Session 7.
Evaluating interventions – Process evaluation

Health Systems Research Course
Western China School of Public Health
7-11 December 2015
Four key steps in HSR

1. Identify research focus (problem/concern/opportunity) and question
2. Design study
3. Ensure quality and rigour
4. Apply ethical principles
Session objectives

By the end of the lecture you should be able to:

• Understand what a process evaluation is, including the type of questions it answers
• Define intervention implementation in terms of fidelity, dose, reach, recruitment and context and identify methods to assess these
• Identify how contexts may shape the implementation of interventions and propose methods for documenting and interpreting context in intervention trials
• Recognise the importance of evaluating impact beyond pre-specified outcomes and consider what unintended consequences may result from interventions
1. What is a process evaluation?
2. Rationale for conducting a process evaluation
3. Identify the core functions of a process evaluation
4. How to undertake a process evaluation
   a. Assessing intervention implementation
   b. Importance of context
   c. Evaluating unintended consequences
Programme evaluation


*Figure 1: Example Theory of Change framework and key*
1. What is a process evaluation?

- Explores the implementation, receipt and setting of an intervention
- Help in the interpretation of the outcome results
- What can a process evaluation do?
  - Examine the views of participants on the intervention
  - Study how the intervention is implemented
  - Distinguish between components of the intervention (HR, financing)
  - Investigate contextual factors that affect an intervention
  - Monitor dose to assess the reach of the intervention
  - Study the way effects vary in subgroups
  - Evaluate unintended consequences

2. Why do a process evaluation?

“Distinguish between interventions that are inherently faulty (failure of concept/programme theory) and interventions that are badly delivered” (Oakley et al. 2006)
A rigorous outcome evaluation conducted after 18 months of implementation finds no difference in the rate of institutional deliveries between intervention and comparison areas. Why might this be?
2. Why do a process evaluation?

• Explore why an intervention worked/failed:
  • Implementation failure?
    – Was the intervention implemented as intended?
  • Theory of Change failure?
    – Was the underlying theory wrong?
  • Failure due to a particular context?
    – Distance, “cultural beliefs”, barriers to access...
2. Why do a process evaluation?

The ingredients or components of Programme X may not be fully spelt out

Programme X as designed by the implementers (Protocol)

Programme X as implemented in practice
- And variation in practice

-An issue for understanding causal effects and drawing lessons across studies
-An issue for intervention replication

Complex means that what is implemented may differ from what was intended

Process evaluation can help define the intervention as implemented in practice and any deviation from original design (as well as understanding the reason for deviation)
Consideration of context
When interpreting results from an intervention:
- The situation in which the intervention takes place
- Context of evaluation activities

Unintended consequences
Many evaluations only focus on intended outcomes and impacts. Process evaluation also focuses on unintended consequences:
- Unintended consequences are changes brought about by the intervention that were not intended to happen
- Can be very positive or negative

2. Why undertake a process evaluation?
2. When to do a process evaluation

- **Design stage:** will the intervention be acceptable to stakeholders, is it feasible? – formative research

- **Implementation stage:** can inform improved design during implementation
  - Acceptability of the programme to different stakeholders
  - What works well/works less well
  - Did the intervention have any unintended consequences
  - Exposure to the intervention among different sub-groups

- **Scale-up/replication stage:**
  - Describe the intervention as it was actually delivered
  - What are the active ingredients?
3. Key functions of process evaluation

Context
Contextual factors that shape theories of how the intervention works
Contextual factors that affect (and may be affected by) implementation, intervention mechanisms and outcomes
Causal mechanisms present within the context which act to sustain the status quo, or potentiate effects

Implementation
Implementation process (How delivery is achieved; training, resources etc)
What is delivered
Fidelity
Dose
Adaptations
Reach

Mechanisms of impact
Participant responses to and interactions with the intervention
Mediators
Unexpected pathways and consequences

Outcomes

Graham F Moore et al, BMJ 2015;350:bmj.h1258
Data collection and analysis methods in process evaluation

Context
- Stakeholder interviews
- Quantitative testing of hypothesised moderators

Documentary analysis
- Stakeholder interviews
- Qualitative observation

Qualitative observation
- Routine monitoring data

Description of intervention and its causal assumptions
- Development of a model through: Consultations with intervention developers/implementers Discussion within wider evaluation

Implementation
- Stakeholder interviews
- Documentary analysis
- Structured observation
- Implementer self-report
- Routine monitoring data
- Implementer interviews
- Participant interviews

Mechanisms of impact
- Routine data
- Mediation analysis of quantitative mediators
- Interviews with participants and implementers

Outcomes

Fig 3 | Commonly used data collection and analysis methods for process evaluation

Graham F Moore et al. BMJ 2015;350:bmj.h1258
4. How to undertake a process evaluation
## Assessing implementation

