Studying implementation

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Today

- PROCESS EVALUATION
- THE PeriKIP PROJECT
PROCESS EVALUATION
What is process evaluation?

To understand the effects of interventions

- Allows for exploration of implementation and change processes and the factors associated with variations in effectiveness.
- Can examine the utility of theories underpinning intervention design and generate questions or hypotheses for future research.

Process evaluation is needed for us to move from “what works” to “what works where and why”.
Aims to understand why certain implementation strategies bring about improvement (while others don’t) – illuminates mechanisms of change

Provide an understanding of the determinants of success/failure

Provides understanding of the planned vs delivered vs ‘exposure’ etc

Can ensure in-depth understanding from smaller studies which can inform scale-up

Can assist in understanding outcome-heterogeneity of large-scale projects

Commonly requires mixed-methods
Process evaluation steps

- **Planning**: methodological expertise, appropriate interdisciplinary mix, degree of separation between teams and means of merging findings.
- **Design and conduct**: describe the intervention and causal assumptions, identify key uncertainties, select research questions and methods, balance data collection *all sites/selected sites*, timing of data collection.
- **Analysis**: descriptive quantitative information on fidelity, dose, and reach. More detailed modelling of variations between participants or sites.

*UK Medical Research Council, 2015; Moore et al., 2015*
Process evaluation steps cont.

- Describe the implementation strategy (theory)
- Clarify causal assumptions (logic model)
- Identify key uncertainties
- Identify and prioritise research questions
- Select a combination of research methods
MRC guidance for process evaluations

- Description of the intervention and its causal assumptions
- Mechanism of impact:
  - Participants' response to the intervention
  - Participants' interaction with the intervention
  - Mediators
  - Unexpected pathways and consequences

UK Medical Research Council, 2015; Moore et al., 2015
MRC guidance for process evaluations cont.

- Clearly defining the components of the intervention (implementation strategy)
  - Naming
  - Defining
  - Operationalizing (Actor, Action, Action targets, Temporality, Dose, Implementation outcome addressed, Theoretical justification)

Proctor et al 2013
MRC guidance for process evaluations cont.

- Fidelity: whether the intervention was delivered as intended
- Dose: the quantity of intervention strategy implemented
- Reach: whether the intended audience came into contact with the intervention, and how
- Adaptations made
Mechanisms through which interventions bring about/trigger change

- How the effects of the specific intervention occurred
- How these effects might be replicated by similar future studies

**Mechanism of impact**
- Participants response to the intervention
- Participants interaction with the intervention
- Mediators
- Unexpected pathways and consequences
Anything external to the study that may act as a barrier or facilitator to the implementation of the strategy, or its effects

Understanding context is critical for interpretation of the findings and for understanding of its generalizability.

Interaction with context can be complex even with ‘simple’ interventions
Key terms

- **Reach**: Characteristic of the target audience.
- **Dose delivered**: A function of efforts of the providers of the intervention.
- **Dose received**: Assess the extent of engagement of participants with the intervention.
- **Fidelity**: The extent to which the intervention was delivered as planned.
- **Recruitment**: Procedures used to approach and attract participants.

*Linnan and Steckler, 2002*
**Implementation**: A composite score that indicates the extent to which the intervention (implementation strategy) has been implemented and received by the intended audience.

**Context**: Aspects of the larger social, political, and economic environment that may influence the implementation of the strategy.

*Linnan and Steckler, 2002*
For whom and how are process evaluations helpful?

For researchers and policy makers
- Explaining success (*Will outcomes be similar in other contexts? How can the effects be replicated?*)
- Explaining failure (*Is it due to the intervention or to poor implementation?*)
- Does the intervention have different effects on subgroups?

For systematic reviewers
- Understanding the nature of intervention and implementation heterogeneity
Methods: Observations

- Person, camera or audiotape
- Not intrusive, i.e. not altering behaviour
- Can capture performance
- Takes time to learn
- Can provide data difficult to analyze
- The less structured the observation/the more complex the change the harder it is
- Important to train observers
Methods: Self-reports and documentation

- Interviews and questionnaires
- Periodic or retrospective (periodic likely more reliable data)
- Collect data shortly after the implementation has occurred
- Program records and documentation
Cost evaluation

- The set-up cost
- **Running cost** for e.g. time used by involved people, materials, potentially purchased equipment
- **Changes because of an intervention** e.g. more use of health care -> change in cost for health providers and health consumers
- **Relate cost** of the intervention to for example life years saved or some other factor
The PeriKIP project
Objective: To test the feasibility of a multilevel health system intervention applying participatory groups to improve perinatal health.

