



# Embedded research: A 'how to' guide on health service development and implementation research

At COMDIS, we believe that operational research is best prioritised, designed, conducted and replicated when it is embedded within ministries of health and national programmes. We identify national and local priorities before designing any research intervention. We call this our 'embedded research approach' and there are 4 stages to this:

**Stage 1:** In line with ministry of health priorities, develop a service delivery package, including evidence-based guides and tools, designed to be implemented at scale if shown to be effective.

**Stage 2:** Pre-test and pilot and refine the service delivery package, as well as research tools, in partnership with local NGOs and ministries.

**Stage 3:** Implement the service delivery package with evaluation, preferably as a controlled trial of the effectiveness of the package.

**Stage 4:** Scale up successful service delivery packages with support from ministries and NGOs. This involves getting the evidence from using the service delivery package into national and international policy and practice.

Our embedded approach develops research questions from the perspective of the users and decision makers and then conducts the research and evaluation process at their sites. This approach typically includes developing or redesigning necessary guidelines and tools.

This multi-stage approach to research and development is supported by strong research uptake activities and communication tools. These help to maximise the impact our research findings have on policy and practice, nationally and internationally. This is because:

- the research addresses the policies and priorities of the ministry of health and other stakeholders, and the results will therefore be of interest to national decision-makers;
- national decision-makers are involved in the development of the research, delivery strategies and procedures to be tested, enabling dissemination, uptake and scale-up;
- the research contributes knowledge and practical tools that can be easily implemented and assist the development of the health service;

- the embedded operational research develops effective and feasible health service delivery strategies, relevant to both the local setting and other low- and middle-income countries.

This ‘how to’ guide describes our embedded approach to health service development and operations research. By sharing our methods and experiences, we hope that others will be able to replicate our approach in their research activities.

## **Stage 1: Design and develop the service delivery package**

The intervention and its associated guidelines and tools should be designed according to the best evidence available and in line with the local context.

The intervention design starts with a review of international and national policies, health systems, practice and research literature. A programme review is similar to a ‘situation analysis’ or a ‘health needs assessment’. Where information is lacking, e.g. on health behaviours, exploratory research may be carried out to inform and refine the intervention. Exploratory research can be done alongside the development.

