A guide to implementation research in the prevention and control of noncommunicable diseases

WHO /Andrew Esiebo

World Health Organization

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Abbreviations

ACP	Academias das Cidades de Pernambuco
AS	Academia da Saude
CDC	Centers for Disease Control and Prevention
COTPA	The Cigarettes and Other Tobacco Products Act
FCTC	Framework Convention on Tobacco Control
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
GRC	Guidelines Review Committee
GUIA	Guide for Useful Interventions for Physical Activity in Brazil and Latin America
HIC	High-income country
KDPP	The Kerala Diabetes Prevention Program
LMIC	Low- and middle-income country
MeSH	Medical subject heading
M-PACE	Method for Program Adaptation through Community Engagement
NCD	Noncommunicable disease
NPDCS	The National Programme for Prevention and Control of Diabetes, Cardiovascular diseases and Stroke
PICO	Population, Intervention, Comparison, Outcome
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
T2DM	Type 2 diabetes mellitus
WHO	World Health Organization

Executive summary

Implementation research remains relatively new to population-based health programmes and is an area in which language and terminology are still being developed. In this guide implementation research is defined as "the scientific study of the processes used to implement policies and interventions and the contextual factors that affect these processes". In other words, implementation research investigates the various factors that affect how a new policy or intervention may be used (or implemented) in real-life settings.

As well as providing some context and introducing terminology, the guide covers the various steps needed to carry out implementation research, from the initial situation analysis (which ascertains the need for a policy or intervention) and knowledge synthesis (formally identifying and assessing relevant evidence) through to the four key parts of the implementation research cycle: identification of an appropriate policy or intervention; adaptation and piloting of the policy or intervention; implementing the policy or intervention and evaluating this; and finally, scaling up the policy or intervention.

The guide explores the way in which the interplay between a policy or intervention and its local context (e.g. culture and language) can affect implementation. The importance of social validity and other key aspects of implementation, known as *implementation outcome variables* (reach, adoption, fidelity, implementation cost and sustainability), are discussed.

Programmes are said to have social validity when they address problems considered relevant by consumers in a suitable way and have outcomes that are considered valuable. This social validity can be assessed qualitatively, e.g. through surveys and questionnaires. Programmes with poor social validity may need some adaptation, where elements of the policy or intervention other than key evidence-based kernels are modified.

Reach is a combination of both the number of people reached by a policy or intervention and how representative they are of the target population. Better reach, in general, will lead to better impact. Adoption reflects willingness to initiate a programme (policy or intervention) and will differ with contexts and implementers as it is affected by the availability of resources and expertise etc.

Meanwhile, implementation fidelity indicates how close the implementation of a policy or intervention is to that developed by the programme's developers. Implementation costs include direct labour costs (associated with consumer- or implementer- contact), indirect labour costs (associated with the consumers and implementers but do not require direct contact) and non-labour costs (e.g. building space, printing of resources, etc.).

Finally, the guide touches on sustainability and scale-up strategies, referring to a nine step guide for developing a scaling-up strategy. Overall this document aims to provide guidance, tools and examples for implementation research that support the effective implementation of NCD policy options and cost-effective interventions as proposed in the *Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020*.[1]

[1] For further information, visit: http://www.who.int/nmh/events/ncd_action_plan/en/

1

Introduction

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1. Introduction

1.1 Burden of noncommunicable disease

Noncommunicable diseases (NCDs) are noninfectious health conditions typically caused by genetic and/or environmental and lifestyle factors. As NCDs tend to be long-lasting or recurrent, they are sometimes also referred to as chronic diseases *(1)*.

Currently, NCDs account for almost two-thirds of deaths globally *(2)*. Four main diseases account for the majority of deaths from NCDs: cardiovascular disease, chronic respiratory disease, cancer and diabetes. Importantly, these four NCDs share common behavioural risk factors including tobacco use, unhealthy diet, physical inactivity and harmful use of alcohol *(2)*.

1.2 Global response to NCDs

In 2011, the World Health Organization (WHO) published *A prioritized research agenda for the prevention and control of noncommunicable diseases (3)*, which identified key areas of research relating to the prevention and control of NCDs. In September of that year, participants at the United Nations High-level Meeting on Noncommunicable Disease Prevention and Control recognized the existence of cost-effective interventions regarding the preventability of NCDs and the numerous opportunities for global action, and subsequently The Sixty-sixth World Health Assembly endorsed the *Global Action Plan for the prevention and control of noncommunicable diseases 2013–2020 (4)*. This called upon international partners to take coordinated action to attain nine voluntary global NCD targets by 2025 – including a 25% reduction in premature mortality due to NCDs.

One of the *Global action plan's* main objectives focuses on research. This objective calls on stakeholders to promote and support:

- national capacity for high-quality research related to the prevention and control of NCDs (and so increase the knowledge base for national, regional and global action);
- the translation of high-quality NCD basic research into practice;
- development for the prevention and control of NCDs.

1.3 Purpose and objectives of this guide

Although some practical tools for facilitating the use of implementation research for the prevention and control of disease already exist, these mainly focus on communicable diseases.[2] None exist specifically for NCDs. The main purpose of this guide is to provide practical guidance, tools and examples for implementation research so as to support effective implementation of NCD policy options and cost-effective interventions. Specific objectives of this guide are to:

- raise awareness about the purpose and potential impact of implementation research;
- assist countries to capture, collate and analyse information and to translate and adapt evidence-based policy options and interventions to local contexts;
- help identify barriers to the implementation of policies and interventions;
- help identify the best approaches to implementation research.

[2] One such tool is the Implementation research toolkit, which was developed by the Special Programme for Research and Training in Tropical Diseases (TDR). The TDR is hosted by the WHO and the toolkit can be found at: http://www.who.int/tdr/publications/topics/ir-toolkit/en/ (accessed 14 October 2016).

In this guide we provide an introduction to basic implementation research terms and concepts and briefly outline what implementation research involves. We have collated and summarized recent relevant evidence and provide links to resources for further information on many of the topics covered. The guide also includes case studies that showcase examples of the implementation of NCD prevention and control policies and interventions. At the end of the guide we provide some practical tools to support the implementation research process.

1.4 Target audience

This guide has been written for programme implementers, health professionals (including researchers) and national health policy-makers who are involved in the selection and implementation of policies and interventions for the prevention and control of NCDs around the world.

1.5 Achieving national goals and targets in relation to NCDs: The evidence-implementation gap

A major challenge in the prevention and control of NCDs has been that despite a wide range of global, regional and national plans, initiatives, policies and interventions, the impact on health outcomes still needs to be increased significantly. There is still a very notable 'evidence-into-implementation (or action)' gap. This translation gap – between research evidence and practice – is now very well recognized in many health fields *(5-7)*. For example, a review of healthcare delivered to adults from the USA shows that up to 45% of patients fail to receive treatments that have been shown to be effective *(7)*, while 11% receive treatments that are not needed or potentially harmful *(7)*.

Reducing the gap between evidence and practice is associated with reductions in morbidity and mortality *(8-10)* and reduced healthcare costs *(11)*. Therefore, in recent years there has been increased attention on barriers to the translation of research and on how to develop evidence-informed implementation in order to improve patient outcomes *(12-14)*. Evidence is now also needed on effective implementation of primary prevention of NCDs in different contexts through policies and intersectoral health promotion.

2

Implementation Research

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2. Implementation Research

2.1 What is implementation research?

Implementation research investigates the various factors that affect how a new policy or intervention may be used (or implemented) in real-life settings. Such research remains relatively new to population-based health programmes, so a common language and terminology are still being developed. For reference, key terms used in this guide are outlined below.

	Defined as…	Further details
Implementation	A specified set of activities designed to put into practice a policy or intervention of known dimensions *(15)*	Implementation processes are: ■ purposeful ■ described in sufficient detail to allow independent observers to detect the presence and quality of the specific set of implementation-related activities *(16)*
Implementation research	The scientific study of the processes used to implement policies and interventions and the contextual factors that affect these processes *(17)*	Investigates all aspects of implementation, including: ■ the uptake of evidence-based policies and interventions ■ activities used to put these into practice ■ factors that influence these activities ■ impact of factors on health outcomes
Implementer(s)	An individual (or group of individuals) responsible for management of the implementation process	Some examples: ■ policy-makers ■ health professionals ■ community-based organizations
Consumers	The group(s) of individuals that are targeted by an intervention, programme or a policy	Typically, they: ■ are at high risk of developing NCDs, or ■ have a high prevalence of NCDs
Context	The setting within which a policy or intervention is to be implemented	Includes all characteristics of said setting, for example: ■ stakeholders ■ social, economic and political environment ■ geographical setting ■ epidemiologic profile
Knowledge synthesis	The identification, assessment and collation of evidence	This process: ■ relates to existing policies and interventions ■ aims to achieve a desired outcome
Knowledge exchange	The process of collaborative problem-solving	This occurs throughout the implementation process between: ■ researchers ■ decision-makers (including policy-makers) ■ consumers ■ other relevant stakeholders
Knowledge translation	The process by which relevant research information is made accessible and available	Through interactive engagement with audiences, this is used for: ■ practice ■ planning ■ policy making

Questions addressed by implementation research include:

- *Which policy or intervention is best for a new context?*
- *What is the best way to implement it?*
- *How can the target population be reached?*
- *What factors might affect implementation and adoption?*
- *How can the costs of implementation be minimized?*
- *How can uptake and health outcomes be improved?*

2.2 Why is implementation research important?

One of the purposes of implementation research is to support the successful selection of policies and interventions that have been shown to be efficacious *(16)*. It also helps identify how to implement these policies and interventions in contexts where populations and/or resources may differ from that where they were initially formulated and evaluated, and helps identify which components of a policy or intervention are needed to obtain intended outcomes. Moreover, when prevention and control efforts fail, implementation research can help identify whether failure was due to a policy/intervention being ineffective in the setting (*intervention* failure) or whether a so called good policy/intervention was deployed incorrectly (*implementation* failure) *(18)*.

