as the number of children fully immunised).

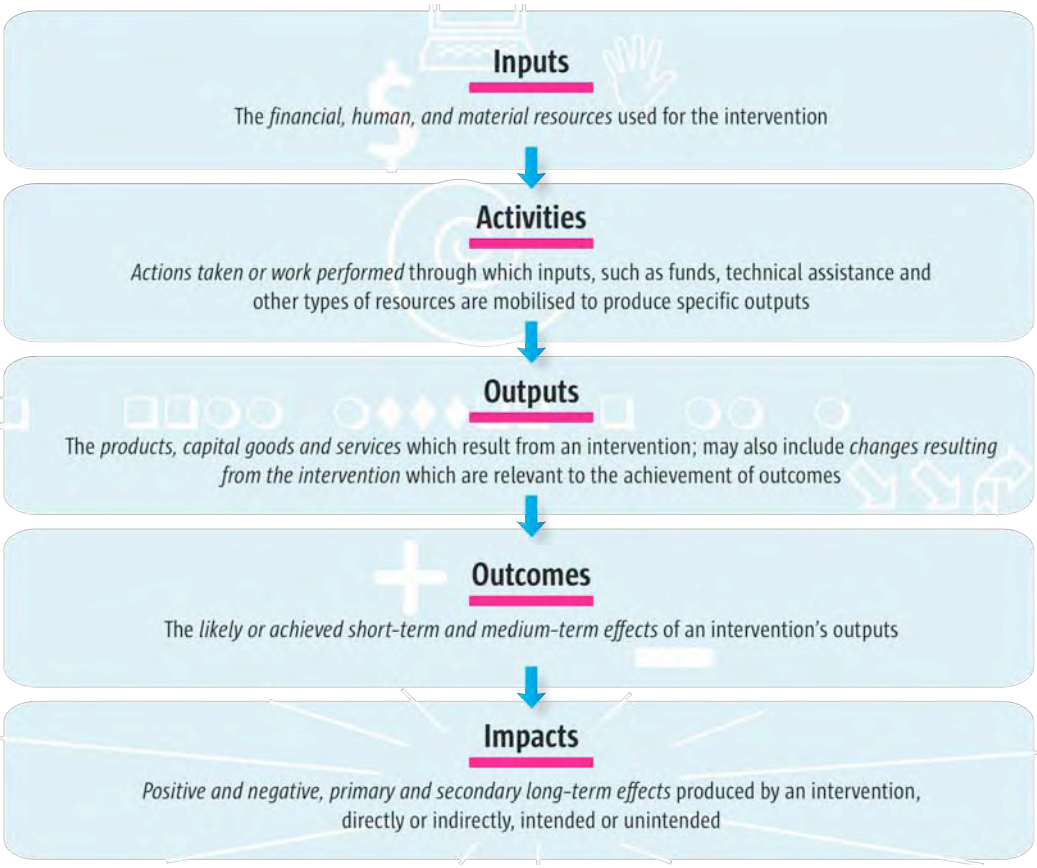

Figure 18.1
Results chain-model (definitions adapted from [2])

A number of factors need to be considered when selecting which indicator(s) to use [4,5]:

- *Validity*: the extent to which the indicator accurately measures what it purports to measure
- *Acceptability*: the extent to which the indicator is acceptable to those who are being assessed and those undertaking the assessment
- *Feasibility*: the extent to which valid, reliable and consistent data are available for collection
- *Reliability*: the extent to which there is minimal measurement error, or the extent to which findings are reproducible should they be collected again by another organisation
- *Sensitivity to change*: the extent to which the indicator has the ability to detect changes in the unit of measurement
- *Predictive validity*: the extent to which the indicator has the ability to accurately predict relevant outcomes

Costs related to data collection and the capacity to analyse and feed back data to managers and providers may also limit the choice of indicators. In settings where analytical resources are scarce, it may be preferable to select a simple indicator even if it does not have the best predictive validity, rather than an indicator that requires statistical manipulation.

A trade-off is often apparent between, on one hand, wanting to use desired and optimal indicators and on the other hand, having to use those indicators which are based on existing data. There are good reasons not to select more indicators than are absolutely essential. These reasons include the need to limit the burden of data collection within a health system, avoid the collection of data that are not utilised, and focus on collecting data of higher quality, even if this means collecting less data overall [6].

Routinely collected information from health systems may provide valuable data that can be used as a data source for monitoring purposes. Data can also be collected specifically for the purpose of monitoring, e.g. through surveys or interviews. Consideration should be given to the level of motivation among those expected to collect data. In many instances, health personnel will need to integrate data collection into a busy daily schedule. Therefore if the information being collected has little or no local obvious value to them, their motivation for undertaking such tasks may be low. Similarly, if incentives or penalties are associated with the findings from the monitoring process (e.g. where the payment of providers is linked to performance indicators), the risk of data manipulation or system gaming should be considered.