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<tr>
<th>Implementation aspect</th>
<th>Definition</th>
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<tr>
<td>Fidelity (quality)</td>
<td>The extent to which the intervention was implemented as planned</td>
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<td>Dose delivered (completeness)</td>
<td>Amount or number of intended units of each intervention or component delivered or provided by interventionists</td>
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<td>Dose received (exposure)</td>
<td>Extent to which participants actively engage with, interact with, are receptive to and/or use materials or recommended resources. Can include ‘initial use’ and ‘continued use’</td>
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<td>Reach (participation rate)</td>
<td>Proportion of the intended priority audience that participates in the intervention; often measured by attendance; includes documentation of barriers to participation</td>
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<td>Recruitment</td>
<td>Procedures used to approach and attract participants at individual or organizational levels; includes maintenance of participant involvement in intervention</td>
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<td>Context</td>
<td>Aspects of the environment that may influence intervention implementation or study outcomes; includes contamination</td>
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Methods for capturing implementation

- Self-reports from those involved in delivering or receiving the intervention
  a) Self-reports may be elicited through pre-defined and piloted records or questionnaires
  b) For example for trainers or participants in an intervention to complete after giving or attending a training session
  c) They may be asked to record the amount of content actually delivered, the relative participation of different members of the group, and their impressions of the level of understanding for the various objectives of the training.
  d) Data collected might be quantitative, such as number of participants who attended, or qualitative, such as listing commitments made by participants during the training.

- Direct observations of the intervention in process
- Collect data through surveys, interviews and/or focus groups
Why evaluate context?

• So far – “does the intervention work work?”
  • the intervention implementation
  • its intended pathway of change
• By conceptualising an intervention as a transferrable ‘thing’ that would have the same effect somewhere else, we assume the same:
  • People
  • Structures
  • Resources
  • Cultures, etc.
• But intervention in practice is the product of the ideas, resources and people brought in and those already active in the local context
  • *Where* and *how* particular intervention ideas, resources and people might produce similar effects - realist evaluation
  • ‘*what works*’ but, ‘*for whom, under what circumstances, and why?’
• Analysing triangles of context-mechanisms-outcome.
• Context may also be considered not as an independent or separate variable but as how an intervention is situated – it is part of what the intervention becomes.
1. Select contextual factors
   a) Judgement of what is relevant contextual information to interpret the way an intervention is operating, is being received and its impacts.
   b) More and less structured ways this may be undertaken.

2. Structured methods
   a) Data can be collated and compared over time
   b) E.g. a series of open text boxes on specific topics anticipated to be relevant to the intervention may be completed intermittently either by field staff or on consultation with key informants.
ACT consortium intervention

3. **Unstructured methods**

a) Allow for unanticipated issues to be captured and investigated

b) Allow for the development of a ‘thick’ description of the situation.

c) Methods:
   - Ethnography
   - Participant observation
   - Informal interviewing - led by what appears important as it arises for the various actors involved.
   - In-depth interviews – create a ‘social commentary’ of the intervention, but timing of these will impact what is captured.
Why should un-intended consequences be evaluated?

When?
• Should try to anticipate unintended consequences during the development of the Theory of Change, and monitor these during the evaluation
• During process evaluation

How?
• Qualitative tools will yield information on unintended consequences
  – Use questions that are open and exploratory
  – Encouraging people to report unexpected results.
Methods to assess unintended consequences

1. **Key informant interviews**
   a) Ask experienced people to identify possible negative impacts, based on their experience with similar programs.
   b) Program critics can be especially useful.

2. **Negative programme theory**
   a) Identify ways in which program activities might produce negative impacts rather than their intended impacts.

3. **Risk assessment**
   a) Identify the potential negative impacts, their likelihood of occurring and how they might be avoided.

4. **Six Hats Thinking about unintended results:**
   a) Promote holistic and lateral thinking in decision-making and evaluation.
   b) Alone or in groups participants (project members, key decision-makers and stakeholders) wearing different conceptual “hats”.
   c) Information, emotions, negatives, positives, creativity, overview

5. **Unusual events reporting**
   a) Ensure unforeseen events, incidents or outcomes are recorded.

A process evaluation of user fees abolition for pregnant women and children under five years in two districts in Niger (West Africa)

Valéry Ridde*1,2 and Aissa Diarra3

• 2006 two health districts in 43 health centres in Niger
• Abolish user fee for specific services (drugs and ambulances)
• Process evaluation
Exercise

• Findings:
  – Population was well informed about the programme
  – Grants were sufficient to cover costs of the intervention
  – NGO had previously delivered food. Patients stock-piled drugs in case this was a short-lived intervention
  – Some health workers continued to charge patients because salaries were not covered by the intervention
  – Deterioration of doctor-patient relationship (doctors assumed patients just wanted free medication)
  – Nurses started charging for services that were previously free
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Acknowledgements

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