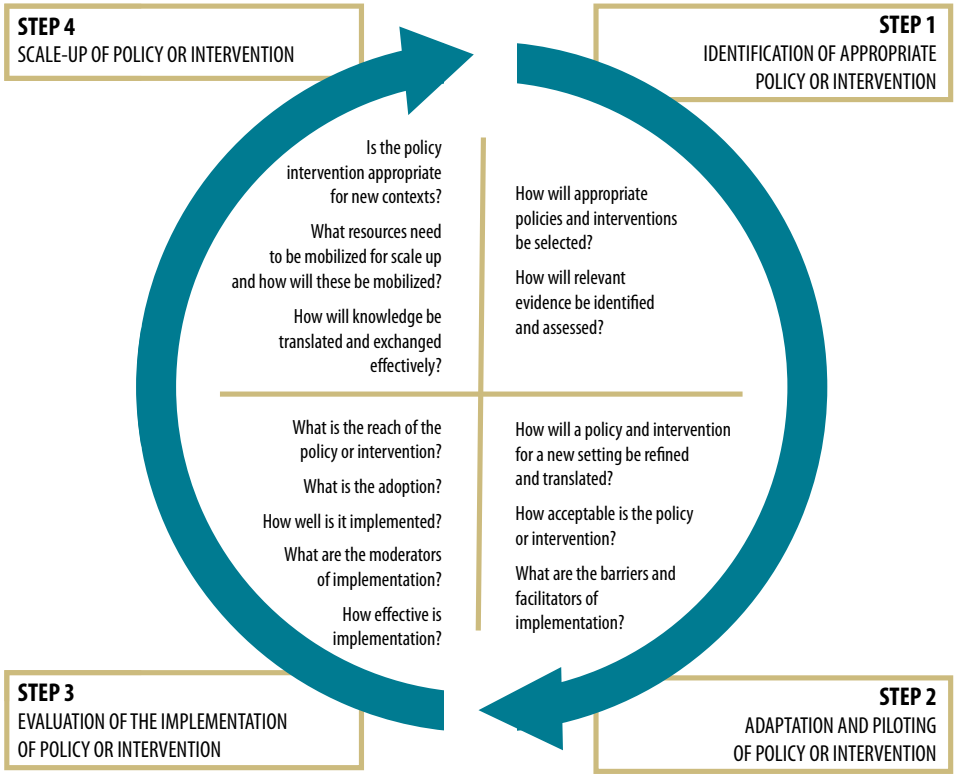
In effect, implementation research is about learning how to optimize implementation, scale up promising strategies, evaluate impact and, importantly, how to sustain these strategies over the long term. Notably, implementation research has the potential to bridge the evidence-into-action gap.

2.3 Implementation and the implementation research cycle

There is a growing number of theories and models describing implementation and the implementation research process *(19-22)*. Implementation typically involves a stepwise, cyclical process (Fig. 1). The first step is to work with key stakeholders in order to define the specific health need and then identify an appropriate policy or intervention to address that need. The second step is adaptation of the selected policy or intervention to the local context and undertaking some piloting. The third step involves implementation of the adapted policy or intervention. The fourth and final step is assessing if the adapted policy or intervention can be more widely implemented or scaled up and, if so, defining the resources and further steps that will be required to achieve this *(23, 24)*.

In practice, the path from selection (step 1) through to scale up (step 4) is rarely direct, as it is usually determined by multiple stakeholders, the availability of resources and other contextual factors. Instead, it normally has numerous iterations involving going back and forth between two or more process steps.

Figure 1. Implementation and the implementation research cycle



This cyclical process is often depicted in implementation models and frameworks. One commonly used framework is the Knowledge to Action Cycle outlined by Graham *et al. (25)*. The KT Clearinghouse provides a range of resources, tools and information about this model.[3]

[3] For further information, visit http://ktclearinghouse.ca/knowledgebase/knowledgetoaction

3

Practical steps on how to undertake implementation research

WHO/ Patrick Brown

3. Practical steps on how to undertake implementation research

3.1 Identifying evidence-based policies and interventions that are appropriate to your local context

Before a policy or intervention is selected and implemented it is important to ascertain that there is a need for it and that there is enough high quality evidence to suggest that it will be effective in the local context. This process is outlined in the following subsections.

3.1.1 Situation analysis: ascertaining the need for a policy or intervention

The selection of policies and interventions for NCD prevention and control typically starts with a situational analysis. This is an information-gathering process that helps understand the specifics of the NCD burden in a particular area (e.g. health needs, risks and local context).[4] The situational analysis also provides an opportunity to garner intersectoral collaboration.

The first stage of a situational analysis is usually to establish a group of relevant stakeholders – this includes implementers, potential consumers and other appropriate parties. The exact point at which this group is established and its composition depends on the local context; in some instances, the individuals who set up the situational analysis will have already done work on the topic and a group may already exist.

The stakeholder group should then engage in knowledge exchange activities; this means that they should discuss the health problem and also collate and discuss evidence about environmental, behavioural and personal determinants related to the health problem. This stage helps identify which factors are modifiable and could be prioritized as targets of policies and interventions. The group should also discuss and clearly identify expected outcomes – such as changes in mortality, morbidity or prevalence of risk factors in a target population.

Case study 1 (below) gives an example of a situational analysis carried out in India in relation to diabetes prevention.

Case study 1: Situational analysis – Diabetes prevention, India

Why this case study?	This illustrates how a situational analysis was carried out in the state of Kerala, India in order to assess the need to implement a diabetes prevention programme. The situational analysis laid the foundation for the adaptation of diabetes prevention programmes from Europe, the USA and Australia to the local context.
Title	Carrying out a situational analysis for the implementation of NCD prevention and control policies and interventions
Source	Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, India
Health issue	Type 2 diabetes mellitus
Setting	Trivandrum region in Kerala, India
Target population	Men and women at high risk of developing diabetes

[4] It is beyond the scope of this guide to describe the situational analysis process and the establishment of multisectoral collaborations in detail. However, WHO has published a comprehensive resource on this process which can be found at: http://www.who.int/nmh/action-plan-tools/en/ (accessed 14 October 2016).

Background	India has approximately 65 million individuals with type 2 diabetes mellitus (T2DM) – the second-largest number for a single country in the world. This number is expected to double by 2030 *(26, 27)*. Studies estimate that T2DM affects between 9% and 20% of the country's adult population *(28, 29)*. Kerala has the highest prevalence of T2DM, with up to 20% of adults estimated to have the disease in parts of the state *(30, 31)*.
Description of policy or intervention	The Kerala Diabetes Prevention Program (KDPP) is a lifestyle intervention aimed at individuals in rural areas of Kerala at high risk of developing diabetes. The programme is designed to reduce the risk of developing diabetes through a series of peer-led sessions held within local communities. Following training on diabetes prevention and group facilitation, peer leaders identified from within the community conduct small group sessions focused on increasing knowledge about diabetes and on prevention strategies. Sessions are supplemented with community-wide activities such as yoga, walking and gardening which help participants to put into practice the learning from the group sessions.
What took place?	A situational analysis was carried out prior to the development of the KDPP by triangulating evidence from: (i) previous research on the prevalence and control of diabetes in India and elsewhere; (ii) policy and other programme documents relevant to diabetes prevention specific to Kerala or India and (iii) a collection of novel qualitative data in Kerala through engagement with local stakeholders (including consumers) *(32)*. Relevant published research was retrieved following PubMed searches using medical subject heading (MeSH) terms related to diet, physical activity, tobacco and health promotion interventions conducted in India. The search engines of relevant government department websites (e.g. of the Ministry of Health & Family Welfare) were used to retrieve relevant policy and programme documents (including guidelines at both the state and national level on NCD prevention and control, diet, physical activity and tobacco and alcohol use). The qualitative research component consisted of focus groups (with pre-diabetic individuals from rural areas of Kerala, identified from the database of an earlier survey *(33)* that explored perceptions and attitudes towards T2DM and its prevention). These group discussions helped to identify specific needs for cultural adaptation and for delivery of the programme to target communities.
What was learnt?	The National Programme for Prevention and Control of Diabetes, Cardiovascular Diseases and Stroke (NPDCS) – with recommendations on diet and physical activity – only launched recently in India. This contrasts to the situation in high income countries (HICs), where most diabetes prevention programmes were implemented almost a decade ago. Despite the large burden of NCDs in the state and across the country, the situational analysis revealed gaps in NCD research and policy in Kerala/India. A review of epidemiological studies revealed a higher prevalence of risk factors for T2DM in Kerala than in the rest of the country *(29)*, with some risk behaviours (such as smoking) higher than the national average. Adult physical inactivity during leisure time was also high *(34)*. The focus groups highlighted the important role of families and cultural norms in making lifestyle choices in India. This underpinned the importance of developing a more integrated approach to behaviour change interventions than used in HICs. Multiple strategies involving family and community empowerment were called for – as corroborated by other studies in India *(32, 35-36)*.