3. Should an impact evaluation be conducted?

One of the limitations of monitoring activities, as described above, is the fact that such activities do not necessarily indicate whether a policy or programme has had an impact on the indicators that have been measured. This is because indicators used for monitoring will almost always be influenced by factors other than those related to particular interventions. This makes it extremely difficult to determine which factors caused the observed changes. If monitoring reveals that performance is improving, this does not necessarily mean that the intervention is the (only) causal factor. It is conceivable that the indicators would have improved anyway even in the absence of the intervention (see Figure 18.2).

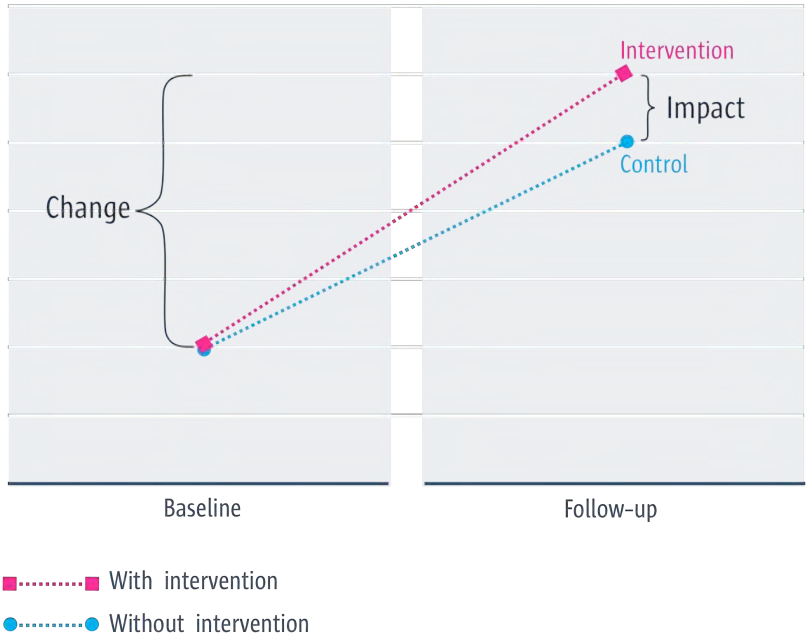

Figure 18.2
Comparing change in performance in two areas: one with an intervention and one without*

** The Figure illustrates that attributing the change from 'Baseline' to 'Follow-up' in response to an intervention is likely to be misleading. This is because, in this instance, there is also an improvement in the 'Control'. Even with regard to the Control, it is uncertain whether the difference between the 'Intervention' and 'Control' (i.e. the 'Impact') can, in fact, be attributed to the programme or intervention. There may be other differences between the 'Intervention' and 'Control' settings that might have led to the observed difference in the indicator measured*

The establishment of a causal relationship between a programme or policy and changes in outcomes is at the core of what impact evaluation is about. What would have happened to those receiving an intervention if they had not in fact received it, is *the* central impact evaluation question, according to the World Bank [7].

There may be strong reasons to expect positive results based on solid documentation from, for example, previous evaluations. However, very often such evidence is lacking. Or the evidence available may not be applicable to the current setting. Thus, there is a real risk that a new programme may be ineffective or, even worse, cause more harm than good. This issue is important for policymakers to clarify when implementing new programmes. It is also important because of the benefit that such knowledge could bring to future health policymaking both in the programme setting and other jurisdictions.

Conducting impact evaluations can be costly. Whether such studies represent good value for money can be ascertained by comparing the consequences of undertaking an evaluation with the consequences of not undertaking an evaluation. For example, is it likely that a programme would be stopped or modified if the results proved to be negative? If the answer is 'no', the value of undertaking an impact evaluation is clearly limited.

An impact evaluation is generally more likely to represent value for money when results can be obtained as the intervention is being rolled out. In such circumstances there is an opportunity to improve or stop the rollout based on the results of an impact evaluation conducted in the early stages of implementation. This would provide value for money in two instances: firstly, when a pilot study is not possible and, secondly, when it would be possible and practical to modify or stop the rollout (if needed) based on the results.

The Mexican government's health insurance scheme, Seguro Popular, is an example of an impact evaluation embedded in a programme rollout [8-10]. Implemented in 2001, the scheme was established in order to extend health insurance coverage to the almost 50 million Mexicans not yet covered by existing programmes. Taking advantage of the timetable of the progressive rollout, the government set up an evaluation comparing the outcomes for those communities receiving the scheme with those still waiting for it. In addition to evaluating whether the reform achieved the outcomes intended and did not have unintended adverse effects, the evaluation also provides for shared learning.

An impact evaluation may also be useful after a programme has been fully implemented, e.g. when there is uncertainty about continuing a programme. For example, the conditional cash transfer scheme, Progresa (later known as Oportunidades), which was introduced in the mid-1990s provided cash "on the condition that families fulfil particular elements of co-responsibility, such as sending children to school rather than work, providing them with a specially formulated nutritional supplement, and attending a clinic to receive a specified package of interventions for health promotion and disease prevention." [11]. For evaluation purposes, 506 communities were randomly assigned to either enter the programme immediately or 2 years later [12]. The findings from this impact evaluation directly informed policy decisions in Mexico, persuading the government "not only to continue with the programme, but also to expand it" [11].

