COMDIS-HSD

‘HOW TO’ GUIDE ON RESEARCH & DEVELOPMENT:
THE EMBEDDED APPROACH

CONTENTS

INTRODUCTION

COMDIS-HSD aims to develop feasible and effective health service delivery strategies for underserved populations in low and middle income countries.

The purpose of this guide is to describe COMDIS-HSD's embedded approach to health research and service development, to enable it to be replicated by COMDIS-HSD partners, and other researchers.

PRINCIPLES OF THE COMDIS-HSD EMBEDDED APPROACH

From the earliest stages of research we must ensure we address the priorities and needs of stakeholders such as the Ministry of Health (MoH).

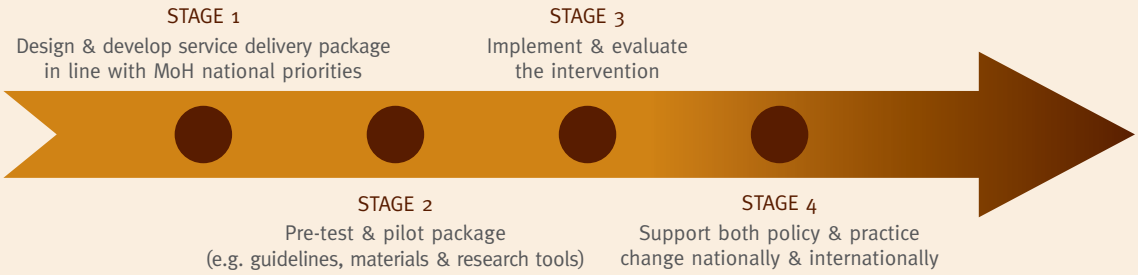
Operational research is best prioritised, designed, conducted and replicated when it is embedded within MoH and national programmes. COMDIS-HSD partners design, conduct and disseminate research projects embedded within the MoH services in their country.

Our approach aims to develop research questions from the perspective of the users and decision-makers, and then conduct research, service development and evaluation in their sites. We find this approach more successful than conducting research separately and then later trying to disseminate results to national decision-makers. This multi-stage research development approach, supported by a strong communications strategy, ensures the research will be scaled-up in country and beyond. We commonly link research together with the development of guidelines and tools. These include details of the intervention, which are developed, evaluated and revised as part of the research. This approach to research and development, supported by communications activity, maximizes uptake into policy and practice nationally and internationally in the following ways:

- The research addresses the priorities of the MoH and other stakeholders, therefore the results will be of interest to national decision-makers.
- National decision-makers are involved in the development of research, delivery strategies and procedures to be tested, enabling dissemination and scale-up.
- Research leads to the development of practical tools that can be easily implemented and assist the development of the health service.
- This embedded operational research aims to develop effective and feasible service delivery strategies, relevant to both the local setting and other low- and middle-income countries.

The figure below illustrates the general approach COMDIS-HSD takes to research and development after national and local priorities have been identified.

FIGURE 1: THE FOUR STAGES OF EMBEDDED RESEARCH & DEVELOPMENT



The approach is explained, with the example of COMDIS TB DOT(S) work in Pakistan and China, in a one-page editorial: **Walley J, Khan M A, Shah S K, Witter S and Wei X. How to get research into practice: first get practice into research. Bulletin of the World Health Organization. 2007.**

STAGE 1: DESIGN & DEVELOP SERVICE DELIVERY PACKAGE

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

Practical guides and tools aim to help deliver quality healthcare that is realistic within local settings. Desk guides for clinicians and educators are concise, practical handbooks. Tools include treatment cards, registers and training modules for health workers. Together these may be termed a 'package of care'. This package is evidence-based and takes into account the local context such as time, resources, and drug and equipment availability. The package may be used as a vehicle to introduce research informed policies into practice at scale, for example new diagnostic procedures, drug regimens, education, treatment support and other innovations.

The national programme may already have guidelines providing broad policy, drug regimens, roles and responsibilities. These are necessary but not sufficient. A user-friendly case management desk guide is also required to meet the needs of doctors, nurses and paramedics to use during patient consultations. It may follow the identification, diagnosis, education and follow-up through each step of the care process. The guide and tools may be used by public, NGO and private providers. COMDIS, and then COMDIS-HSD have developed desk guides for TB, STIs, malaria, cardiovascular disease and diabetes. For community health workers, simple and concise case management and health education tools may be required, often called "job aides".