3.1.2 Knowledge synthesis: formally identifying and assessing relevant evidence

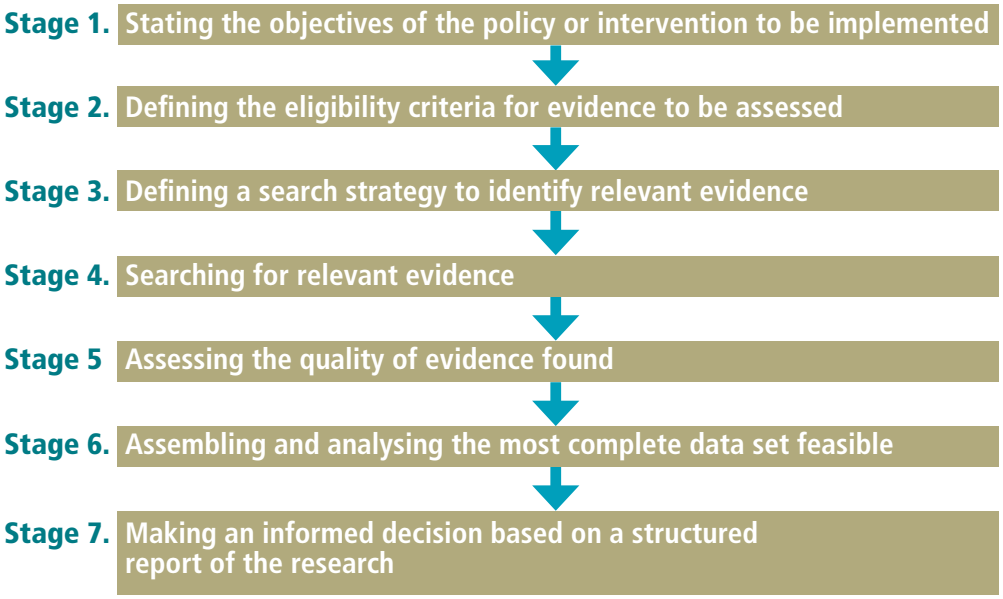
Implementing a policy or intervention that has only been shown to be effective in one research study can be problematic. Few studies by themselves are persuasive enough to change policy or practice; in fact, individual studies may even be misleading due to chance or bias *(37)*. Therefore, after carrying out the situational analysis and identifying the health need and desired outcomes, implementers need to perform a formal synthesis of evidence on potential policies and interventions – termed a knowledge synthesis.

Failure to use such a knowledge synthesis can lead to delays between the generation of research evidence about an intervention and the time when clinical experts make recommendations in line with research findings. For example, Antman observed a 15 year gap between the time when meta-analysis could have demonstrated the effectiveness of a particular method to treat myocardial infarction and widespread recommendations for its use *(38)*.

Stages of knowledge synthesis

There is a growing range of methods for knowledge synthesis; most involve an initial review of existing literature. Depending on time, resources available, and other constraints, this literature review can be rapid or involve a lengthier meta-analytical process. These issues are explored in more details later in this guide; in this section, we highlight the common stages in knowledge synthesis (see Fig. 2) based on published frameworks *(39, 40, 41)*.

Fig. 2. The stages of knowledge synthesis



Stage 1: Stating the objectives of the policy or intervention to be implemented

The first stage in the knowledge synthesis process is to formulate the objectives of the synthesis; this is arguably the most important stage in the process and is partially informed by the situational analysis described earlier in Section 3.1.1.

The more explicit the objectives (for example, in terms of how specifically the population or the intervention is defined), the more you will limit available evidence. On the other hand, making the objectives broader is likely to require more resources as there will be more evidence to sift through and assess.

One method for devising objectives is summarized by the acronym PICO:

- **P**opulation
- **I**ntervention
- **C**omparison
- **O**utcome

For example, your objectives may be to identify evidence on approaches to the prevention of secondary heart attacks *(outcome)* in elderly men and women who live in rural areas *(population)*. These are very

broad objectives, so you may refine these based on information gathered during the situational analysis. For instance, the situational analysis may have revealed that the majority of people in your target population have access to mobile phones; you may therefore want to narrow your objectives by stating that you are seeking evidence on mHealth programmes *(interventions)* and their effectiveness compared with face-to-face secondary prevention services *(comparison)*.

The PICO model is very widely used and it is recommended by Cochrane (previously The Cochrane Collaboration) as a strategy for formulating questions and search strategies and for characterizing clinical studies or meta-analyses.[5] Appendix 1 provides an example of PICO and a template to apply this to your context.

Stage 2: Defining the eligibility criteria for evidence to be assessed

In the second stage you should set the criteria that will determine whether you retain (and assess) a particular piece of evidence that you identify or whether you should discard it. This stage is partially guided by the objectives outlined earlier.

First, you need to specify the characteristics of the evidence (e.g. research studies) that are to be included in your knowledge synthesis – in effect, the 'eligibility criteria'. The following are typical:

- the nature of what was studied (e.g. specific policies or interventions);
- the context (in other words setting and population – e.g. adults; ethnic groups);
- the date of research (e.g. ever; since 1920; since 1990);
- the research methods (e.g. all methods; only empirical; only certain designs);
- the language of report (e.g. English only; French only; both).

Taking forward the scenario mentioned in stage 1 above, you might want to limit your search to 'evidence on interventions that use information and communication technology for secondary prevention of heart attacks in men and women living in rural areas'. Ideally, you would also limit your search to evidence from your own country, although this may not always be possible as the evidence available may be too limited or nonexistent. In that case you may wish to look for evidence from the region (e.g. South Asia if you are based in Bangladesh; sub-Saharan Africa if you are based in Uganda; and so on).

You also have to decide if you only wish to search for recent evidence (often the case, to ensure relevance) and if you want to include peer-reviewed studies that use randomized controlled designs only, or whether you also want to include grey literature.[6]

Stage 3: Defining a search strategy to identify relevant evidence

After you have set the objectives for the knowledge synthesis, and after you have decided which evidence you will assess, you need to prepare the search strategy. This specifies the detailed method for conducting the search; it outlines exactly which terms (in a structured list) you will search for in databases, how these terms will be linked and what databases you will use. The search strategy should be grounded in the research question and should be recorded in detail.

Your choice of key terms will be guided by the objectives. Bear in mind that the same concept may be referred to in a number of ways (e.g. self-esteem might be referred to as self-worth elsewhere). You therefore need to examine each of your concepts and develop a list of the different ways in which they could appear in the literature. You will also need to think about how your search terms may be linked.

[5] For further information about PICO, visit: http://linkeddata.cochrane.org/pico-ontology (accessed 14 October 2016).

[6] Grey literature is information that is unpublished or not published commercially; its value has been formally acknowledged by prestigious evidence-based research organizations, including Cochrane. Examples include (but are not limited to) conference papers, reports, policy statements, government documents, statistics, interviews and focus groups reports. Grey literature is particularly useful when the literature relating to polices and interventions of interest is limited in quantity and/or has limited applicability to the local context.

Searches are usually conducted online, using existing research literature and/or policy databases. Key databases that are useful in the identification of relevant evidence include:

- **Cochrane Library:** http://www.thecochranelibrary.com
- **The Joanna Briggs Institute Database of Systematic Reviews and Implementation Reports:** http://joannabriggslibrary.org/index.php/jbisrir/index
- **Database of Abstracts of Reviews of Effects (DARE):** http://www.crd.york.ac.uk/CRDWeb/HomePage.asp
- **NICE Evidence Services:** https://www.evidence.nhs.uk
- **PubMed Health:** https://www.ncbi.nlm.nih.gov/pubmedhealth
- **WHO Library Database (WHOLIS):** http://dosei.who.int

Different databases work in different ways, so you may need to adapt your search strategy to each database that you use. This process is often referred to as 'tailoring' your search. You may also decide to develop separate search strategies for different aspects of your research.

Note that implementers do not all always have access to all databases or to the evidence identified through the databases. This underpins the importance of establishing an intersectoral collaborative team from the outset (as mentioned in Section 3.1.1); ideally, this team will include academic researchers who will typically have access to most online databases and sources of evidence.

When searching for relevant evidence there is a trade-off between sensitivity and specificity; specificity decreases as sensitivity increases. Searches that are highly sensitive will identify all or most of the relevant literature, however they will also likely identify literature that is not relevant. Searches that are highly specific will exclude all or most of the literature that is not relevant, however they may also exclude some of the literature that is relevant. The more sensitive the search, the more time needs to be spent sifting out irrelevant studies. Given that implementers are often time-constrained or resource-limited, some sensitivity may have to be sacrificed in the knowledge that some potentially relevant evidence may be missed. Defining a search strategy will benefit from the expertise of an information specialist. They can provide guidance on defining search terms that will help balance sensitivity and specificity.

Stage 4: Searching for relevant evidence (applying the search strategy)

This stage involves searching for all relevant evidence using the selection criteria identified and the predetermined search strategy for a specific database(s). The search will aim to identify as much of the literature that meets the inclusion criteria as possible.

If time and resources allow, it is a good idea to have more than one person performing the same search independently, and then comparing the evidence identified to make sure that findings are consistent and there is no bias in the way that searches are made and evidence is selected.

When searching for research evidence, it is important to ensure you consider which study design will best answer your research question. For example, a systematic review of randomized control trials is ideal if you wish to determine the best type of intervention to prevent or manage a condition. However, if you are wishing to know how common the problem is, then local and current random sample surveys (or censuses) would be more appropriate. The Oxford Centre of Evidence Based Medicine (OCEBM) provides a hierarchy of evidence depending on the research question.[7]

[7] For further information, visit the OCEBM website: http://www.cebm.net/ocebm-levels-of-evidence/ (accessed 14 October 2016).