4. How should the impact evaluation be done?

Attributing an observed change to a programme or policy requires a comparison between the individuals or groups exposed to it, and others who are not. It is also important that the compared groups are as similar as possible in order to rule out influences other than the programme itself. This can effectively be done by randomly allocating individuals or groups of people (e.g. within geographic areas) to either receive the programme or not to receive it, in what is called a *randomised trial*. Usually such trials are conducted as pilot projects before a programme is introduced at a national level. But they can also be undertaken in parallel with full scale implementation, as illustrated by the Mexican examples given above.

Randomised trials may, however, not always be feasible. Alternative approaches include the comparison of changes before and after programme implementation, with observed changes during the same time period in areas where the programme was not implemented (e.g. in neighbouring districts or countries). This is called a *controlled before-after evaluation*. Alternatively, an *interrupted time-series* may be used in which data are collected from multiple time points before, during, and after programme implementation.

Simply comparing the value of an indicator before and after programme implementation is not generally recommended since the risk of misleading findings is high – observed changes, e.g. HIV-incidence may be caused by known and unknown factors other than those related to the programme itself (see Figure 18.2) [13,14].

An overview of a number of evaluation designs is provided in Appendix 1 at the end of this chapter. The weaknesses and strengths of each method described in Appendix 1 are outlined in Appendix 2.

Impact evaluations should be planned well ahead of programme implementation in conjunction with relevant stakeholders, including policymakers. After a programme has been rolled out widely it is usually too late to carry out baseline measurements or to establish appropriate comparison groups. For example, using random assignments to decide whether communities will be included in a programme or not, cannot be done after the programme has been implemented nationally. Impact evaluations that are built into a programme from the start are thus more likely to yield valid findings than those evaluations conducted as an afterthought. Furthermore, if impact evaluations are seen as an integrated part of programme implementation, policymakers and others may be more committed to taking the findings into account.

The number of individuals or communities required for an impact evaluation should also be estimated at an early stage. This will ensure that there is sample size large enough for meaningful conclusions to be drawn from the evaluation findings.

In healthcare, as in most other areas, programmes need to be both effective *and* cost-effective. To assess the economic aspects of a programme, resource use and costs must be estimated, preferably based on data collected from real-life implementation [15]. Decisions on what economic data to collect should therefore also be made at an early stage, before the evaluation starts.

Impact evaluations are likely to be most informative if a process evaluation is included. A process evaluation may examine whether the programme or policy option was delivered as intended. It may also investigate the processes of implementation and change, explore responses to the programme, and explore reasons for the findings of the evaluation [16].

See Table 18.2 for examples of impact evaluations.

Budget, time or data constraints may act as disincentives to ensuring rigorous implementation. Such constraints can affect the reliability of impact evaluations in a number of ways:

- By compromising the overall validity of the results, for example, due to insufficient planning or follow-up, or through a paucity of baseline data, a reliance on inadequate data sources, or the selection of inappropriate comparison groups
- Through the use of inadequate samples, e.g. due to the selection of samples that are convenient to sample but may not be representative, as a result of sample sizes being too small, or by a lack of sufficient attention to contextual factors

Such constraints can be addressed by starting the planning process early or finding ways to reduce the costs of data collection. It is important to ensure, however, that neither the possible threats to the validity of the results, nor the limitations of the sample, are such that the results of the evaluation will be unable to provide reliable information. Before conducting

an evaluation, an assessment should therefore be made as to whether an adequate evaluation is possible. If it is not, an assessment needs to be undertaken as to whether a programme should be implemented without prior evaluation, in the face of uncertainty about its potential impacts [21].

Table 18.2
Examples of impact evaluations

Home-based antiretroviral therapy (ART) in Uganda [17-19]
Shortages of clinical staff and difficulties with accessing care due to transportation costs are major obstacles to scaling up the delivery of ART in developing countries. One proposed solution is home-based HIV care, where drug delivery, the monitoring of health status, and the support of patients is carried out at the home of the patient by non-clinically qualified staff. It is highly uncertain, however, whether this strategy is able to provide care of sufficient quality, including timely referrals for medical care, or whether such a system is cost-effective. Therefore, before implementing home-based care programmes widely it is important that they are evaluated for their (cost-) effectiveness.

To ensure a fair comparison between home-based and facility-based ART, researchers in Uganda conducted a randomised trial. The study area was divided into 44 distinct geographical sub-areas. In some of these, home care was implemented, while in others a conventional facility-based system continued to be used. The selection and allocation of areas to receive, and not to receive, the home-based care system, was randomly determined. This reduced the likelihood of important differences between the comparisons groups which might otherwise have influenced the study if, for example, the districts themselves had decided whether to implement home-based care, or if decisions had been based on an existing preparedness to implement home-based care. The random allocation system used was also the fairest way of deciding where to start home-based care since each district had an equal chance of being chosen.