Setting: Nguyen Binh, Ha Quang and Phuc Hoa districts in Cao Bang
Initiation of monthly facilitated local stakeholder group meetings at

- 48 commune health centers
- 3 district hospitals
- 1 provincial hospital
- i-PARIHS
The Plan-Do-Study-Act

- **Plan**: make a clear plan for actions targeting a certain problem including assigning:
  - who is responsible
  - a deadline for undertaking the planned action
  - expected outcome of the action
The Plan-Do-Study-Act cont.

- **Do:** carry out the planned action.
- **Study**: compare the expected outcome of action with the result of the action.
The Plan-Do-Study-Act cont.

- **Act**: discuss the lessons learnt relating to the action and its outcome including taking decisions on refinements, adjustments or how to support the action to become routine.
Before and after study applying process evaluation Knowledge survey:
- Focusing on antenatal care and postnatal care
- Client case using vignettes for monitoration of labour, management of preeclampsia and haemorrhage

Observation of
- Antenatal care visits in sub-sample of units
- Labour and immediate postnatal care

Village Health Workers will collect data on pregnancies and birth outcomes using mobile phones.
<table>
<thead>
<tr>
<th>PeriKIP groups at CHC, DH and PH level</th>
<th>Facilitators:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trained facilitators</td>
<td>Support the group to identify problems and implement change</td>
</tr>
<tr>
<td>Supervisors</td>
<td>Make sense of what is going on</td>
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<td></td>
<td>Deal with difficult issues</td>
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<td>Handle emotions in the group</td>
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<td>Help the group to work together in a structured way</td>
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<td>Create a climate where openness, integrity and personal values are respected</td>
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<td></td>
<td>Encourage use of innovations (e.g. clinical guidelines)</td>
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<td>Have dialogue with supervisor</td>
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**Recipients (PeriKIP groups):**
- Collective ideas of goals
- Development of mutual respect and trust
- Shared participation and active engagement
- Understanding of unique competences of PeriKIP group members
- Sense of ownership and accountability

**Innovation**
- Use of clinical guidelines
- Other sources

**Context**
- Inner (commune: CHC, district and province)
- Outer (national)

**Mechanisms of impact of primary intervention**

**Secondary interventions (examples)**

**Outreach activities targeting community members:**
- Health promotion
  - Communication
  - Counselling
  - Mobilisation
- Health care
  - Distribute medication
  - Immunization

**Interventions targeting all health care cadres:**
- Situation analysis to identify needs
- Mapping occurrence and reasons of incorrect behaviour (e.g. home delivery)
- Implementation of innovations (for example recommendation from clinical guidelines)
- Continuous medical education
- Inventory of resources needed to improve practices
- Collection and use of locally derived data
- Development and implementation of new quality of care indicators

**Interventions targeting health system and influential stakeholders**
- Mobilisation of support
- Mobilisation of resources
- Create a platform for dialogue between health system levels