Review Literature and Exploratory Studies

Exploratory work is often required when designing an intervention. This can include a literature review of the disease, programme reports and programme guidelines. Sources of evidence that should be used to develop guidelines will include WHO and other international agency guidelines and documents. Ideally it is best to record the source and grade of evidence e.g. systematic reviews and original research papers. In addition, it is important to prepare an adaptation guide, which includes the options and evidence relevant to country adaptation.

See the editorial: Walley J, Graham K, Wei X, Kain K and Weston R. Getting research into practice: primary care management of noncommunicable diseases in low- and middle-income countries. *Bulletin of the World Health Organization. June 2012. www.who.int/bulletin/volumes/85/6/07-042531/en/index.html*

Qualitative and quantitative research should be reviewed and/or undertaken in order to better understand beliefs and practices of clients and providers relating to the disease and context. This will help to ensure that the package of care is adapted to take into account beliefs, practices and systems that are very widespread throughout the country.

Adapt the evidence-based intervention

The package of care (which may include desk guides, job aides, associated tools, training modules, supervision and monitoring guides) must be adapted to the country context, taking into account local literature and any exploratory research that has been conducted.

There are **2 stages** in the adaptation process:

1. Initially, the package is "pre-edited" by a **health professional(s)** experienced in the country, specific disease and service delivery context facilitated by a researcher.
2. A technical **working group** is formed. This should consist of around 6 people, so they can work around a table. Participants should be chosen from practitioners familiar with the content and setting. They should understand the public health approach requiring standardisation and simplification of procedures in order to be feasible when scaled-up. They should not assume, for example, that many lab tests and treatments used in tertiary hospitals can be feasible in primary care. Specialists can be asked to comment. A steering committee including senior health decision makers can then review and endorse use of the materials. Good communication will be essential. They should meet weekly or attend a 2-3 day workshop and should review and edit the pre-edited materials section by section. During the meetings or workshop, particular issues should be discussed, and changes agreed, while the facilitator (commonly from research-development NGO e.g. COMDIS-HSD partner) notes down what requires further editing.

See Wei X, Walley J D, Liang X, Liu F, Zhang X and Li R.Adapting a generic tuberculosis control operational guideline and scaling it up in China: a qualitative case study. *BMC public health. 2008 8:260.*

The types of adaptation include:

- Using local terminology suitable for health facility staff such as the health worker manager;
- Editing treatment regimens according to the national guidelines;
- Including treatment record cards and registers;
- Health education, life style and adherence messages for the specific disease;
- Adherence support strategies e.g. by family member/volunteer, mobile phone;
- Follow-up care in the health centre and at the diagnostic centre.

Training and instructions are provided for the individuals who are using the desk guide and job aides to ensure they are locally (and individually) relevant. This allows them to elicit understanding about local and individual beliefs and practices to be able to discuss them in a sensitive and appropriate way. The users of the tools should be able to distinguish between positive or negative beliefs and practices that are "good", "harmless" or "harmful". A belief or practice that has a negative effect on the disease or condition in question must be addressed in a sensitive and appropriate manner.

Pre-testing involves taking the tools and testing them with people who are going to be using them. Piloting involves implementing the intervention and study at a single or a few sites and testing the feasibility and acceptability of the intervention.

Pre-testing the tools

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

Once the working group is satisfied that the materials do what they are supposed to do (e.g. a picture conveys the message that it should be conveying or a role play exercise teaches the individual the communication skill it aims to teach them), then the entire package can be piloted.

Piloting

Piloting is trying things out on a small scale and revising the procedures accordingly before expanding to everywhere else. If the intervention is to be nation-wide then the piloting may be in one or two districts or health facility village areas. Piloting will involve implementing the entire intervention (including training, supervision, monitoring) for a specified period of time in the chosen "early intervention sites".

It is important to try out the new intervention under routine conditions to test feasibility of the delivery strategy, to assess the research procedures and enrolment rates before full implementation. During the pilot, the numbers and percentage for each stage of the process are recorded.

The package may be tested using one or more qualitative methods such as:

- Interviews
- Group discussions
- Observation of use
- Exit interviews

Studies assess the feasibility and acceptability of the intervention package from the perspective of the service providers and users. The intervention and study can then be adapted based on the findings of the pilot before rolling out to other investigating centres.

Unfortunately, "piloting" has a bad name because it has often been done badly, resulting in a "pilot project trap" where projects do not get beyond the pilot stage. The bad name is because the intervention has not been designed to be sustainable and replicable. The pilot project may achieve good results while well resourced by a donor, but is not sustained when donor funding ends. The level of resources such as project team time during piloting may not be available when scaled-up. Therefore, it is vital that interventions are designed from the start to be feasible, sustainable and replicable to other areas. The pilot project is an opportunity to refine procedures, guides and tools to fit with the realistic level of human, material and financial resources that will be available during scale-up.