The researchers found that the home-based care model using trained layworkers was as effective as nurse- and doctor-led clinic-based care.

Mandatory use of thiazides for hypertension in Norway [20]
As a cost-containment measure, policymakers in Norway decided that thiazides would be prescribed as anti-hypertensive drugs instead of more costly alternatives, in those instances where drug expenses were to be reimbursed. The policy was implemented nationally a few months after the decision was made. Because critics continued to argue that the new policy was unlikely to lead to the expected results, the Ministry of Health sponsored a study to assess the impact of the policy they had implemented.

The mandatory prescription of thiazides for treating hypertension was implemented across Norway with an urgency that made a planned, rigorous impact evaluation impossible to conduct. However, by accessing the electronic medical records of 61 clinics at a later stage, researchers extracted prescription data ranging from one year before to one year after the new policy was introduced. They analysed the data using an interrupted time-series. Monthly rates of thiazide prescribing and other outcomes of interest were analysed over time to see if any significant changes could be attributed to the implemented policy. Analysis indicated that there was a sharp increase in the use of thiazides (from 10 to 25% over a pre-specified three month transition period), following which the use of thiazides levelled off

Impact evaluations are not worthwhile if the findings are not used. Results should be used to inform decisions about whether to continue, change or stop existing programmes. Clearly, other interests will also need to be taken into consideration. For instance, decision makers may elect not to emphasise particular findings from certain evaluations when such findings

conflict with other interests that are perceived as more important [22]. However, it is important to avoid the suppression of findings from impact evaluations, e.g. for political reasons. Failing to use evaluation findings contradicts one of the main objectives of conducting such evaluations: to learn from experience and share the knowledge that has been generated. Using independent parties to conduct impact evaluations may decrease the risk of having the findings manipulated or held back from the public.

Conclusion

A number of aspects related to monitoring and evaluation have been described in this chapter. At present, many programme monitoring and evaluation efforts are commonly done using methods that do not yield valid assessments of the implementation of a policy or programme or valid estimates of effects. Sometimes such evaluations are not done at all. By taking the issues described in this chapter into consideration, policymakers and those who support them should be able to develop plans that will generate new and directly useful knowledge.

Resources

Useful documents and further reading

- Segone M (ed). Bridging the gap: The role of monitoring and evaluation in evidence-based policy making. UNICEF, the World Bank and the International Development Evaluation Association. www.unicef.org/ceecis/evidence_based_policy_making.pdf

- MacKay K. How to Build M&E Systems to Support Better Government. 2007. Washington DC, The World Bank. www.worldbank.org/ieg/ecd/docs/How_to_build_ME_gov.pdf

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Links to websites

- *Independent Evaluation Group (IEG) at the World Bank:* www.worldbank.org/ieg – IEG is an independent unit within the World Bank. IEG assesses what is effective or not effective with regard to policy options, how a borrower plans to run and maintain a project, and the lasting contribution of the Bank to a country's overall development

- *International Initiative for Impact Evaluation (3ie):* www.3ieimpact.org – 3ie seeks to improve the lives of poor people in low- and middle-income countries by providing and summarising evidence related to what policy options work, as well as when and why, and the costs involved

- *Health Metrics Network:* www.who.int/healthmetrics/en – The Health Metrics Network (HMN) has the strategic goal of increasing the availability and use of timely and accurate health information. To achieve this, HMN identifies strategies for HIS development and strengthening, supports countries in implementing HIS reform, and increases knowledge about global public goods through research, technical innovation, and sharing lessons learned

- *NorthStar:* www.support-collaboration.org – NorthStar is a tool for planning, conducting and evaluating quality improvement programmes

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Appendix 1. Evaluation designs (adapted from the Cochrane Handbook for Systematic Reviews of Interventions*)

Randomised controlled trial	An experimental study in which individuals are randomly allocated to receive different interventions (e.g. using the toss of a coin or a list of random numbers generated by a computer)
Cluster randomised trial	An experimental study in which groups of people (e.g. school classes or hospitals) are randomly allocated to receive different interventions
Non-randomised controlled trial	An experimental study in which people are allocated to different interventions using methods that are not random (e.g. patients admitted during Week 1 receive intervention A, those admitted in Week 2 receive intervention B, those in Week 3 receive intervention A again, and so on)
Controlled before-and-after study	A study in which observations are made before and after the implementation of an intervention, both in a group that receives the intervention and in a control group that does not. Data collection should usually be done concurrently in the two groups
Interrupted-time-series study	A study using observations at multiple time points before and after an intervention. Measurements are *interrupted* by the intervention. The design attempts to detect whether an intervention has had an effect significantly greater than any underlying trend over time
Historically controlled study	A study comparing a group of participants receiving an intervention with a similar group from the past who did not
Cohort study	A study in which a defined group of people (the cohort) is followed over time, to examine associations between different interventions received and subsequent outcomes. A *prospective* cohort study recruits participants before any intervention and follows them into the future. A *retrospective* cohort study identifies subjects from past records, describing the interventions received and follows them from the time of those records
Case-control study	A study comparing people with a specific outcome of interest (*cases*) with people from the same source population but without that outcome (*controls*), to examine the association between the outcome and prior exposure (e.g. receiving an intervention). This design is particularly useful when the outcome is rare
Cross-sectional study	A study collecting information on past or present interventions and current health outcomes for a group of people at a particular point in time. This kind of study examines associations between the outcomes and exposure to interventions
Qualitative study	A study conducted in a natural setting which is usually designed to interpret or make sense of phenomena in terms of the meanings people bring to them. Typically in such a study, narrative data are collected from individuals or groups of 'informants' or from documents. These are then interpreted by the researcher(s)

