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Studying implementation

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Today

- PROCESS EVALUATION
- THE PerikIP PROJECT





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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”.



What is process evaluation? cont.

- 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.

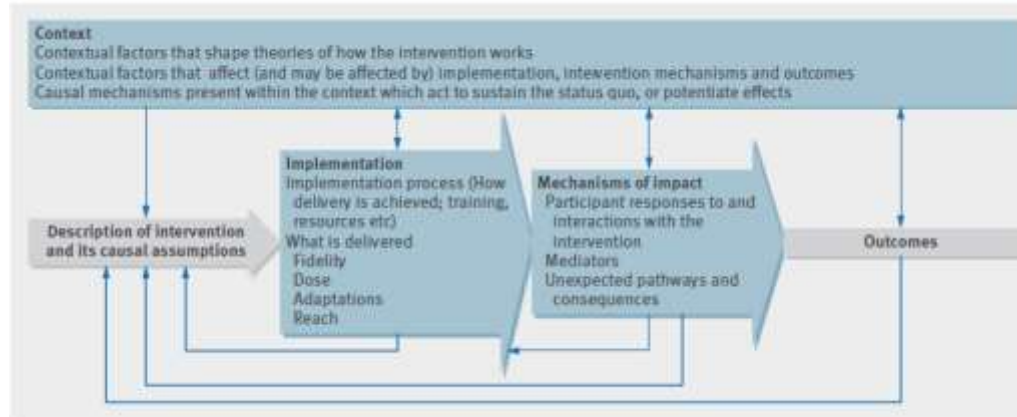


Process evaluation steps cont.

- 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



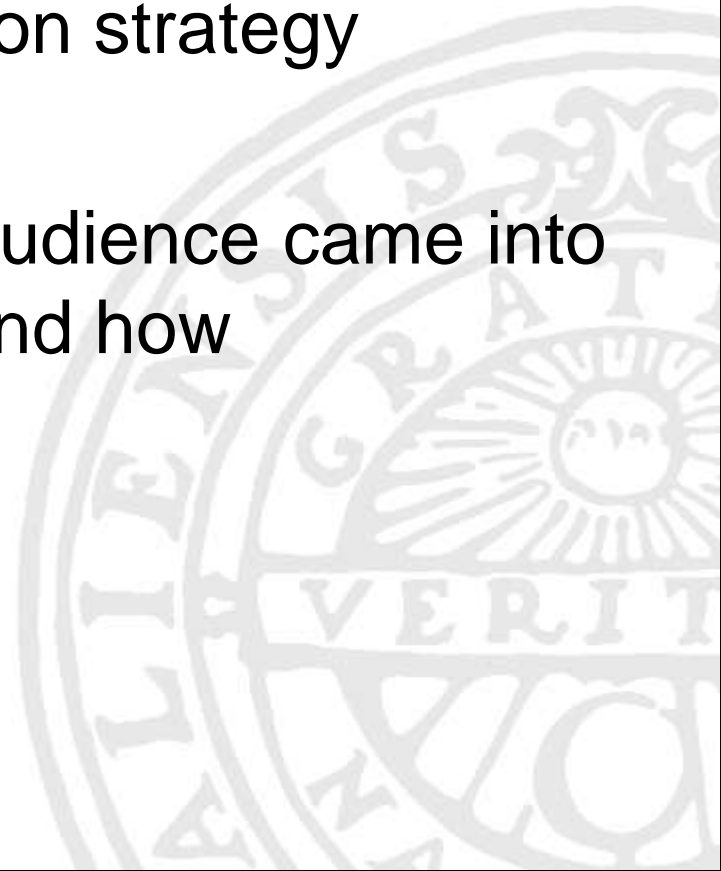
MRC guidance for process evaluations cont.

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



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





MRC guidance for process evaluations cont.

- 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



MRC guidance for process evaluations cont.

- 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.



Key terms cont.

- **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.



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?

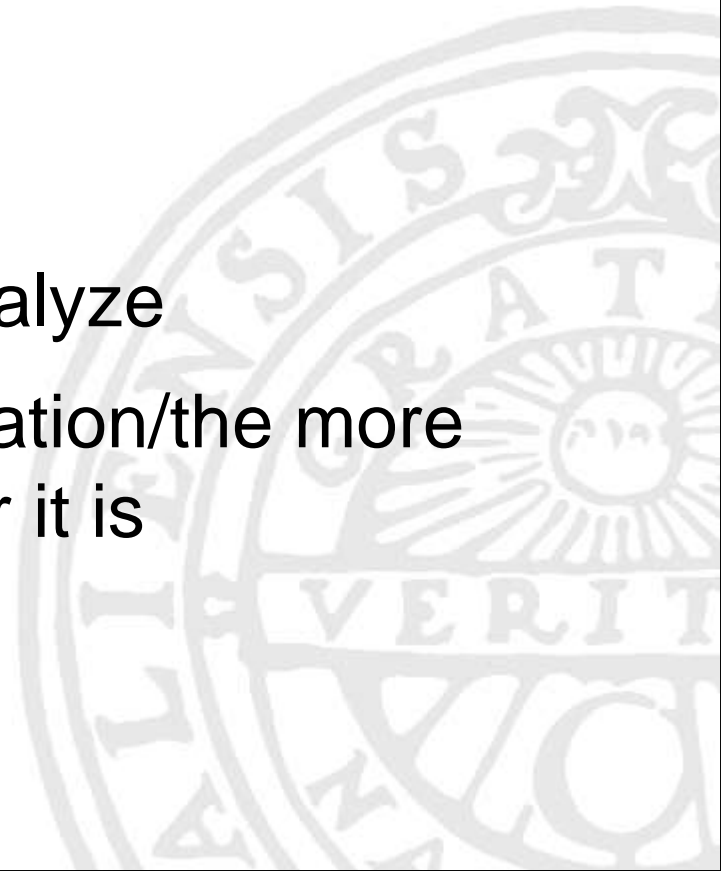
For systematic reviewers

- 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



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The PeriKIP project





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The Perinatal Knowledge Into Practice (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