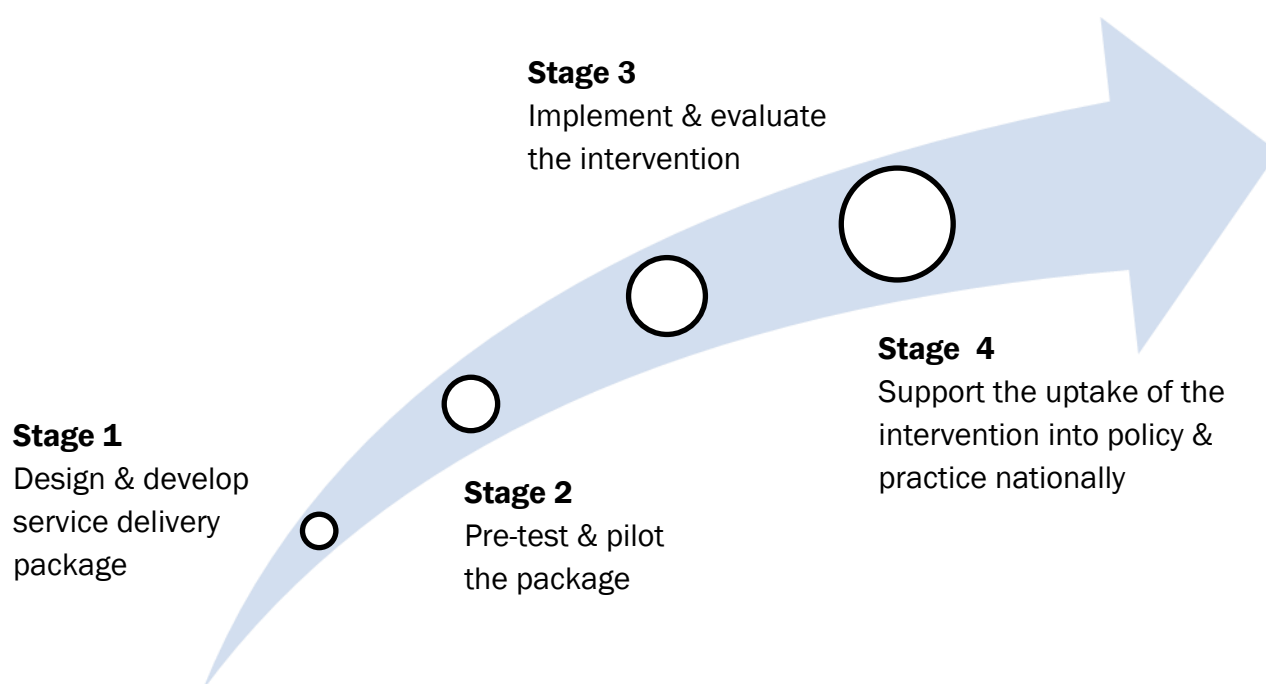


Figure 1. The 4 stages of embedded research and development<sup>1</sup>.

The intervention should be designed to be effective and feasible within the country health service context. The package of care that is designed should be evidence-based and take into account the local constraints, such as the availability of staff, resources and equipment. The package should include concise and practical guides, and tools for clinicians and educators. Tools can include treatment cards, registers and training modules for health workers. Together these form the 'package of care'. The details of the package should be compatible with local policies and help to deliver them.

Indeed, the package may be used as a vehicle to introduce research-informed policies into practice and at scale, e.g. new diagnostic procedures, drug regimens, education and treatment support.

### **Guides, tools and job aids**

The national programme may already have guidelines providing broad policy details, drug regimens, roles and responsibilities. These are necessary but not sufficient.

In our experience, user-friendly operational guides are needed to meet the needs of managers. Case management desk guides are needed for doctors, nurses and other health workers for use during patient consultations. Guides should reflect each step of the care process, from case identification, diagnosis and patient education to follow-up treatment. The guide and tools may be used by public, NGO and private health care providers.



### **Evaluating the best health service delivery strategies in malaria control**

Intervention strategies may be preventive and curative. In malaria control, including bed net promotion and treatments, the efficacy of the interventions is assessed from the trials and systematic literature reviews. In operational research we evaluate which are the best delivery strategies; how best to achieve high coverage with quality, e.g. coverage of intermittent preventive treatment in pregnancy within antenatal care; provision of bed nets through antenatal care, vouchers and social marketing; and diagnosis and treatment by community-based and facility-based health workers with rapid diagnostic tests and drugs (artemisinin-based combination therapy).

These health service delivery strategies will include activities addressing district health system constraints, such as ordering supplies, guides, training, modules and supervision tools.

COMDIS has developed desk guides for non-communicable diseases (NCDs), tuberculosis, sexually transmitted infections and malaria. For community health workers, simple and concise case management and health education tools (often called job aids) may be required.

### **Exploratory studies and literature reviews**

Exploratory work is often required when designing an intervention. Qualitative and quantitative studies can be reviewed and/or undertaken to better understand the beliefs and practices of clients and providers relating to the disease and country context. This will help to ensure that the guides, tools and case studies used in training reflect beliefs, practices and systems that are widespread throughout the country.

Exploratory studies can include a literature review of the best interventions for the disease, programme reports, programme guidelines, World Health Organization (WHO) and other international agency guidelines and documents. Ideally, the source and type of evidence should be recorded, e.g. systematic reviews and original research papers.

### **Adapt the evidence-based intervention**

Initially the package is 'pre-edited' by a health professional(s) with experience of the country, the specific disease and the service delivery context. Following this, a technical working group is formed, consisting of around 6 people so they can easily work around a table.

Technical working group members are usually practitioners familiar with the content and setting of the package of care. They should understand the public health approach that is being developed and be on board with simplifying procedures so they are feasible when scaled-up.