* Cochrane Collaboration. Cochrane Handbook for Systematic Reviews of Interventions. Chichester: The Cochrane Collaboration and John Wiley & Sons Ltd.; 2008

Appendix 2. Selected strengths and weaknesses of evaluation designs

Study design	Strengths	Weaknesses
Randomised controlled trial	Widely considered to be the strongest design for establishing cause-effect relationships, which is the key focus of impact evaluation	May be time consuming and represent logistical challenges The results are not necessarily transferable to settings outside the study setting
Cluster randomised trial	Same strengths as for ordinary randomised trials. In addition, the risk of 'contamination' is reduced e.g. that intervention A may be received by, or affect, individuals allocated to receive intervention B only. For example, if nurses are allocated randomly to implement a new routine, other nurses may be influenced by these changes and may start undertaking the same activities. It may therefore be better to randomise wards, and all of the staff within them, rather than individual nurses	Baseline differences may be a problem as the number of units (or *clusters*) that are randomised would usually be lower than in a trial where individuals are randomised. May be time consuming and logistically challenging, but less so than an ordinary randomised trial
Non-randomised controlled trial	May be easier and more practical to conduct than a randomised controlled trial	When allocation is not done using random methods, selection biases may occur, e.g. because patients and health workers adjust their behaviour to the allocation procedure if they prefer one intervention to another
Controlled before-and-after study	May be the only practical option, e.g. for large-scale interventions where randomisation is not feasible for practical or political reasons	Known or unknown differences between the groups that are compared may exert more influence on the findings than the fact that they received different interventions. Consequently, drawing conclusions about cause-effect relationships may be risky Requires the availability of baseline data
Interrupted-time-series study	May be feasible and relatively easy to conduct if the necessary data are made available. No control group required	The effect size is always difficult to estimate in such analyses because influences other than the intervention under investigation may impact on the observed changes

Historically controlled study	May be quickly and easily done if the necessary data are available	Known or unknown differences between the groups that are compared may exert more influence on the findings than the fact that they received different interventions. Consequently, drawing conclusions about cause-effect relationships is risky
Cohort study	Often large studies with a high degree of external validity (i.e. the findings can be generalised). Often conducted over several years, which makes it possible to detect the long-term effects of an intervention	Cohort studies are typically lengthy and costly, mainly due to the need for following up the (usually) high number of participants Known or unknown differences between the groups that are compared may exert more influence on the findings than the fact that they were exposed to different interventions. Consequently, drawing conclusions about cause-effect relationships is risky
Case-control study	More quickly and easily done than cohort studies	The retrospective nature of such studies entails collecting information about events that occurred earlier. Such time delays may be a source of error Known or unknown differences between the groups that are compared may exert more influence on the findings than the fact that they received different interventions. Consequently, drawing conclusions about cause-effect relationships is risky
Cross-sectional study	Requires no follow-up time and can therefore be conducted quickly and often at a low cost	Known or unknown differences between the groups that are compared may exert more influence on the findings than the fact that they received different interventions. Consequently, drawing conclusions about cause-effect relationships is risky
Qualitative study	Allows for the collection of more in-depth information than other quantitative designs. Enables an understanding of how interventions and programmes are (or are not) working	Does not generate data that can be used to estimate the effect of an intervention that are beyond the perception of those who are interviewed or surveyed

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Glossary of selected terms

For additional definitions see the list of further glossaries at the end of this glossary.

Absolute effectiveness: (see Table 10.4, Chapter 10) also absolute effect

Acceptability (related to indicators): the extent to which the indicator is acceptable to those being assessed and those undertaking the assessment

AMSTAR (A MeaSurement Tool to Assess Reviews): a tool designed to assess the quality of the methods used to conduct a systematic review (see www.biomedcentral.com/1471-2288/7/10)

ART: antiretroviral therapy. Also referred to as HAART – highly active antiretroviral therapy

Balance sheet: see discussion in Table 16.1, Chapter 16

Baseline conditions (also known as baseline characteristics): values of demographic, clinical and other variables collected for each participant at the beginning of a trial, before the intervention is administered

Baseline risk: the risk (likelihood) of an outcome without implementing an intervention or at the beginning of a study