**Mechanisms of impact of secondary interventions**

**Outcomes**
- Increased community awareness on pregnancy, maternal health and neonatal health issues
- Increased use of health care services
- Increased knowledge
- Improved quality of provided health care services
- Appreciation of the usefulness of locally derived data in quality improvement processes
- Mobilized resources to improve newborn health
- Increased sense of accountability
- Improved health outcomes for newborns
- Enhanced understanding of quality improvement processes
- Strengthened linkage between levels of the health care system
<table>
<thead>
<tr>
<th>MRC</th>
<th>Process evaluation component</th>
<th>Process evaluation question</th>
<th>Data source</th>
<th>Procedures and tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>Context</td>
<td></td>
<td>How does health workers perceive aspects of context influencing implementation of EBPs?</td>
<td>All health care workers in the intervention area (CHC staff, staff in district and provincial hospital involved in perinatal health)</td>
<td>COACH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Are there other MNH initiatives in Cao Bang?</td>
<td>Representatives from reproductive health center at provincial and district level</td>
<td>Interviews and document analysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>How does stakeholders from the inner context perceive PeriKIP</td>
<td>Representatives from Provincial health bureau, district health bureau and population committee at provincial and district level</td>
<td>Interviews</td>
</tr>
<tr>
<td>Reach</td>
<td></td>
<td>Are PeriKIP groups formed as intended?</td>
<td>Facilitators diary</td>
<td>Document analysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>What is the level of attendance in PeriKIP meetings?</td>
<td>Facilitators diary</td>
<td>Document analysis</td>
</tr>
<tr>
<td>Recruitment</td>
<td></td>
<td>How were members of the groups recruited?</td>
<td>Nga and Hoa/Hoa Cao Bang</td>
<td>Interview</td>
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<td></td>
<td></td>
<td>How are representatives of stakeholders selected? (e.g. VHWs)</td>
<td>Nga and Hoa/Hoa Cao Bang</td>
<td>Interview</td>
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<tr>
<td>Implementation</td>
<td></td>
<td>How were facilitators trained?</td>
<td>Facilitators guide</td>
<td>Document analysis (Facilitators guide and notes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>How was the intervention introduced to the PeriKIP groups?</td>
<td>Supervisors guide</td>
<td>FGDS with all facilitators</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Were PeriKIP meetings held once a month?</td>
<td>Facilitators</td>
<td>FGDS with homogeneous representatives</td>
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<tr>
<td></td>
<td>Dose delivered</td>
<td>Did groups apply PDSA and accompanying tools?</td>
<td>Facilitators</td>
<td>FGDS with all facilitators</td>
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<td></td>
<td></td>
<td>Was supervision undertaken as planned?</td>
<td>Facilitators</td>
<td>FGDS with all facilitators</td>
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<tr>
<td></td>
<td>Fidelity</td>
<td>How do facilitators perceive the functioning of the intervention?</td>
<td>Facilitators</td>
<td>FGDS with all facilitators</td>
</tr>
<tr>
<td></td>
<td></td>
<td>How do PeriKIP members at hospitals perceive the functioning of the intervention?</td>
<td>PeriKIP group at hospital level</td>
<td>FGDS with PeriKIP groups at hospital</td>
</tr>
<tr>
<td></td>
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<td>How do representatives of different homogeneous stakeholder groups perceive the functioning of the intervention?</td>
<td>Selection of sub-sample</td>
<td>FGDS with homogeneous representatives</td>
</tr>
<tr>
<td></td>
<td>Mechanisms of impact</td>
<td>Which problems and actions were identified?</td>
<td>Facilitators diary</td>
<td>Document analysis</td>
</tr>
<tr>
<td></td>
<td>Dose received</td>
<td>Why were identified problems prioritised?</td>
<td>Problem identification list</td>
<td>FGDS with homogeneous representatives</td>
</tr>
<tr>
<td></td>
<td></td>
<td>How did PeriKIP groups manage the ACT step?</td>
<td>Meeting summary</td>
<td>FGDS with PeriKIP groups at hospital</td>
</tr>
<tr>
<td></td>
<td></td>
<td>How were guidelines used when prioritising problems and selecting actions?</td>
<td>Facilitator diary</td>
<td>Document analysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>How did supervision influence facilitators?</td>
<td>Facilitators</td>
<td>FGDs with facilitators</td>
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<td>Supervisors</td>
<td>FGDs with PeriKIP groups at hospital</td>
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<td>Supervisors diary</td>
<td>Document analysis</td>
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</table>
Qualitative data collection
- Heterogeneous groups
- Homogeneous groups
- Facilitators
- Key informants
Context assessment using the COACH tool
- Facilitators guide (content)
- Supervisors guide (content)
- Facilitators diaries
- Supervisors diaries
- Meeting summary (attendance, meeting time, etc)
- Problem identification list
Could your study include aspects around how a certain intervention was implemented?

Would it make sense to investigate the fidelity to which an intervention was implemented across your study setting? The reach? The recruitment?

Is there already a logic model for your piece of the larger program? If not – would that be helpful to have?

Is the perceptions from recipients of the intervention known?