### **Guides and tools to manage NCDs in primary care**

Based on WHO guidance and on the best available evidence, COMDIS and our partners in China, Pakistan and Eswatini have developed [desk guides and implementation tools](#) for primary care patients with hypertension, diabetes, cardiovascular disease, asthma, chronic obstructive pulmonary disease (COPD), epilepsy and depression. These include case management and lifestyle change desk guides, training modules, registers, patient cards and adaptation guidelines; and [trials, costing and process evaluation articles, and briefs](#) (discussed on p8).

Good communication will be essential. The technical working group should meet weekly or attend a 2-3 day workshop. The group should review and refine the pre-edited materials, section by section. During the meetings or workshop, any particular issues should be discussed and changes agreed. The group facilitator should note down in detail what requires further editing. The types of changes and discussions can include:

- using local terminology suitable for health managers and facility staff;
- editing treatment regimens according to national guidelines;
- adding or amending treatment record cards and registers; or
- including health education, lifestyle and adherence messages for specific diseases, as well as adherence support strategies, e.g. by a family member/volunteer, mobile phone reminders or follow-up care in the health centre.

Training and instructions for health staff on how to use the desk guide, job aids, tools and other materials should be built into the research intervention during any planning process.

## **Stage 2: Pre-test and pilot the package**

Pre-testing involves asking the users about the guides and tools. Piloting involves implementing the intervention at 1 or more sites and testing its feasibility and acceptability.

### **Pre-testing the tools**

Pre-testing involves asking the views of people who are going to use the tools to assess whether they are acceptable and valid. Commonly this is done in a focus group with target users, e.g. health workers.

Once the technical working group is satisfied that the materials do what they are intended to do (e.g. a picture conveys the appropriate message, or a role-play exercise teaches a specific skill) then the entire package can be piloted.

### **Piloting**

Piloting involves trying out the service delivery package on a small scale so any necessary revisions or refinements can be made before extending it to other areas. Piloting may be in an accessible district, selecting 2 or more health facilities or villages as 'early intervention sites'.

A pilot course can be run with a group of health workers. The facilitators take turns running the sessions and annotating the guides and module content where amendments or refinements are needed.

During the pilot, health workers record key patient data (e.g. using treatment cards and registers). The percentage ‘drop-off’ at each stage of the process is analysed to see where problems may be occurring.

The intervention is then implemented and monitored for some months in the chosen ‘early intervention sites’. It is important to run the new intervention under routine conditions to test feasibility of the delivery strategy, and to assess the research procedures and enrolment rates before full implementation.

### **Avoiding the ‘pilot project trap’**

Unfortunately, ‘piloting’ has a bad name because it has often been done poorly, resulting in a ‘pilot project trap’ where projects do not get beyond the pilot stage – because the intervention has not been designed to be sustainable and replicable. For example, the pilot may achieve good results while it is well-resourced by a donor, but is not sustained when donor funding ends. The required level of resources, such as project team time during piloting, may not be available when the intervention is scaled-up.



### **Developing packages of care for drug-sensitive and drug-resistant TB**

In Pakistan and China we have researched, developed, piloted, evaluated, and scaled-up strategies and packages of care for drug-sensitive and drug-resistant TB, including how to provide patient support.

We conducted qualitative research, a randomised controlled trial<sup>2</sup> and a costing study of TB directly observed treatment (DOT). Implementing the TB public health package, known as ‘DOTS’, improved treatment outcomes. However, the DOT component showed no statistical difference in the trial, whether by health workers, family members or self-administered treatment. This trial contributed to a change in WHO StopTB policy from DOT, to a focus on patient support and supervision for most types of TB.

We developed [case management desk guides, training modules and tools](#), which were used to scale-up TB care across Pakistan with much improved successful treatment rates. Similarly, in China we developed and evaluated a context-adapted package of TB care, which was scaled-up across two provinces and further distributed by the national TB programme<sup>3</sup>. Subsequently, we developed a care package for multi-drug resistant (MDR) TB, which has been scaled-up across Pakistan, and conducted research on how best to deliver MDR-TB care in China<sup>4</sup>.