Stage 5: Assessing the quality of evidence found

The quality of evidence is likely to vary considerably. Therefore, you must decide on explicit criteria for appraising studies in order to separate those of higher quality from those of lower quality.

Three main dimensions considered when appraising the quality and relevance of studies *(41)* are:

- the methodological quality of the study;
- the relevance of that research design to the objectives;
- the relevance of the study focus to addressing the objectives.

Checklists such as the Jadad scale (also known as the Oxford quality scoring system) are commonly used for assessing the methodological quality of trails *(41)*. The Joanna Briggs Institute provides a range of different checklists to critical appraise other study designs.[8]

WHO uses the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach to assess the quality of a body of evidence. WHO uses this approach as it represents internationally agreed standards for making transparent recommendations. Detailed information on GRADE is available through the WHO Guidelines Review Committee (GRC) secretariat and on the following websites:

- GRADE working group: www.gradeworkinggroup.org
- GRADE online training modules: http://cebgrade.mcmaster.ca
- GRADE profile software: http://www.cochrane.org

Other sources of information can also help you in assessing evidence:

- The Trip Database[9] is a medical search engine that allows you to search for evidence based on PICO and to find out about evidence by study design, relevance and timeline.
- The Critical Appraisal Skills Programme (CASP)[10] provides a range of training, workshops and tools to help you critically evaluate the quality, results and relevance of research.

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) is another widely used method to assess an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses. PRISMA focuses on the reporting of reviews evaluating randomized trials, but can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions.[11]

Assessing evidence and developing evidence summaries using GRADE (or otherwise) is a specialized task that is best done by a methodological expert, so it may be prudent to enlist such help. This is especially important if you are assessing evidence for large scale NCD prevention and control policies. Nevertheless, if appropriate it is possible to assess the evidence more rapidly and in-house using the three dimensions listed above with existing online resources.

Stage 6: Assembling and analysing the most complete data set feasible

After assessing the evidence, you will have to collate and analyse all your assessments to determine if there are sufficient grounds to implement the policy or intervention that you are interested in. This is likely to be the stage that implementers, particularly policy officials, are most interested in. You should therefore ensure that output from the knowledge synthesis is presented in a clear format that meets their needs (for example, by drawing out policy implications).

[8] For further information, visit: http://joannabriggs.org/research/critical-appraisal-tools.html
[9] For further information, visit the Trip Database website: http://www.tripdatabase.com (accessed 14 October 2016).
[10] For further information, visit the CASP website: http://www.casp-uk.net (accessed 14 October 2016).
[11] For further information, visit the PRISMA website: http://prisma-statement.org/Default.aspx (accessed 14 October 2016).

There are various approaches to collating, analysing and presenting the evidence you found; in Appendix 2 we provide a mock matrix which you can use to collate and rank evidence.

Stage 7: Making an informed decision based on a structured report of the research

Only when all available evidence has been collated and assessed, and evidence for the effectiveness has been ranked, is it possible to select a policy or intervention for adaptation to and implementation in your local context.

Systematic reviews and other approaches to knowledge synthesis

The guidance provided above is sufficient to identify and assess evidence relevant to the effectiveness of policies and interventions for an outcome of interest within a relatively short amount of time and with limited resources. A more rigorous approach to identifying, assessing and synthesizing evidence from numerous sources is to carry out a systematic review. Systematic reviews bring the same level of rigour to reviewing research evidence as should have been used in producing that research evidence in the first place. Using the systematic review approach, however, is time and resource consuming and is not usually possible in the circumstances where most programme implementers are seeking to implement a new policy or intervention (or to implement an existing policy or intervention in a new setting).

A faster approach is that of rapid evidence assessment, which uses targeted literature searches to produce a report in a relatively short period of time. This is less rigorous than a full systematic review, but more so than an ad hoc search.[12] It is well aligned with the approach described here.

Case study 2 (below) provides an example of knowledge synthesis in practice.

Case study 2: Knowledge synthesis – Tobacco-related NCDs and plain packaging policies, India

Why this case study?	This showcases knowledge synthesis in preparation for the implementation of tobacco plain packaging policies and interventions in India. The case study also illustrates that, although there may be evidence for a policy or intervention's effectiveness, it is important to take account of local context.
Title	Knowledge synthesis on plain packaging to assess existing evidence to promote the selection of evidence based policies and interventions for implementation in India
Source	Nossal Institute for Global Health, The University of Melbourne, Melbourne, Australia
Health issue	Respiratory diseases and other NCDs caused by tobacco
Setting	India
Target population	Individuals who use tobacco products
Background	Tobacco is responsible for 25% of deaths from respiratory diseases in India *(42)*, which is the world's second largest consumer of tobacco (smoking and smokeless forms) *(43)*. The prevalence of tobacco use is 48% in males and 20% in females, with many others exposed to second-hand smoke *(44, 45)*. Tobacco attributable deaths in India are expected to rise to 1.5 million annually by 2020 *(46)*. It has been suggested that the cost of respiratory diseases attributable to tobacco in India in 2011 was US$ 600 million *(47)*. In 2003 the Indian government, consistent with the WHO Framework Convention on Tobacco Control (FCTC) *(48)*, passed The Cigarettes and Other Tobacco Products Act (COTPA). This prohibited tobacco-related advertising and sponsorship and specified health warnings on tobacco packs *(49)*. However, the impact of these measures was limited *(50)*, prompting the Indian Government to consider larger, more effective pictorial health warnings *(4, 51-56)*. The next step would be plain packaging, for which there is growing international evidence.

[12] The UK Government has developed and made available online a toolkit which provides additional information on rapid evidence assessment. This tool can be found at: http://www.civilservice.gov.uk/networks/gsr/resources-and-guidance/rapid-evidence-assessment/how-to-do-a-rea (accessed 28 November 2016).

Description of policy or intervention	Plain packaging entails the removal of all branding (colours, imagery, corporate logos and trademarks), with brand names mandated a uniform size and font and placed together with current or enhanced graphic health warnings on the tobacco packaging. Plain packaging would apply to packaging of all forms of tobacco; in India this includes *beedis* and chewed forms of tobacco as well as conventional cigarettes. The aim of plain packaging is to decrease the attractiveness of the package, enhance the effect of pictorial health warnings on the package, increase thoughts about quitting and promote negative attitudes towards tobacco use. Plain packaging of tobacco products has a significant evidence base from a number of countries *(54, 57-60)* – especially from Australia where it was first introduced. However, evidence on such packaging in rapidly developing countries such as India is relatively scant *(61, 62)*.
What took place?	A joint Indian and Australian taskforce was convened with support from a small grant from the Australia India Institute. Following a comprehensive knowledge synthesis project, the taskforce produced a report on the possibility of plain packaging in India *(60)*. The report included evidence from other jurisdictions, local market research on plain packages *(63)* and results from a stakeholder analysis undertaken with legal experts, policy-makers and tobacco control experts. It summarized all the behavioural, political and legal evidence and provided graded recommendations as to the way forward. The report was launched at a high level event attended by politicians from India, WHO representatives, leading tobacco control experts and legal experts. In response, a private members bill on plain packaging was introduced to the Indian parliament in 2013 and a follow up international conference was also held at which the Indian health minister and health secretary gave presentations. However, a number of contextual barriers have slowed progress on plain packaging. These include a change of government and health ministers, a demand for local evidence and opposition from a significant tobacco farming industry in India. Further research is planned to respond to these concerns and produce additional local evidence.
What have we learnt?	While external (international) evidence and the input of international experts is a helpful start in formulating policies, it is not sufficient for successful policy change. To increase the chances of the knowledge synthesis leading to a change in policy, the following points are useful: ■ It is important to know the specific audience for whom the knowledge synthesis is being undertaken. ■ Research needs to take account of the policy-making timetable – e.g. regulatory committee meetings or election cycles. ■ A mechanism is needed to ensure the knowledge synthesis is fed to the appropriate groups to inform debate and policy. In particular, a clear communication strategy is needed to reach decision-makers. ■ The knowledge synthesis team need to involve credible figures to maximize the likelihood of evidence reaching decision-makers. (In this example, two coinvestigators sat on government advisory committees). ■ Contextual information can often result in a need to include and/or produce unique evidence in addition to that available from other jurisdictions. (For example, in this case the tobacco products and industries of Australia and India were very different, so further information was needed).

Finally, note that while the stages of knowledge synthesis outlined above will help to identify policies and interventions that may be pursued in the prevention and control of NCDs, they may not provide information about *transferability* of these to new and different contexts. Approaches to the assessment of suitability and adaptation of policies and interventions to new contexts are discussed later in the guide.

3.2 Adapting and piloting the policy or intervention

The interplay between a policy or intervention and its local context can impact both its implementation and its effectiveness *(64, 65)*. For example, differences in culture, language, age and socioeconomic status of the target population can – and often do – influence successful implementation of a policy or intervention either positively or negatively *(66)*. This means that a policy or intervention may need some adaptation.

Adapting a policy or intervention to the context in which it will be delivered is a delicate balancing act: on the one hand adaptation is crucial to ensure relevance to the local context, improve feasibility, increase local pertinence and adoption, encourage fidelity, foster sustainability and maximize effectiveness; on the other hand, one has to be careful not to modify the policy or intervention so much that fidelity to some of the core components of the policy or intervention is lost and effectiveness is threatened.

Guidelines on the adaptation of interventions typically share the following steps:

- identifying differences between the population for which the policy or intervention was initially designed and the new target population;
- identifying which component(s) of a policy or intervention need to be adapted;
- making modifications to the policy or intervention;
- piloting the modified policy or intervention.