Bayesian meta-analysis: an approach to statistics based on application of Bayes' theorem that can be used in single studies or meta-analysis. A Bayesian analysis uses Bayes' theorem to transform a prior distribution for an unknown quantity (e.g. an odds ratio) into a posterior distribution for the same quantity, in light of the results of a study or studies. The prior distribution may be based on external evidence, common sense or subjective opinion. Statistical inferences are made by extracting information from the posterior distribution, and may be presented as point estimates, and credible intervals (the Bayesian equivalent of confidence intervals)

Burden of disease: this refers to the impacts (or burden) of a health problem or condition (such as hypertension) in an area (such as a country or province), as measured by mortality, morbidity or other indicators. Burden of disease is sometimes measured using the 'disability-adjusted life year' or DALY – a time-based measure combining years of life lost due to premature mortality and years of life lost due to time lived in states of less than full health

Case survey: a method for synthesising findings from a number of qualitative studies or to combine qualitative and quantitative evidence within a single review. It involves the systematic coding of relevant data from the included qualitative case studies and the subsequent conversion of these codes into a quantitative form. This then allow statistical analysis

CASP (Critical Appraisal Skills Programme): a UK-based programme that aims to enable individuals to develop the skills to find and make sense of research evidence, thereby helping them to put knowledge into practice (see: www.phru.nhs.uk/pages/PHD/CASP.htm)

Chi-squared test for homogeneity: a statistical test based on comparison of a test statistic to a chi-squared distribution used in meta-analyses to test the statistical significance of **heterogeneity** (see 'Heterogeneity')

CHSRF: Canadian Health Services Research Foundation

Confidence interval (CI): a confidence interval is a range around an estimate that conveys how precise the estimate is; for example an estimate of the risk of an event occurring or an estimate such as a risk ratio that compares the risk with and without an intervention. The confidence interval is a guide to how sure we can be about the quantity we are interested in. The narrower the range between the two

numbers, the more confident we can be about what the true value is; the wider the range, the less sure we can be. The width of the confidence interval reflects the extent to which chance may be responsible for the observed estimate (with a wider interval reflecting more chance)

Control group: a group of participants in a study not receiving a particular intervention, used as a comparator to evaluate the effects of the intervention (see 'Intervention group')

Controlled before-after study: a **non-randomised study** design where a control **population** of similar characteristics and performance as the **intervention group** is identified. Data are collected before and after the **intervention** in both the **control** and intervention groups

Controlled trial (See trial)

Cost-effectiveness analysis: an economic evaluation in which the costs and consequences of alternative interventions are expressed as a cost per unit of health outcome (e.g. cost per additional stroke prevented) (for a more detailed discussion see Table 5.2, Chapter 5)

Cross-case techniques: a method for synthesising findings across a number of qualitative studies or cases

Deflator: a statistical factor designed to remove the effect of inflation

Differential effectiveness: different degrees of effectiveness (or adverse effects) in different groups or settings

Disaggregated data: often data are reported for whole populations or areas. This can be referred to as aggregate data. In some cases, it may be desirable and possible to further break down or analyse these data to look at specific groups (such as people over the age of 65 years) or areas (such as a health district). This can be referred to as disaggregated data

Effectiveness: The extent to which a specific intervention, when used under ordinary circumstances, does what it is intended to do

Egger regression test: a statistical method for detecting publication bias in a review or meta-analysis. The test has a similar purpose to that of the **funnel plot** (see 'funnel plot')

Empirical evidence: empirical results based on observation rather than on reasoning alone

Epidemiology: the study of the health of populations and communities, not just particular individuals

Equity considerations: attention to how a policy or programme may impact on inequities (see **inequity**) (for a more detailed discussion see Chapter 10)

Estimate of effect: the observed relationship between an intervention and an outcome expressed as, for example, the number needed to treat for one person to benefit, odds ratio, risk difference, risk ratio, standardised mean difference, or weighted mean difference

Evaluation: a term often used interchangeably with monitoring. The former usually suggests a stronger focus on the achievement of results

Evidence-based medicine (EBM): evidence-based medicine is the conscientious use of current best evidence in making decisions about the care of individual patients or the delivery of health services. The terms 'evidence-based health care' and 'evidence-based practice' are often used interchangeably with 'evidence-based medicine' (see Chapter 1)

Evidence-informed health policymaking: evidence-informed health policymaking is an approach to policy decisions that aims to ensure that decision making is well-informed by the best available research evidence. It is characterised by the systematic and transparent access to, and appraisal of, evidence as an input into the policymaking process (see Chapter 1)

Feasibility (related to indicators): the extent to which valid, reliable and consistent data are available for collection

Funnel plot: a graphical display of some measure of study precision plotted against effect size that can be used to investigate whether there is a link between study size and treatment effect. One possible cause of an observed association is reporting bias. The plot is therefore often used to assess whether publication bias is likely within a systematic review

GRADE assessment system: see Table 16.8, Chapter 16

Grey literature: grey literature is the kind of material that is not published in easily accessible journals or databases. It includes things like conference proceedings that include the abstracts of the research presented at conferences, unpublished theses, and so on

Grounded theory: an approach used widely within primary qualitative research and focused on the generation of theory or explanations for social phenomena, based on empirical data. The method can also be used to synthesise findings across a number of qualitative studies

