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SUPPORT Tools for evidence-informed health Policymaking (STP)

4. Framing options to address a problem

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Abstract

Background: This article is number 4 in a series of 21 articles on tools for evidence-informed health policymaking. Policymakers and those supporting them may find themselves in three situations that 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 the 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 being presented to them, or
3. A policymaking process has not yet begun and their role is to identify options, characterise their costs and consequences, and look for 'windows of opportunity' to act. Research evidence, particularly evidence about benefits, harms, and costs, can help to inform whether an option is considered viable

Objective: In this article we suggest 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.

Key messages:

- 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 the problem?
    2. What benefits are important to those who will be affected and which benefits are likely to be achieved with each option?
    3. What harms are important to those who will be affected 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 might they alter its benefits, harms and costs?
    6. Which stakeholders' views and experiences might influence the acceptability of an option and its benefits, harms, and costs?
- When using research evidence to answer questions about benefits, harms, and costs, policymakers should take into account its quality, local applicability, and equity considerations.

Background

This article is number 4 in a series of 21 articles on tools for evidence-informed health policymaking. It is also the 1st of 3 articles in this series about identifying potential policy and programme options and finding evidence about them. The purpose of this article is to suggest questions to guide those involved in identifying policy and programme options to address a high-priority problem and characterising the costs and consequences.

Policymakers and those supporting them may find themselves in three situations that require them to characterise the costs and consequences of options to address a problem. First, policymakers may find themselves in a situation in which a problem has been framed in a particular way, an option has been selected to address the problem, and a political constituency has already been mobilised to support this. The best option for those who support policymakers under such circumstances, is to assist policymakers 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). Article 15 in this series describes how to develop a monitoring and evaluation plan [1].

Second, policymakers may be actively engaged in a policymaking process. This may mean that policymakers will need to participat 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 [2]. In this scenario, they will need to assess the options being presented to them, the attention being given to the problem that the option is meant to address, as well as any political events that may present a window of opportunity during which particular actions could be undertaken.

Third, 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 will be 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 [2]. Research evidence can form part of this mix in several ways and help to determine the following 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 [3].

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 the problem?
2. What benefits are important to those who will be affected and which benefits are likely to be achieved with each option?
3. What harms are important to those who will be affected 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 might they alter its benefits, harms and costs?
6. Which stakeholders' views and experiences might influence the acceptability of an option and its benefits, harms, and costs?

1. Has an appropriate set of options been identified to address the 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 the programmes, services or drugs while neglecting concerns related to the health system arrangements needed to ensure a high coverage rate for the 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, 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 it; how patients/consumers face 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 to consider whether these elements 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 self-management support, decision support, delivery system design, clinical information systems, the health system, and the community more generally, can contribute to effective chronic care [4]. Alternatively, frameworks may be embedded in systematic reviews or overviews of systematic reviews if they were used to organise the search for, and presentation of, research evidence. For example, an overview of systematic reviews has been used to provide a framework for addressing challenges related to human resources for health [5]. One dimension of this framework provided an inventory of 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 options' 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, frameworks, just like the options they are meant to help to identify, may not be mutually exclusive.

Box 1 provides an example of how the teams supporting the widespread use of artemisinin-based combination therapy in Africa identified relevant policy options and then approached the characterisation of the costs and consequences, using questions 2 to 6 below 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 involved 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 (or are likely to be) important to those who will be affected by the decisions taken. Some of the studies consulted may focus on issues related to survival, for example, while others may address health-related quality of life. 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 mnemonic '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 the 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 found 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 take care to minimise the possibility that the measured effect of a policy is attributable to another factor which has not been measured (see Table 1 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, which will save them a significant amount of time. In Article 5 in this series we discuss how to find systematic reviews [6]. But, in addition, policymakers will need to assess the quality and applicability of any systematic reviews they find and incorporate equity considerations (see Table 2).

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

The next step in characterising the costs and consequences of options is to determine the likely harms (or negative effects) of each option. Again, policymakers will need to decide which harms are (or are likely to be) important to those who will be affected by the decisions they make. Some studies may address very infrequent outcomes such as death. Others will address frequent outcomes like the minor side-effects of a drug, and still others will 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 mnemonic 'POCO' 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, the 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 [7]. 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 Article 5 for further information on finding systematic reviews) [6]. Local evidence about harms may also be found by policymakers and this issue is discussed in Article 6 in this series [8]. Once potential harms have been identified, the next step is 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 each option's costs and, if possible, its relative cost-effectiveness. Two options may both be effective but one might deliver better outcomes for a given cost, or it may achieve the same outcomes at less cost. Article 10 in this series addresses ways in which economic evidence can be incorporated in the assessment of options [9]. In this article we discuss how data about costs need to be collected in the setting where the options are being considered. 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.