The Method for Program Adaptation through Community Engagement (M-PACE) developed by Chen *et al. (66)* outlines a way of systematically adapting interventions to a new setting. This involves convening an adaptation steering committee (including experts who can advise on whether an element of a policy or intervention can be changed without reducing effectiveness) and then exposing a limited group of participants to the unadapted intervention. This is followed by collecting participant and instructor feedback after each implementation session (if appropriate), or conducting a pilot through individual interviews and then conducting focus groups with participants and instructors at the end of the intervention (or pilot). Further details about M-PACE can be found in reference *(66)*.

When adapting a policy or intervention it is important to know that certain elements are essential for desired outcome(s). These elements are known as evidence-based kernels and can be likened to a drug's active ingredients, without which its effects would be lost *(66)*. Therefore, as far as possible, these kernels should not be modified. However, methodically determining the kernels of a policy or intervention is not typically feasible – it requires the same intervention to be implemented multiple times, with the presumed kernel being changed each time the intervention is reimplemented while other variables are kept constant. Although research teams have successfully articulated and validated the kernels of some programmes *(63, 67-70)*, there are few adequately defined programmes in the research literature. The amount of evidence for evidence-based kernels in different fields should grow with increasing recognition of the importance of implementation research.

The case study below gives an example for how an intervention was adapted to the local context.

Case study 3: Adapting interventions – Hypertension, Mongolia

Why this case study?	This case illustrates the importance of adapting interventions to the local context and piloting them prior to scale up. The case study also highlights some of the barriers and facilitators to the adaption and piloting process and proposes ways in which to address these.
Title	Adapting policies and interventions to new contexts
Source	The George Institute for Global Health, Sydney, Australia
Health issue	Hypertension and comorbidities

Setting	Mongolia
Target population	General population of Ulaanbaatar (Mongolia's capital city)
Background	Population-wide salt reduction programmes are widely viewed as one of the most cost-effective interventions for the prevention of hypertension and associated NCDs. The number of such national programmes has almost doubled between 2010 and 2014 and programmes are now being implemented in most regions of the world. However, to date, most of those that have demonstrated an impact are from HICs. There is some way to go to translate the lessons from these countries to low and medium income countries (LMICs).
Description of policy or intervention	Successful salt reduction programmes identify the main sources of salt in the diet and then develop a strategy to reduce them. The Ministry of Health in Mongolia (MMoH) implemented a pilot intervention to reduce population salt intake in Ulaanbaatar during 2012–2013. The results of this pilot, combined with a series of other initiatives, informed the development of a National Salt Reduction Strategy.
What took place?	The MMoH established an intersectoral working party and organized a two-week national consultation and training programme on salt reduction. Actions arising included implementation of a pilot salt reduction intervention. The main objective of the pilot intervention was to reduce salt intake of the employees of three factories, based on the notion that simply telling people what they should/should not eat does not work – the food environment also needs to change. Adapting this to the Mongolian context, implementation strategies included training employees on the negative health impact of salt and on consuming a healthy diet, as well as actually reducing salt levels in the food served in company canteens/kitchens. Pre- and post-intervention monitoring showed that salt intake reduced between 2011 and 2013. The number of people that did not know which foods were high in salt also declined substantially during the same period. These activities demonstrated the potential for action and helped to convince policymakers to scale up the policy to national level, resulting in the Mongolian National Salt Reduction Strategy being endorsed by the government in 2015 – with the ultimate goal to reduce population salt intake in Mongolia by 30%.
What have we learnt?	Success of the pilot intervention and scaling up of the policy to national level was possible for a number of reasons: ■ The importance of multisectoral action was recognized from the outset. ■ The project emerged from consultation and training on salt reduction and raised awareness of the health impacts of salt. ■ The approach started by trying to understand the main sources of salt in the diet and how best to reduce them (rather than simply replicating salt reduction initiatives from other countries). Lessons for other countries: ■ **Do not** just replicate other programmes. A good understanding of how consumption patterns are contributing to salt intake in the country of interest is also needed. ■ **Do** ensure that your strategy is multifaceted, combining a change of the food environment together with programmes to change consumer behaviour. ■ **Do** continue with advocacy programmes to ensure strong government support and adequate financing. ■ **Do** establish effective multisectoral stakeholder engagement, community participation and training procedures from the outset. ■ **Do**, where possible, implement pilot interventions. ■ **Do not** leave evaluation until the end of the programme. Regular monitoring ensures programmes are on track to achieve targets.

3.2.1 Social validity: How acceptable is the policy or intervention in your local context?

Despite a policy or intervention being highly effective at achieving a desired outcome, its implementers and/or consumers may consider it inappropriate for a particular setting. In order for a policy or intervention to achieve intended outcomes in the practice setting, it must be both effective and socially valid. A programme is said to have social validity when it addresses problems considered relevant by consumers, it does so in a manner that consumers can enjoy or at least tolerate, and it produces outcomes that are considered valuable *(71)*.

A social validity assessment can provide information regarding how well specific elements of a policy or intervention are liked or disliked. Most current approaches define three elements of a policy or intervention that can be assessed for their social validity. These are: (i) the social significance of the goals of policy or intervention, (ii) the social appropriateness and acceptability of the policy or intervention's procedures and (iii) the social importance of the effects or the outcomes produced by policy or interventions.

Most methods for assessing social validity ask parties other than policy-makers or researchers about their opinions on policies and interventions *(71)* and use questionnaires/rating scales and focus groups or interviews *(72)*. One common approach with questions on each of the three elements of social validity *(73)* is provided in Appendix 3. This qualitative approach can be combined with quantitative data collection (e.g. by survey) if necessary.

Case study 4: Establishing acceptability – Respiratory diseases, Senegal

Why this case study?	This illustrates the negative consequences of implementing an effective intervention without first assessing acceptability in a new context.
Title	The importance of establishing acceptability
Source	Beltramo T, Levine DI. The effect of solar ovens on fuel use, emissions and health: Results from a randomised controlled trial *(74)*.
Health issue	Respiratory diseases
Setting	Senegal
Target population	Households where cooking is conducted using solid fuels
Background	Traditional stoves for cooking and heating in LMICs are frequently fuelled with dung, coal and wood. The smoke resulting from burning such solid fuels pollutes the air and has been linked to a range of respiratory and other diseases. Improved stoves have the potential to reduce exposure to household air pollution and so improve health outcomes. One such improved stove is the solar oven. During laboratory testing in highly controlled contexts, solar ovens frequently show positive results and do not emit any emissions. However, studies in real-world contexts are far less promising.
Description of policy or intervention	A phased, randomized controlled trial to test the effects of a solar oven called 'the HotPot' was carried out in Senegal.
What took place?	The solar oven was provided to 465 households. After six months, the intervention group had just as high carbon monoxide exposure as the control group and there was no reduction in self-reported health symptoms. In the laboratory these stoves were shown to be effective – so what went wrong? The study showed poor levels of adoption of the HotPot, with households using the stove very infrequently. A major reason for this was that the solar oven was far too small for the majority of households in the study. Other studies *(75)* indicated additional reasons for solar oven unacceptability to communities: cooking could take longer, the ovens could not be used for heating and light, and the oven might need be used outdoors during sunlight.
What have we learnt?	Adoption of new technologies is challenging and interventions must be tailored to the needs and preferences of communities in order to succeed *(76)*.

3.3 Evaluating the implementation of a policy or intervention

Typically, evaluation efforts have focused on assessing how effective NCD policies and interventions are at achieving health improvement at the individual or population level. Assessing the *effectiveness* of a policy or intervention, however, is not sufficient. Planning and focused efforts to evaluate the *implementation* of NCD policies and interventions must also be in place. Thus, the evaluation should look at the implementation of policies and interventions as well as their effectiveness.

Put simply, the focus of an evaluation of the implementation process is on the types and quantities of policies and interventions delivered, the beneficiaries of those policies and interventions, the resources used to deliver the policies and interventions, the practical problems encountered, and the ways in which such problems were resolved.

The steps involved in planning an evaluation of the implementation process are analogous to those for planning an evaluation of effectiveness. Evaluation of the implementation process must be addressed early in a programme's planning process, or else the collection of relevant data could be compromised or even missed.

Public Health Ontario has devised ten steps for conducting an evaluation *(77)*; we have adapted these below so that they are inclusive of implementation processes and effectiveness:

1. Clarify what is to be evaluated.
2. Engage stakeholders.
3. Determine your evaluation questions.
4. Develop an evaluation framework.
5. Determine appropriate methods of measurement and procedures.
6. Develop an evaluation plan.
7. Collect data.
8. Process data and analyse results.
9. Interpret and disseminate results.
10. Apply evaluation findings.

3.3.1 What research questions should the implementation evaluation be asking?

Key questions should be designed in order to assess implementation research or to report on implementation research. For example:

- What specific policy or intervention was put into place by the implementers in order to address the NCD issue being tackled?
- To what extent was the policy or intervention implemented as intended?
- To what extent was the policy or intervention adopted by implementers?
- What are the factors that can influence how well a policy or intervention is implemented?
- To what extent did these factors influence how well a policy or intervention is implemented?
- What is the association between the health outcomes (i.e. effectiveness) of a policy or intervention and how well this is implemented?
- Was the implementation approach that was used cost effective?

Peters et al *(78)* have developed a useful table which can help develop the research questions for evaluations.[13]

3.3.2 What are implementation outcomes?

In implementation research studies, implementation outcomes describe the intentional actions to deliver a policy or an intervention *(18, 78)*; they are distinct from, but related to, health outcomes.