Health status: the state of health of a person or population assessed with reference to morbidity, impairments, anthropological measurements, mortality, and indicators of functional status and quality of life

Health system arrangements: the delivery, financial and governance arrangements within which clinical or public health programmes and services are provided

Health technology assessment (HTA): HTA is the systematic evaluation of the properties, effects and/or other impacts of health care technology. Its primary purpose is to provide objective information to support healthcare decisions and policymaking at the local, regional, national and international levels. HTA reports typically include a range of economic, social, ethical and legal considerations, as well as a review of the research evidence about the effectiveness of a technology. Some HTA reports contain a systematic review that can be applied in contexts other than the one for which the report was produced

Hedges: validated search strategies to find specific types of single studies

Heterogeneity: 1. Used in a general sense to describe the variation in, or diversity of, participants, **interventions**, and measurement of outcomes across a set of studies, or the variation in internal **validity** of those studies. 2. Used specifically, as statistical heterogeneity, to describe the degree of variation in the **effect estimates** from a set of studies. Also used to indicate the presence of variability among studies beyond the amount expected due solely to the play of chance

Impact evaluation: an evaluation that aims to determine whether the observed changes in outcomes (or "impact") can be attributed to a particular policy or programme

Indicator: a quantitative or qualitative factor or variable that provides a simple and reliable means to measure achievement, to reflect the changes connected to an intervention, or to help assess the performance

Indirect evidence: research that has not directly compared the options in which we are interested in the populations in which we are interested, or measured the important outcomes in which we are interested

Inequity in health: a difference in health that is not only unnecessary and avoidable but, in addition, is considered unfair and unjust

Intermediary outcome: outcome measures that are not of direct practical importance but are believed to reflect outcomes that are important; for example, blood pressure is not directly important to patients but it is often used as an outcome in clinical trials because it is a risk factor for stroke and heart attacks. Surrogate endpoints are often physiological or biochemical markers that can be relatively quickly and easily measured, and that are taken as being predictive of important outcomes. They are often used when observation of important outcomes requires long follow-up

Interrupted time series analysis or study: a research design that collects observations at multiple time points before and after an intervention (interruption). The design attempts to detect whether the intervention has had an effect significantly greater than the underlying trend

Intervention: the process of intervening on people (e.g. clinical interventions), groups or entities (e.g. health policy or programme options)

Intervention group: a group of participants in a study receiving a particular policy or programme option

LMIC: Low- or middle-income country

MeSH term (or headings): an abbreviation for Medical Subject Headings Terms used by the United States National Library of Medicine to index articles in MEDLINE. The MeSH system has a tree structure in which broad subject terms branch into a series of progressively narrower subject terms

Meta-analysis: the use of statistical techniques in a **systematic review** to integrate the results of included studies. Sometimes used as a synonym for systematic reviews, where the review includes a meta-analysis

Meta-ethnography: a method of translating ideas, concepts and metaphors across different qualitative studies in order to synthesise their findings. The method draws on the ethnographic approach used in primary qualitative research

Modifying factor: a factor or characteristic, such as the size of a health facility that may change or modify the effect of the proposed causal factor being studied, such as health worker motivation

Monitoring/performance monitoring: describes the process of systematically collecting data to inform policymakers, managers and other stakeholders whether a new policy or programme is being implemented in accordance with their expectations

Narrative review: a summary in words (rather than numerically) of, for example, the effects of a policy or programme option. Narrative reviews are not always based on a thorough and reproducible search of the literature for studies that address the review question

Narrative summary/synthesis: see 'Narrative review'. The approach can be used to synthesise findings across a number of qualitative studies or to combine qualitative and quantitative evidence within a single review

Observational study: a study in which the investigators do not seek to intervene, and simply observe the course of events. Changes or differences in one characteristic (e.g. whether or not people received the intervention of interest) are studied in relation to changes or differences in other characteristic(s) (e.g. whether or not they died), without action by the investigator. There is a greater risk of selection bias than in experimental studies. See also randomised controlled trial. (Also called non-experimental study)

OECD: Organisation for Economic Co-operation and Development

Outcome: a change resulting from an intervention. In evaluations, a potential consequence of an intervention that is measured after the intervention has been implemented, that is used to assess the effects of the intervention

PICO (Population, Intervention, Comparison, Outcomes): the acronym, PICO, is used to summarise the four key components of a review or research question. In this book we also introduce the acronym, POCO, replacing intervention with option. POCO similarly summarises the four key components of a question

Policy brief: see discussion in Chapter 13

Policy dialogue: see discussion in Chapter 14

Policy entrepreneur: a person who seeks to initiate policy change

Primary outcome: the outcome of greatest importance

Primary study: 'original research' in which data are collected. The term primary study is sometimes used to distinguish it from a secondary study (re-analysis of previously collected data), meta-analysis, and other ways of combining studies (such as economic analysis and decision analysis). (Also called original study)