Nevertheless, 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 payer, provider 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 might 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, which can 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). Article 3 in this series provides tips for finding qualitative studies [10].

6. Which stakeholders' views and experiences might influence the acceptability of an option 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 consumers, healthcare providers, managers working in healthcare organisations, and policymakers. If the answer is 'yes', then policymakers need to seek out qualitative studies that specifically examine the views and experiences of such stakeholders. (Article 3 outlines tips related to finding qualitative studies) [10].

Box 2 below provides guidance on identifying different types of research evidence.

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/Canadian Cochrane Network and Centre (PPD/CCNC) database – Source of systematic reviews of studies about health system arrangements (benefits, harms, key features, and the views and experiences of stakeholders)
  www.researchtopolicy.ca/search/reviews.aspx
- Cochrane Library's Cochrane Database of Systematic Reviews (CDSR) and Database of Abstracts of Reviews of Effects (DARE) – Source of systematic reviews of programmes, services and drugs (benefits and possibly harms)
  http://thecochranelibrary.com
- Cochrane Library's Economic Evaluation Database (EED) – Source of economic evaluations
  http://thecochranelibrary.com
- PubMed – Source of 'hedges' (i.e. validated search strategies) to find select types of single studies (harms, key features, and the views and experiences stakeholders)
  http://www.ncbi.nlm.nih.gov/pubmed/

Box 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 characterised the costs and consequences of three options considered viable in each of their respective countries for supporting the widespread use of artemisinin-based combination therapy to treat malaria.

The impetus for these activities was the WHO guidelines on malaria treatment, published in 2006, which endorsed artemisinin-based combination therapy (ACT) to treat uncomplicated falciparum malaria [11]. 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 can be marketed, who can prescribe them (and how), who can sell or dispense them (and how), and what safeguards should be applied to protect against counterfeit or substandard drugs

EVIPNet teams from each participating country considered options comprising different 'bundles' of heath system arrangements. For example, one country 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 then approached characterising their costs and consequences, using questions 2-6 discussed above as prompts.

Type of information about each option	Examples of the nature of the research evidence sought about each option
Benefits	• People: Everyone except groups other than children under five (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)

Type of information about each option	Examples of the nature of the research evidence sought about each option
Potential harms	• As above except for outcomes, where process indicators of interest included the adherence of community health workers to non-malaria related guidelines (because of a fear that ACT would be provided at the expense of treating other important conditions)
Costs and cost-effectiveness	• Conducted in their own setting • Conducted using a societal viewpoint given that policymakers were acting in their role as stewards for the entire health system, not just as payers for those programmes, services and drugs that are financed publicly
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 enough to allow them to expect similar benefits to those achieved only with lay health workers [12]
Views and experiences of stakeholders	• Policymakers were aware that a large proportion of malaria treatments were dispensed by 'medicine sellers' [13] rather than health professionals or lay health workers. They therefore wanted to know more about the views and experiences of these sellers

Table 1: 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	• An experimental study in which individuals are randomly allocated to be exposed to different policy and programme options (e.g. by the toss of a coin or using a list of random numbers generated by a computer)
	Interrupted time series	• A study that uses 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 the policy or programme has had an effect significantly greater than any underlying trend over time
	Controlled before/after studies*	• A 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 should be done simultaneously in the two groups
Potential harms (i.e. negative effects)	Effectiveness studies (see above)	
	Observational studies	• A 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	• A study that compares the relative expenditure (costs) and outcomes (effects) of two or more courses of action
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 which is usually aimed at interpreting or making sense of phenomena in terms of the meanings people bring to them. Typically, in such a study narrative data is 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 that examine the stakeholders'	• See above
	Observational studies	• See above

*These studies can be very time-consuming to find, yet provide little information of value given 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 2: 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	• Article 7 in this series addresses how to critically appraise the quality of systematic reviews [14] • Article 10 addresses how to use a balance sheet incorporating assessments of the quality of evidence [9]
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	• Article 8 in this series addresses how to assess the applicability of the findings from systematic reviews to specific settings [15]
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	• Article 9 addresses how to identify and incorporate equity considerations [16]

Box 2: Finding research evidence about policy and programme options

Characterising the costs and consequence of policy and programme options involves finding and using many types of research evidence. Systematic reviews (the subject of Article 5), when they're available, can help to characterise the benefits, harms, and key features of the options, as well as the views and experiences of stakeholders [6]. 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:

- Opening in an internet browser the relevant database:
  - 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 Article 5 for additional information [6]
  - 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 Article 5 for additional information [6]
  - Cochrane Library's Economic Evaluation Database (EED) (http://thecochranelibrary.com) for economic evaluations
  - PubMed (http://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 stakeholders' views and experiences) – see Article 3 for additional information [10]
- 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

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