Implementation outcome variables include: acceptability, reach, adoption, fidelity, implementation cost and sustainability. Acceptability has been covered in Section 3.2.1; cost and sustainability are discussed later in Sections 3.3.6 and 3.3.8, respectively. In the following subsections we will focus on reach, adoption and fidelity.

What is the reach of the policy or intervention?

Reach is defined as the absolute number, proportion and representativeness of a study sample *(79)*. Population impact is a function of how well a policy or intervention is implemented, its effectiveness at the individual level and its reach. For example, the population impact of a smoking cessation programme depends both on how many smokers are reached and try to stop smoking, and what the average success rate is. Research indicates that in this example the reach of the programme has much greater impact, since the success rate seems to vary less.

Reach is a combination of both the number of people reached by a policy or intervention and how representative they are of the target population. Most studies report the size of the study sample and the proportion of individuals who are willing to participate, but few report on representativeness (which indicates the similarities and/or differences between those who participate in the study and those who are eligible but do not).

The representativeness is important, as generalization of an intervention into real-world settings is likely to have better impact if sample representativeness – and therefore reach – is good. Comparisons for representativeness should be based on basic demographic characteristics and, when possible, on primary outcomes. Case study 5 (below) explores the issue of reach.

Case study 5: Considering reach – Diabetic foot, India

Why this case study?	This illustrates the importance of assessing reach to ensure that populations with the greatest health need are reached by a new policy or intervention.
Title	Why do we need to assess reach as well as effectiveness?
Source	Christian Medical College, Vellore, Tamil Nadu, India
Health issue	Diabetic foot
Setting	Integrated Diabetes Foot Clinic, Department of Endocrinology, Diabetes and Metabolism, Christian Medical College, Vellore, Tamil Nadu, India
Target population	Type 2 diabetes mellitus patients affected with diabetic foot problems
Background	Diabetic foot problems are the most common reason for hospitalization of diabetic patients and absorb some 20% of the total healthcare costs of the disease, more than all other diabetic complications put together. Treatment involves footwear modification and offloading (i.e. reducing pressure on affected areas of the foot).

[13] The table can be found here: http://www.bmj.com/content/347/bmj.f6753 (accessed 14 October 2016).

Description of policy or intervention	An Integrated Diabetes Foot Clinic was set up in 2008 at the Christian Medical College in Vellore, India, with a core team of endocrinologists, diabetes nurse educators, vascular surgeons, physiotherapists and orthotists. The clinic was equipped with tools for the diagnosis and treatment of diabetic foot, and radiological investigations were completed and reviewed within the same day. Meanwhile, patient-specific footwear was developed at the Prosthetics and Orthotics Centre. In 2015, a retrospective study was carried out on 138 patients to assess the utility of low-cost footwear modifications (such as anterior rocker modifications) in reducing ulcer healing time.
What took place?	Over half of the group of patients using the anterior rocker modification had healed fully within 8–12 weeks; those noncompliant with or without anterior rocker footwear had a prolonged healing time of 4–6 months.
What have we learnt?	Adequate foot care and offloading techniques remain inaccessible for a significant proportion of diabetic patients due to socioeconomic factors and lack of awareness, leading to amputations and healthcare expenditure. So, although treatments may be effective their reach may be limited. The care provided at the clinic had a greater reach. The study indicates that use of simple diagnostic criteria and development of cost-effective modifications such as the anterior rocker significantly reduced healing time and hence reduced economic burden.

What is the adoption of the policy or intervention?

Adoption has been defined as the absolute number, proportion and representativeness of settings (contexts) and intervention agents (implementers) that are willing to initiate a programme (policy or intervention) *(79)*.

Different contexts (e.g. worksites, medical offices, schools, communities, etc.) and implementers (e.g. health practitioners, policy-makers, government staff, researchers, etc.) can differ in their adoption of a policy or intervention, as this is affected by the availability of resources, the level of expertise and the commitment to programmes. Researchers seldom report on issues of adoption, but understanding how adoption varies among different contexts and implementers is critical to the impact of a policy or intervention.

The approach to measuring adoption should change depending on the policy or intervention, as well as on whether adoption at the context level or implementer is of interest. Providing detailed guidance on the many tools and approaches for the assessment of adoption is beyond the scope of this guide. The National Institutes of Health in the United States of America, however, maintains the Grid-Enabled Measures Database[14] – a database of measures that are used to assess adoption (as well as other implementation outcomes).

What is the fidelity of the policy or intervention?

Implementation fidelity refers to the extent to which a policy or intervention is delivered as intended by its developers and in line with the programme model *(80)*. Evaluation of implementation fidelity is important because it may affect the relationship between an intervention and its outcomes. It may also:

- prevent potentially false conclusions from being drawn about an intervention's effectiveness in achieving the intended health outcomes;
- help in the achievement of improved outcomes;
- give primary researchers confidence in attributing health outcomes to the intervention;
- give evidence-based practitioners confidence that they are implementing the chosen intervention properly;
- give secondary researchers more confidence when synthesizing studies *(81)*.

[14] Please see: https://www.gem-measures.org/public/ConstructDetail.aspx?cat=1&cid=1193&tab=1 (accessed 14 October 2016).

Two aspects of interventions affect fidelity *(81)* – structural and dynamic.

- *Structural aspects* – e.g. adherence to basic programme elements such as hiring high-quality staff or providing participants with the recommended service dosage and duration.
- *Dynamic aspects* – these relate to quality and content of the relationship between the implementer and the consumer.

There are also two primary components to implementation fidelity – initial and ongoing fidelity.

- *Initial fidelity* – reflects the implementer's ability to meet the initial requirements for implementing a new policy or intervention in a new site, e.g. compliance with all training requirements.
- *Ongoing fidelity* – reflects the implementer's ability to maintain the implementation and reporting standards of the intervention once a particular site is operational, e.g. the ability to consistently implement an intervention.

Assessment of the dynamic aspects of fidelity may require the development of unique fidelity criteria that relate to the components of policies and interventions being evaluated. These should be objective and measurable *(82, 83)*. Appendix 4 provides templates for the development of tools for the assessment of structural and dynamic fidelity.

3.3.3 What are the moderators of the implementation of the policy or intervention?

As already mentioned, the interplay between a policy or intervention and the context within which it is implemented is complex. Various moderating factors – moderators – can affect the fidelity with which a policy or intervention is implemented; the effect can be positive or negative. Moreover, these moderators interact with each other, and the effect of one moderator on fidelity might be influenced by another moderator.

Factors identified as potential moderators of effective programme implementation include: complexity of the intervention, facilitation strategies, quality of delivery, consumer characteristics and responsiveness *(81, 84, 85)* as well as individual practitioner characteristics *(86-88)*, organizational supports for innovation *(19, 96, 100)* and implementation support strategies *(64, 86, 87)*. Active and integrated approaches by those developing/supporting the implementation process *(15, 64)* and the broader context may also influence implementation *(89-91)*. Therefore, social systems, interorganizational linkages and historical/concurrent events should be taken into account when assessing programme implementation *(89)*.

3.3.4 Implementation strategies

Implementation strategies can be defined as methods to enhance the adoption, implementation and sustainability of a policy or intervention *(92, 93)*. For example, they can include methods for training implementers, intervention-specific toolkits, checklists and algorithms as well as formal practice protocols and guidelines.

It is crucial that implementation strategy-related efforts are assessed when evaluating implementation. For example, the training of healthcare workers may be an implementation support strategy when implementing a community-based intervention to control hypertension; in this case the evaluation protocol would assess the training provided (e.g. its frequency, duration, perceived quality), its effect on workers' knowledge and skills, and other contextual factors such as pre-existing skills.

Successful implementation strategies have been identified in a review on ways to improve health service delivery in LMICs *(94)*; a list of these can be downloaded from here: http://hdl.handle.net/10986/12335.

Frameworks are available to enable you to systematically determine the barriers and enablers of implementation. One such commonly used framework is the Theoretical Domains Framework. The framework assesses 14 broad domains including: 'knowledge', 'skills', 'social/professional roles', 'environmental contexts and resources' and 'social influences' *(95)*.

3.3.5 How effective is the policy or intervention?

Indicators used to assess the effectiveness of a policy or intervention are determined by the anticipated health outcome. For example, effectiveness of a diabetes prevention intervention is determined by assessing diabetes incidence in the population of interest, while the effectiveness of a new policy to encourage physical activity in schools may be determined by assessing the levels of high intensity exercise carried out by students. Given the huge variety of health outcomes assessed in NCD prevention and control, and given the objectives of this guide, it is beyond the scope of this guide to explore the wide range of tools and methods for the assessment of health outcomes.

Note that effectiveness is affected by implementation. Therefore, when assessing the effectiveness of a policy or intervention we are not assessing the intervention's absolute effectiveness – but are only assessing its effectiveness *as implemented*. As such, it is inadequate to conclude that a policy or intervention is effective *per se* without providing information about its implementation; the same policy or intervention could be implemented elsewhere with very different health outcomes. Also note that implementation outcomes differ from clinical treatment outcomes, and both should be assessed *(15, 95, 97)*.

Implementation outcomes have three important functions. First, they serve as indicators of the implementation success. Second, they are proximal indicators of implementation processes. And third, they are key intermediate outcomes *(86)* in relation to service system or clinical outcomes in treatment effectiveness and quality of care research.

3.3.6 How do you assess costs associated with implementation?

Economic evaluation within healthcare generally compares two or more intervention options in relation to their cost and consequences. Commonly used methods include cost effectiveness, cost-utility and cost-benefit analysis.