Process evaluation: process evaluations explore the delivery of a process or programme and the mechanisms underlying its effects. They verify what the policy or programme is and whether or not it is delivered as intended to the target recipients

Process indicator: an indicator for actions taken or work performed through which inputs, such as funds, technical assistance and other types of resources are mobilised to produce specific outputs (see 'Indicator'). Processes may also be referred to as 'activities' in the results chain (see Figure 18.1, Chapter 18)

Publication bias: a bias caused by only a subset of all the relevant data being available. The publication of research can depend on the nature and direction of the study results. Studies in which an intervention is not found to be effective are sometimes not published. Because of this, systematic reviews that fail to include unpublished studies may overestimate the true effect of an intervention. In addition, a published report might present a biased set of results (e.g. only outcomes or sub-groups where a statistically significant difference was found

Purchasing power parity (PPP): a criterion for an appropriate exchange rate between currencies

Qualitative comparative analysis: a method for synthesising findings from a number of qualitative studies or to combine qualitative and quantitative evidence within a single review

Qualitative study: qualitative approaches attempt to describe and interpret human phenomena rather than to measure these. These methods focus on finding answers to questions centred on social experience, including the values and perceptions of individuals and groups and how they experience the world around them, including healthcare

Randomised controlled trial (RCT): an experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants

Randomised trial: (see '**randomised controlled trial**')

RCT: randomised controlled trial

Realist review/synthesis: a theory-based method for synthesising findings from a number of qualitative studies

Relative effectiveness (see Table 10.4, Chapter 10)

Relative reduction: see **relative effectiveness**

Results chain: the causal sequence for a development intervention that stipulates the necessary sequence to achieve desired objectives – beginning with inputs, moving through activities and outputs, and culminating in outcomes, impacts, and feedback. In some agencies, reach is part of the results chain

Retrospective analysis/study: an analysis or study planned and conducted after the dataset has already been collected. For example, routinely collected data may be analysed retrospectively to evaluate the effects of a new programme

Risk factor: an aspect of a person's condition, lifestyle or environment that affects the **probability** of occurrence of a disease. For example, cigarette smoking is a risk factor for lung cancer

Routine data: data or information collected as part of normal health service management, monitoring and evaluation. This may include information on the prevalence of diseases, on healthcare utilisation, or on service costs

Stakeholder: a person, group or organisation that has a legitimate interest in or can be affected by a health policy or programme

Statistical pooling: the use of quantitative, statistical methods to combine the findings of a number of studies of the effects of programme or policy options. This is also referred to as **meta-analysis** and may be part of a **systematic review**

Statistical significance: the likelihood that a finding or a result is caused by something other than just chance (see Table 17.2, Chapter 17)

Subgroup analysis: an analysis in which the intervention effect is evaluated in a defined subset of the participants in a study or **systematic review**, or in complementary subsets, such as by sex or in age categories

Surrogate outcome: outcome measures that are not of direct practical importance but are believed to reflect outcomes that are important; for example, blood pressure is not directly important to patients but it is often used as an outcome in clinical trials because it is a risk factor for stroke and heart attacks. Surrogate endpoints are often physiological or biochemical markers that can be relatively quickly and easily measured, and that are taken as being predictive of important outcomes. They are often used when observation of important outcomes requires long follow-up

Systematic review: summaries of research evidence that address a clearly formulated question using systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review

Thematic analysis: a method for synthesising findings from a number of qualitative studies. It includes identifying key themes in the included studies and then summarising the evidence within these themes or categories

Trial: the term 'trial' is sometimes used to refer to **randomised controlled trials** (RCTs). The term may also be used to refer to quasi-randomised trials (e.g. where alternation (every other person or group) is used to allocate people, rather than randomisation) (Also called controlled trial)

Validity (related to indicators): the extent to which an indicator accurately measures what it purports to measure

Further glossaries relevant to evidence-informed health policymaking

Canadian Health Services Research Foundation Glossary of knowledge exchange terms as used by the Foundation:
www.chsrf.ca/keys/glossary_e.php

Canadian Institutes of Health Research KT Clearinghouse Glossary:
http://ktclearinghouse.ca/glossary

Cochrane Collaboration Glossary of Cochrane Collaboration and research terms:
www.cochrane.org/resources/glossary.htm

European Observatory on Health Systems and Policies Glossary:
www.euro.who.int/observatory/glossary/toppage

Global Forum for Health Research Glossary:
www.globalforumhealth.org/Glossary

Health Economics Information Resources Glossary of frequently encountered terms in health economics:
http://www.nlm.nih.gov/nichsr/edu/healthecon/glossary.html

National Institute of Health Policy Glossary of health policy terms:
www.nihp.org/NEWglossary.htm

NHS Evidence Glossary of health knowledge management terms:
www.library.nhs.uk/knowledgemanagement/page.aspx?pagename=GLOSSARY

Public Health Agency of Canada:
http://cbpp-pcpe.phac-aspc.gc.ca/glossary/all_terms-eng.html

WhatisKT:
http://whatiskt.wikispaces.com/http://www.evidence.nhs.uk