Intervention and comparison sites

The implementation of new intervention strategies is an opportunity for operational (implementation) research, investigating the best delivery strategies and how best to implement. 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 reasons why the indicators improve. We should compare district sites where the existing intervention is implemented with similar control sites for comparison. If the results are significantly better in the intervention compared to the control sites, then you can be confident the new intervention/delivery strategy is better.

In embedded research we can evaluate as part of phased programme implementation. It is best for programmes not to attempt to implement everywhere at once. This may seem obvious, but often the programmes instruct sites to implement all at once and when they are not ready. Effective implementation requires much careful thought to ensure local procedures are ready. The intervention can then be implemented step-by-step, systematically scaling-up to all the sites. Phased implementation provides an opportunity to develop a controlled trial, where the early implementation phase sites can be compared with sites not yet delivering the intervention.

Suitable and similar sites are listed, and then can be allocated to intervention and control district/ sites. It is better, if feasible, to list suitable similar 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. They become possible where there is a high degree of trust between the programme and researchers, as with COMDIS-HSD. For example, our multi-drug resistant TB service delivery trial in Pakistan involves randomisation of individual patients. It is best to randomise by individuals. However, if this isn't feasible and the intervention is across the facility or village, then randomisation can be from a list of facility or village "clusters". In trials, list all sites with similar characteristics relevant to the intervention as a "sample frame", and random numbers are determined by a computer to decide which will be the intervention and which the control sites.

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 service. Generally we propose an incremental cost effective analysis (ICEA). This form of economic evaluation can describe the likely costs to the provider to replicate the 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. per treated patient. If alternative interventions are found 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 visits such as comparing more hospitalisation or more community-based care (as in our drug resistant TB trial). All costing will be closely linked to the methodology for assessing the effectiveness of the intervention in order to ensure that a coherent economic evaluation can be carried out.

Some examples of costing study questions may be:

- What is the cost of scaling up 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 two approaches, looking at the costs and treatment success rates?
- What are the incremental costs to the providers of the alternative service delivery approaches?

Explanatory studies

Explanatory qualitative studies are conducted to understand the "why" of results, for example why the intervention was (or was not) more effective than the alternative (usual care and/or other alternative strategy tested in the trial). The study may assess patient, family, and community factors such as health services access, quality, time and money that influence the patient's ability to attend, be diagnosed, treated and adhere to follow-up appointments. As with the pilot qualitative study, this may comprise 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: SUPPORT POLICY & PRACTICE CHANGE NATIONALLY & INTERNATIONALLY

The research uptake objective is to achieve change in policy and practice. In the embedded research and development approach this is addressed at each stage from the start. This is done by communicating regularly with the programme managers and service providers who are responsible for the service. The results of the research and use of the refined practical tools and required changes to services are discussed. The learning and products are disseminated both in the country and internationally.

This is the stage, very important in COMDIS-HSD, that moves research into policy and practice nationally and internationally. The adoption of research into policy and practice, that is national scale up of the intervention, often includes the national programme (initially with support from the researchers) to:

- Print the finalised materials for use in pre- and in service courses and on-going service delivery.
- Ensure drugs, cards, registers and lab materials are available in time for health workers to put into practice what they have learned.
- Roll out training, including teaching the skills to use materials through role-play exercises.
- Follow-up after training, including a trainer/supervisor visiting each participant soon after the course to observe and encourage them as they start to use the desk guide and tools. This maintains better quality practice, by observing and asking about the use of the materials in routine supervision.

International dissemination is through communications with stakeholders; directly in meetings and presentations; project brief mailouts; peer-reviewed publications and support to adaptation of guides and tools.

CONCLUSION

The approach links research to service development embedded within the ministry of health programmes. The stages may include to develop, pilot, implement and evaluate, and scale up. The development is of guides and tools required for scale-up nationally of the intervention. Alternative intervention and service delivery strategies can be compared in the evaluation. This may be by allocating similar sites to be intervention and controls, or better, if feasible, by a randomised controlled trial. Costing studies inform programme managers of the incremental cost of expanding the intervention. The pilot study helps refine the intervention procedures, guides and tools. Later, explanatory qualitative studies can help explain the trial results. The evaluation and implementation experience informs further revision of the guides and tools. These are used in national scale-up, and are disseminated internationally.

A longer and non illustrated version of this document is available on the COMDIS-HSD website:
http://comdis-hsd.dfid.gov.uk

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