Assessing the economics of an implementation strategy poses slightly different questions. An implementation strategy generally comes with additional costs. Therefore, the key economic question is whether the relative costs associated with the implementation strategy lead to a justifiable level of enhanced outcome as compared to usual/routine methods *(98)*. If enhanced implementation can be shown to lead to improved service delivery and also result in improved client outcomes, then these may be more cost effective than usual care. Such information is crucial for policy- and decision-makers, managers and service providers.

The total costs of the intervention are estimated as a ratio of the outcome. This has been described using the following ratio *(98)*:

$$\text{Implementation cost effectiveness ratio} = \frac{\text{Cost}_{\text{Implementation strategy}} - \text{Cost}_{\text{Usual strategy}}}{\text{Outcome}_{\text{Implementation strategy}} - \text{Outcome}_{\text{Usual strategy}}}$$

'Cost' may include:

- *direct labour costs* – costs associated with consumer- or implementer- contact (e.g. the time cost of having a clinician coach a consumer through a new health app or deliver a training programme to service delivery staff);
- *indirect labour costs* – additional costs associated with the consumers and implementers which do not require direct contact (e.g. developing resources or planning for the intervention);
- *non-labour costs* – additional overheads and resource costs associated with the intervention (e.g. building space, printing of resources, etc.).

'Outcome' may include:

- *consumer-level health outcomes*;
- *implementer-level outcomes* – associated with the intervention (e.g. enhanced communication, collaboration and/or service delivery).

Additional benefits may be seen in the timeliness of care.

Systematic implementation incurs costs above that of the intervention itself, with the bulk of this cost currently being borne by implementers (e.g. provider organizations). However, economic evaluation is relatively new to the field of implementation and there is a paucity of literature on the topic. The research base around economic evaluation of implementation therefore needs to be developed. If studies reveal added benefits of a particular implementation strategy above usual practice, then policy- and decision-makers will need to think about getting additional resources to successfully implement the strategy *(98)*.

3.3.7 How do you use data for quality assurance and improvement?

Collecting and utilizing data:

- guides quality assurance;
- provides information on the implementation and effectiveness of a policy or programme as implemented;
- builds on the evidence available to other implementers.

The following need to be in place to effectively collect, utilize, and share data:

- an adequate decision support data system;
- adequate capacity among programme implementers to use, interpret and translate data appropriately.

Decision support data systems are sources of information used to help make good decisions internal to an organization. They are an important part of continuous quality improvement for policies and interventions. When setting up a decision support data system it is important to be clear about the data to be collected, where the data will be sourced from, and who will be responsible for data collection. It is also important to establish how the data available will be used for quality assurance and improvement.

If the feedback loops (staff performance evaluations and decision support data systems) indicate that changes are needed, then the organization adjusts the integrated system to improve effectiveness and efficiency.

A template for guidance through some of these issues is provided in Appendix 5.

3.3.8 How to improve sustainability

In order to maximize the health impact of NCD research, effective policies and interventions must be well implemented and well sustained. Too often, effective policies or interventions suffer from a so called innovation–evaporation effect – where they are not sustained after the initial implementation period *(99)*.

The following are all factors for failure to sustain a policy or intervention *(98)*:

- not adapting intervention approaches to the local context
- resisting the introduction of new practices due to capacity constraints
- a lack of human resources
- intervention costs (and other economic factors)
- insufficient investment in implementation infrastructure (including in training, monitoring and evaluation systems)
- staff recruitment and staff turnover
- lack of political will

Important elements of successfully sustained interventions include:

- *Sustainability planning:*
  - It is crucial that sustainability and long-term continuation of the intervention is planned for and considered during all aspects of implementation.
  - Requires a well-defined scale-up strategy.
  - Includes developing strategies for integration into existing services.
- *Leadership and engagement:*
  - A key ingredient for the long term success of NCD policies and interventions is strong and sustained political leadership at the highest national and international levels.
  - Government sectors besides health all have to be part of the government response – e.g. finance, agriculture, justice, education, urban design, transport, foreign affairs and trade; civil society and the private sector also have a part to play *(101)*.
  - Implementers need to be able to understand and manage competing interests and stakeholders and to avoid the rise of conflicts of interest.
- *Communicate the ongoing impact of the change to stakeholders. This requires:*
  - an effective communication strategy;
  - strong advocacy (there should be tools/organization links for this);
  - establishment of monitoring and evaluation systems.
- *Formalize and standardize the change:*
  - Embed the change within organizational structures and processes (e.g. within policies).
  - Remove old ways of doing things.
- *Training / capacity building / linking with other organizations:*
  - This needs infrastructure to support implementation – e.g. training, delivery systems and technical resources.
- *Keep the intervention simple:*
  - In this way, key stakeholders and the target audience are more readily able to understand, engage and scale up the intervention *(98)*.

3.4 Scaling up a policy or intervention

An approach to working with country teams to scale-up strategies has been developed by ExpandNet[15] in collaboration with WHO.

This approach entails a nine step guide for developing a scaling-up strategy[16]:

1. Planning actions to increase the scalability of the innovation
2. Increasing the capacity of the user organization to implement scaling up
3. Assessing the environment and planning actions to increase the potential for scaling-up success
4. Increasing the capacity of the resource team to support scaling up
5. Making strategic choices to support vertical scaling up (institutionalization)
6. Making strategic choices to support horizontal scaling up (expansion/replication)
7. Determining the role of diversification
8. Planning actions to address spontaneous scaling up
9. Finalizing the scaling-up strategy and identifying next steps

Please refer to the guide for further information.

Some other useful sustainability planning tools can be found here:

- *Program Sustainability Assessment Tool* developed by the Centre for Public Health Systems Science at George Warren Brown School of Social Work: https://sustaintool.org/assess (accessed 14 October 2016).
- Ontario Health: *Implementing and sustaining changes*: http://www.hqontario.ca/Portals/0/documents/qi/qi-implementing-and-sustaining-changes-primer-en.pdf (accessed 14 October 2016).
- NHS: *Sustainability Model and Guide:* http://www.qualitasconsortium.com/index.cfm/programs-services/sustainability/sustainability-master-scoring-system/ (accessed 14 October 2016).
- McGrath KM, Bennett DM, Ben-Tovim DI, Boyages SC, Lyons NJ, O'Connell TJ. Implementing and sustaining transformational change in health care: lessons learnt about clinical process redesign. *Med J Aust.* 2008; 188 *(6)*:32.
- *Guidelines for reporting of health interventions using mobile phones: mobile health (mHealth) evidence reporting and assessment (mERA) checklist (102)*: http://www.bmj.com/content/352/bmj.i1174

[15] ExpandNet is a global network of representatives from international organizations, nongovernmental organizations, academic and research institutions, ministries of health and specific projects who seek to advance the science and practice of scaling up. More information can be found here: http://www.expandnet.net/home.htm (accessed 14 October 2016).

[16] Nine steps for developing a scaling-up strategy: http://www.expandnet.net/PDFs/ExpandNet-WHO%20Nine%20Step%20Guide%20published.pdf (accessed 14 October 2016).

Case study 6: Scaling up – Physical activity interventions, Brazil

Why this case study?	This illustrates the importance of engaging different sectors for the scale up of effective interventions. It also highlights challenges to scale up – such as changes in policies and funding mechanisms.
Title	Scaling up of physical activity interventions at the national level in Brazil: An effective solution to increase physical activity at the population level
Source	Washington University in St. Louis, St Louis, Missouri, United States of America
Health issue	Inadequate levels of physical activity and the need to address health disparities in the population of Brazil
Setting	Community (Brazil)
Target population	Brazil (adults and older adults from the general community)
Background	In Brazil, guidelines on physical activity suggest a minimum of 150 minutes of moderate or vigorous physical activity per week. However, the most recent national survey showed that nearly half the adult population did *not* reach this level of activity, with approximately 15% being completely inactive. The most commonly cited barriers to engaging in physical activity include lack of time and work/family responsibilities. Community-based interventions that make use of readily available resources (i.e. parks, trails, community centres), while providing professional guidance can be a promising strategy to increase physical activity at the population level *(103, 104)*. Project GUIA (Guide for Useful Interventions for Physical Activity in Brazil and Latin America)[17] *(105)* is a cross-national collaboration funded by the Prevention Research Centers programme (run by the Centers for Disease Control and Prevention (CDC)); it sets out to evaluate a programme taking place in Brazil for over a decade *(106)*.
Description of policy or intervention	The programme 'Academia da Cidade' or 'City Gym' started in Recife, Pernambuco in the north-east of Brazil, and was institutionalized in 2002. It is carried out at a number of points of intervention or so called polos – new spaces or re-engineered and beautified public spaces. Physical and cultural activities are provided by professional instructors and include: dancing, aerobics, strength training, flexibility and other health enhancing activities.
What took place?	In 2008, Project GUIA evaluated the Academia da Cidade programme using a combination of qualitative and quantitative methods including a phone survey, systematic direct observation, historical evaluation, logic models and qualitative interviews of coordinators, staff and users *(107-111)*. Results from the evaluation showed that the programme was effective in increasing and maintaining physical activity levels of the population and helped meet the guidelines for physical activity. The evaluation also assessed reach, showing that women, older adults, and lower income people were the segments of the population that benefited the most from the programme *(112)*.
What have we learnt?	Two significant events took place after results from the evaluation were shared with Project GUIA stakeholders: 1. In early 2011, the government of the state of Pernambuco created the Academias das Cidades de Pernambuco (ACP), a programme that aimed to expand the basic offering of Academia da Cidade *(113)*. 2. Later in 2011, the ministry of health created the Academia da Saude (AS), a national programme with added nutritional and social development components *(113)*. Changes in the supportive policies and in the funding mechanisms have represented challenges for implementation at a large scale and for sustainability. The experience and lessons learned in Brazil show the challenge of scaling up physical activity interventions and the need to consider long-term political and financial support *(113)*.