Are there reasons to think that the intervention is taken up to different degrees at different sites – and if so would it be interesting to try to find out why?
References process evaluation

Types of evaluations

- Effect evaluation
  - Design
  - Primary outcome, secondary outcomes
- Cost evaluation
- Process evaluation
Studying implementation

- Specific strategy (or a set of strategies)
  - e.g. reminders
- Being used in a specific domain of healthcare
  - e.g. rational prescription of antibiotics
- In a specific setting
  - e.g. amongst physicians in primary health care
OTHER PROCESS EVALUATION FRAMEWORKS
RE-AIM (re-aim.org)

- **Reach** is the absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative.
- **Effectiveness** is the impact of an intervention on outcomes, including potential negative effects, quality of life, and economic outcomes.
- **Adoption** is the absolute number, proportion, and representativeness of settings and intervention agents who are willing to initiate a program.
- **Implementation** refers to the intervention agents’ fidelity to the various elements of an intervention’s protocol. This includes consistency of delivery as intended and the time and cost of the intervention.
- **Maintenance** is the extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies. Maintenance also has referents at the individual level. At
DESIGNS
Quantitative evaluation designs

- Randomized controlled trials, randomized on the level of the individual patients
- Cluster randomized controlled trials on the level of clusters of patients/persons, e.g. professionals, hospitals or communities
- Uncontrolled before and after studies
- Controlled before and after studies
- Time series designs
Types of analysis

- **Cluster level analysis** – the cluster is the level of randomization and analysis
- **Alternative models which can incorporate hierarchical data:**
  - Pregnant women (level 1) – covariates such as age
  - Cared for by midwives (level 2) – covariates such as working experience
  - Nested within practices (level 3) – covariates as size of the hospital
Cluster randomized controlled trials cont.

- Two-armed trials: control vs intervention (/implementation strategy)
- Multiple arm trials: control vs intervention (/implementation strategy A) vs intervention B (/implementation strategy B)
Cluster randomized controlled trials cont.

- Two-armed trials
- Multiple arm trials
- Factorial designs: allows two randomized trials to be conducted for the same sample size as a two-arm trial.

![Diagram showing factorial designs in cluster randomized trials with options for intervention A, intervention B, and no intervention, with a 2nd randomisation point leading to interventions A only, A+B, and B only.](Image)
Cluster randomized controlled trials cont.

- Two-armed trials
- Multiple arm trials
- Factorial designs
- Stepped-wedge design: all clusters receive the intervention – time when initiating the intervention (/implementation strategy) is randomized.
Quasi-experimental designs

- Quasi-experimental studies often are conducted where there are practical and ethical barriers to conducting randomized controlled trials.
- The three most commonly used designs in guideline implementation studies:
  - uncontrolled before and after studies
  - time series designs
  - controlled before and after studies
Uncontrolled before and after studies

- Measure provider performance before and after the introduction of an intervention (e.g. dissemination of guidelines) in the same study site(s)
- Any observed differences in performance are assumed to be due to the intervention.
- Relatively simple to conduct but intrinsically weak evaluative designs (secular trends/sudden changes make it difficult to attribute observed changes to the intervention.
- NB. Risk of Hawthorne effect
Time series designs

- Attempt to detect whether an intervention has had an effect significantly greater than the underlying trend.
- Useful in guideline implementation research for evaluating the effects of interventions when it is difficult to randomize or identify an appropriate control group (e.g. dissemination of national guidelines or mass media campaigns).
- Increase the confidence with which the estimate of effect can be attributed to the intervention.
Data are collected at multiple time points before and after the intervention (the multiple time points before the intervention allow the underlying trend to be estimated, the multiple time points after the intervention allow the intervention effect to be estimated accounting for the underlying trend).
The most important determinant of technique is the number of data points prior to the intervention (providing a stable estimate of the underlying trend).

Rule of thumb: 20 data points before and 20 after.

Data points after the intervention to allow full time series modelling.

Often difficult to collect sufficient data points unless routine data sources are available.
A control population having similar characteristics and performance to the study population (and thus expected to experience secular trends or sudden changes similar to the study population) is identified.

Data are collected in both populations using similar methods before and after the intervention is introduced in the study population.

A ‘between group’ analysis comparing performance in the study and control groups following the intervention is undertaken. Observed differences are assumed to be due to
- Well designed before and after studies should protect against secular trends/sudden changes
- Often difficult to identify a comparable control group
- Even in well-matched groups, baseline performance often