It is vital, therefore, that interventions are designed from the start to be feasible, sustainable and replicable to other areas. The pilot is an opportunity to refine the service delivery package, ensuring the procedures, guides and tools fit with the realistic level of human, material and financial resources that will be available during scale-up.

## Stage 3: Implement and evaluate the intervention

The implementation of new intervention strategies is an opportunity for operational research, investigating the best interventions, delivery strategies and related activities.

The simplest approach is to compare the results, such as TB treatment outcomes, before and after implementing the new approach. However, there may be other confounding factors explaining why the indicators improve. So we should compare sites where the existing intervention is implemented with similar control sites where the intervention is not in place. If the results are significantly better in the intervention sites compared with the control sites, you can be confident the new intervention or delivery strategy is more effective.

In embedded research we can evaluate as part of a phased implementation programme. It is best for programmes not to attempt to



### **Implementing an intervention to reduce antibiotic prescribing**

In China we carried out a cluster RCT, stratified by county, comparing the effectiveness of an intervention programme to reduce antibiotic prescribing in children with upper respiratory tract infections (URTIs) with usual care in 25 township hospitals in rural Guangxi province<sup>5</sup>.

Our intervention involved a comprehensive educational programme for doctors, consisting of an interactive training session to improve their knowledge of appropriate use of antibiotics and monthly peer-review meetings to provide feedback. Leaflets and an educational video played on a loop in waiting areas were used to educate caregivers. This led to a 48% reduction in children receiving antibiotics for URTIs.

A follow-up study 12 months post trial showed persisting effectiveness in terms of reduced antibiotic prescription rate in the intervention versus control facilities.

implement everywhere at once. This may seem obvious, but often programmes instruct sites to implement all at the same time, and when they are not ready. Effective implementation requires careful thought to ensure the necessary local infrastructure and procedures are in place. The intervention can then be implemented step-by-step, systematically scaling-up to all sites.

Phased implementation provides an opportunity to develop a controlled trial, where the early implementation sites can be compared with sites not yet delivering the intervention. In preparation for a trial, suitable and similar sites are listed and then can be allocated to intervention and control sites. If feasible, it is best to list the sites and then randomise.

Randomised controlled trials (RCTs) are a better test. Randomisation avoids both known and unknown causes of bias. RCTs are more likely to be published in high-quality journals. Conducting RCTs has become possible due to the greater awareness of the need for rigorous evaluation and evidence for policy-making. It is best to randomise by individuals. However, if this is not feasible and the intervention is across the facility or village, then randomisation can be from a list of facility or village 'clusters'.

In RCTs and other controlled evaluations it is important to implement standardised case identification and recording on treatment cards and/or



### **Using RCTs, cost-effectiveness analyses and process evaluations to refine NCD care**

At COMDIS we have used RCTS, cost-effectiveness analyses and process evaluations to determine the effectiveness of our interventions.

In rural China we implemented a pragmatic cluster RCT that aimed to assess whether a standard intervention package of CVD care was being delivered effectively, and if it was associated with improved lifestyle and blood pressure, glucose and other biomedical indicators<sup>6</sup>. We found implementation of the package by family doctors was feasible and improved prescribing and some lifestyle changes.

In Pakistan we carried out a process evaluation to understand how our package of integrated care for CVD (especially hypertension and diabetes) at primary level health facilities was implemented and experienced by the care providers and patients, and to inform modifications prior to province-wide scale-up<sup>7</sup>. We found integrated CVD care was effective and feasible, both for providers and patients, and potentially scalable at public and private primary care facilities under routine conditions in Pakistan.



registers in both the intervention and control sites. Ensure the availability of necessary lab tests and drugs for all patients.

The control sites continue with the existing 'usual care' and the intervention sites implement a revised care package. The test can be of the care package as a whole, or of components such as lifestyle behaviour change and tobacco cessation.