[17] For more information about Project GUIA, visit: http://www.projectguia.org/ (accessed 14 October 2016).

4
Conclusions

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4. Conclusions

Implementation research involves the scientific study of the processes used to implement policies and interventions and the contextual factors that affect these processes.

Implementation research can help identify the most efficient and cost-effective methods of implementation, thereby helping to bridge the evidence-into-implementation (action) gap and improving health outcomes.

Implementation research should be embedded in all stages involving the selection, adaptation and evaluation of policies or interventions for the prevention and control of NCDs. It is also important for the knowledge created to be shared among policy-makers, implementers and researchers through cross-country and cross-sectoral platforms and collaborations.

Appendix 1. The PICO Framework for developing objectives and guiding knowledge synthesis

The PICO headings will help you to breakdown your objectives and it will assist in devising the question that will guide your knowledge synthesis. PICO is not a rigid framework and there may be questions that do not need to cover all four aspects of PICO.

Define your objective: Describe your objective in as few words as possible
e.g. To find a policy or intervention to reduce the burden of hypertension in China

Population: Define in detail the population that you are interested in
e.g. For Chinese urban populations

Intervention: Define the type of intervention that you are interested in
e.g. economic incentive measures such as increasing taxes of unhealthy food

Comparison: What comparison group are you using to compare the outcomes from the intervention against?
e.g. Controls (i.e. that receive no intervention)

Outcome: What outcome measure(s) are you interested in?
e.g. Reduction in the consumption of processed foods

Refine your objective: Now rewrite your objective
e.g. To find an effective policy for the reduction of consumption of salt from processed foods in urban populations in China

Using the refined objective above to guide your knowledge synthesis should produce a manageable amount of focused evidence.

The selection of the policy or intervention should be based on the results of a comprehensive situation analysis and/or conducted by expert advisors. Otherwise you may want to broaden your objective to identifying *any* policies or interventions (e.g. *any* policies or interventions for the prevention of hypertension in China). Similarly, if you are not satisfied with the quality and/or amount of evidence you identify, you may wish to broaden your search by using a less specific population (e.g. Chinese groups as a whole, or even other countries in the region).

Appendix 2. Example of a matrix for the synthesis of relevant evidence

Below is a sample matrix that you may wish to use to summarize findings from the knowledge synthesis activities and to inform the selection of an evidence-based practice or intervention. You can adapt this matrix by modifying some of the existing columns or by adding new columns so that the matrix is customized to address the objectives you set out for the knowledge synthesis using the PICO framework.

Note: The sample matrix below uses a fictitious study for demonstration purposes only.

PICO: *Synthesis of evidence for the effectiveness of hypertension prevention programmes in primary healthcare centres in urban centres in China*

Study reference	**Outcomes**	**Measures**	**Effect**: Post intervention results					**Follow up**	**Quality of evidence**
Design	Outcome reported in results	List tools	**Intervention**	**Control**	**Relative effect** (95% CI)	**Absolute effect**	***P* value**	Longest point of follow up (i.e. 6 months; 1 year)	Indicate on a scale from one to five*
No. of participants									
First Author et al 2015 *Journal* 1(1):1-10	Incidence of hypertension	Clinical assessment by primary healthcare centre nurse	8.4%	11.0%	0.76 (0.7–0.81)	2.6%	0.035	1 year follow up	4
Cluster Randomized Control Trial	Sodium consumption	Urine biomarkers from samples collected by participants over 24 hours	180 mEq/L/day	200 mEq/L/day	n/a	20 mEq/L/day	0.072	1 year follow up	
1007	Physical activity	Time use diary	90 min/week	70 min/week	n/a	20 min/week	0.041	1 year follow up	

**You will have to be clear about how you assess and rank quality of evidence.*

Appendix 3. Assessing the social validity of a policy or intervention

Below is a proposed structure:

A. Social significance of goals

These questions should seek to understand whether potential consumers feel that the goals of the policy or intervention are important to them and/or their community.

As far as possible, it is important to ask questions that are not leading.

Questions relating to an intervention aiming to reduce salt consumption to prevent hypertension could be:

1. *What are some of the main health problems you think are common in this community?*
2. *Which of these problems do you think are important?*
3. *Have you heard of hypertension before? If so, what do you know?*
4. *If someone has hypertension, do they need to do anything about it?*

B. Socially acceptable procedures

These questions should seek to understand whether potential consumers feel that the procedures used in an intervention are acceptable.

Questions relating to community health workers providing hypertension education could be:

1. *How do you feel about seeking health advice from your community health worker?*
2. *How good or bad are community workers as a source of knowledge about your health?*
3. *How do you feel about information sessions organized and presented by your local community health worker?*

C. Social importance of effects

These questions should seek to understand whether consumers feel that an intervention or policy is achieving its intended outcomes and whether these are of any importance. Accordingly, these questions can only be asked after the policy or intervention has already been implemented.

Following on from the example above – i.e. a community health worker led intervention for the reduction of salt consumption to prevent and control hypertension – some questions could be:

1. *What did you think of the health information sessions?*
2. *Have you or your family acted upon the information received?*
3. *Have you noticed a difference in how you feel? Have you spoken to your relatives and friends about it?*
4. *Now that you have attended the sessions, would you recommend them to others in your community?*

Appendix 4. Assessing fidelity

The table below provides an example of the type of indicators and data that you may consider collecting to assess structural and dynamic fidelity of implementation. The table also provides suggestions for when data should be collected and which tools may be used.

Before collecting this data, it is important to clearly describe the ideal values for each indicator. The closer the data you collect is to the ideal value, the higher the level of fidelity. Take, for example, the first indicator, 'Organizational structure'. If you were aiming to deliver a nutritional education programme through maternal and child health centres, then your ideal values for the organizational structure may be 'A maternal and child health centre that is (i) well established in the community – e.g. has been in existence for at least five years and has three permanent staff; (ii) receives ongoing funding and (iii) delivers health promotion programmes in addition to a core maternal and child health programme. The definition of the ideal values should, as far as possible, be guided by evidence (e.g. there may be evidence for the ideal organizational context within which to deliver a nutritional programme). It may not always be feasible to engage the ideal implementers, however collecting data about these values prior to beginning delivery of an intervention will provide invaluable information for the analysis of fidelity, effectiveness and moderators of effectiveness.

STRUCTURAL FIDELITY

INDICATORS	TIMING	TOOL
Implementer level – Descriptive data		
Organizational structure of implementer (e.g. school, hospital, community organization, etc.)	Baseline	Implementer profile form
Primary funding source of implementer	Baseline	Implementer profile form
Usual health focus of implementer	Baseline	Implementer profile form
Implementer level – Demographic characteristics of staff		
Gender	Baseline	Implementer staff demographics form
Age	Baseline	Implementer staff demographics form
Date of hire	Baseline	Implementer staff demographics form
Date of certification or completion of model-specific training	Baseline	Implementer staff demographics form
Role	Baseline	Implementer staff demographics form
Education	Baseline	Implementer staff demographics form
Prior experience in implementing similar policies or interventions	Baseline	Implementer staff demographics form

Termination date	Monthly (as needed)	Implementer – staff demographics form
Implementer level – Intervention/policy delivery data		
Implementer delivery load derived from: - e.g. number of individuals who receive an intervention from a staff at a community based organization - e.g. employment time fraction of staff at a community based organization	Monthly (as needed)	Intervention session forms
Training sessions dosage – derived from: - training sessions completed - duration of training sessions completed	Monthly (as needed)	Training records
Consumer level – Intervention/policy delivery data		
Dosage – derived from: - intervention sessions completed - duration of intervention sessions	Monthly (as needed)	Intervention session forms
Duration of intervention – derived from: - date of commencement of intervention - date of completion of intervention	Monthly (as needed)	Intervention session forms

DYNAMIC FIDELITY
(Collected regularly – e.g. once every six weeks)

INDICATORS	RESPONSE
Process	
These questions should seek to understand whether the implementers followed the appropriate processes when implementing a policy or intervention. E.g. The community health worker told us about the intervention, what they would do and what we need to do in a way that I understood	– Strongly disagree – Disagree – Neither – Agree – Strongly Agree
Principles	
These questions should seek to understand whether the implementers followed the appropriate principles when implementing the policy or intervention E.g. The community health worker showed respect for my culture	– Strongly disagree – Disagree – Neither – Agree – Strongly Agree
Outcomes	
These questions should seek to understand whether the consumers feel that the policy or interventions are helping them achieve the intended outcome(s). E.g. The skills I have learnt from the intervention are helping me manage my hypertension	– Strongly disagree – Disagree – Neither – Agree – Strongly Agree

Appendix 5. Decision support data system

When planning for the implementation of a new policy or intervention it is crucial to be clear about what decision support data systems will be used. The question and table below will help you think through some of the important aspects of the decision support data system.

- Who will be responsible for collecting and analysing performance assessment data?
- Who will be responsible for supporting the quality of the data collection, analysis, and report preparation processes (support, guidance, oversight)?
- Who else plays a role? At which level (e.g. team, district, regional, state)?
- How important is data collection, analysis, and report preparation in achieving the desired outcomes for the selected innovation?

What are the right next steps for activating the decision support data system?

Activities	Time frame	Person(s) responsible	Resources needed

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