### **Costing and economic studies**

Costing studies are often conducted alongside clinical or operational studies. At a minimum, costing will include the incremental cost to the health service to add the new service or intervention.

Generally, we propose an incremental cost-effective analysis. This form of economic evaluation describes the likely costs to the provider to replicate the new service should it be found effective in the trial. If the intervention is more effective and more costly than usual care, it is possible to look at the incremental cost per unit of successful care (e.g. cost per treated patient).

If alternative interventions are found to be equally effective, then it is possible to specify the savings that could occur by switching. Depending on the need and the resources, the study may also estimate the 'out of pocket' and opportunity costs related to patient hospital days or clinic visits. The study can also compare costs of hospitalisation with community-based care. Some examples of costing study questions could be: What is the cost of scaling up prevention or treatment approaches and what implications does this have for national or local health budgets? What is the incremental and/or overall cost-effectiveness of the 2 approaches, looking at the costs and treatment success rates? What are the incremental costs to the providers, over and above usual care, of the service delivery strategy?

### **Value for money**

Developing services using this embedded approach ensures that health service expenditure by governments and donors is effective and represents value for money. The approach should ensure that services that can be integrated and decentralised into primary and community care are done well. This approach also helps define the tasks that can be safely shifted from doctor to nurse, and nurse to auxiliary and community health worker.

### **Process evaluation studies**

Process evaluation studies may be conducted to understand the 'why' of results, e.g. why the intervention was (or was not) more effective than the usual or alternative care tested in the pilot.

Process evaluations explore what happened during the pilot. The clinicians and clients at the sites are observed and interviewed to find out what parts of the guides and tools worked well or not. If not, then why not and how could the materials be improved?

The study may assess patient, family and community factors, such as health service access and quality of care. It may also explore time and money issues that influence the patient's ability to attend, be diagnosed, treated and adhere to follow-up appointments. This may involve semi-structured interviews with various categories of patients and care providers, and focus groups with family, community members, providers and managers as appropriate.

## Stage 4: Supporting change in policy and practice

The aim of the embedded approach is to achieve change in policy and practice. This is called 'research uptake' (RU) and should be planned into every stage of the research process, not just the end.

Research uptake is at the heart of our activities at COMDIS. Our embedded approach to RU has given us a reputation for achieving evidence-based policy change, as well as achieving changes in practice through adoption, adaptation and scale-up of our recommendations.



### 3 aims of research uptake

1. Proactively work with ministries of health and other national agencies in our partner countries to ensure ownership and uptake of our embedded research approach and findings
2. Engage with international agencies to increase uptake of our research and to share our embedded approach
3. Increase access to our research findings through networks of policy makers, health practitioners and communities of practice.

For example, our TB/MDR-TB guides and tools have been scaled-up across the whole of Pakistan. Similarly the NCD work, embedded within the department of health/NCD programme in Punjab Province, has led to the NCD guides and tools being scaled-up to all public hospitals, and planned for all the health centres, of Punjab Province, Pakistan.

Through all stages of the embedded approach, the aim is to develop services that align with national policies and are feasible and effective. Interventions are designed to integrate within health systems so they can be sustained and replicated, both in-country and internationally. National scale-up of the interventions often includes working with the national programme, e.g. the national TB programmes.

International uptake and dissemination is through communications with stakeholders (national and international); meetings and presentations; [research and policy briefs, and peer-reviewed publications](#).

### **5 takeaway points**

The embedded approach links research to health service development and embeds both within ministry of health programmes.

1. There are 4 stages of the embedded approach: develop; pilot; implement/evaluate; policy and practice change.
2. Alternative intervention and health service delivery strategies are designed and developed through a technical working group process.
3. The pre-test and pilot helps refine the intervention and any associated guides, tools and research procedures, and refinements are made.
4. Trials test intervention outcomes, while process evaluation studies help explain the trial results, and further refinements are made prior to scale up.
5. Costing studies inform programme managers of the incremental cost of expanding the intervention.

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## Further reading

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