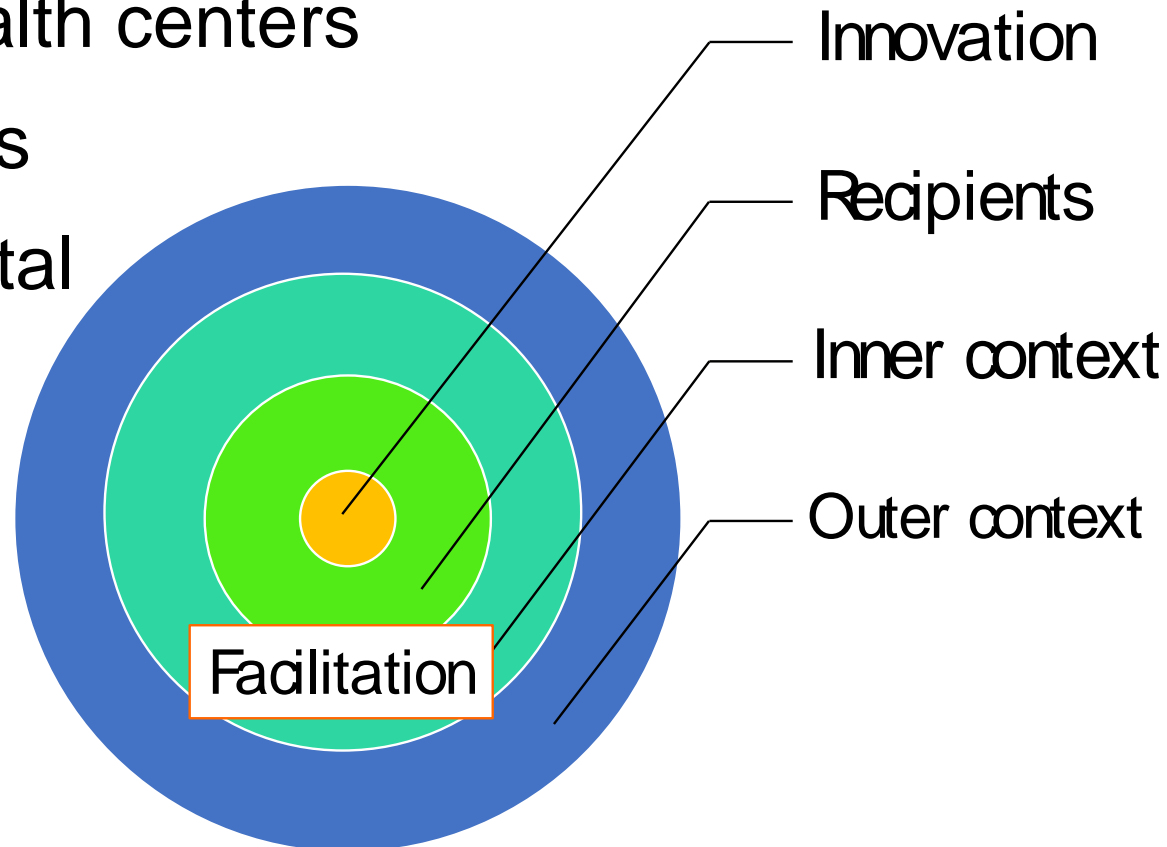




PeriKIP cont.

Initiation of monthly facilitated local stakeholder group meetings at

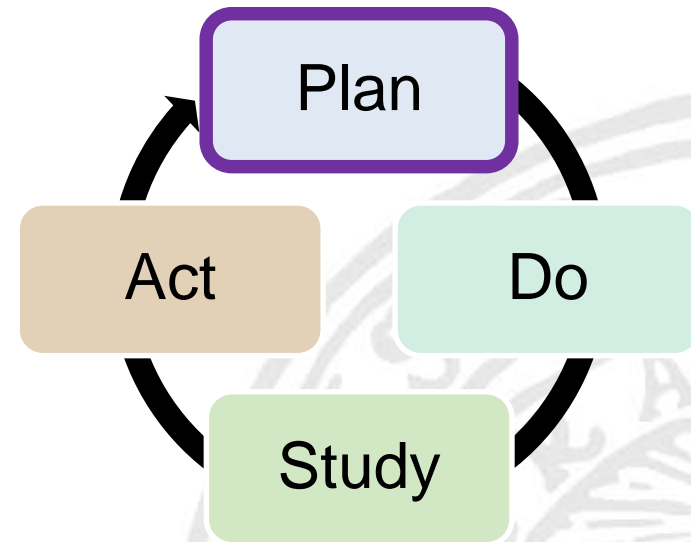
- 48 commune health centers
- 3 district hospitals
- 1 provincial hospital
- i-PARIHS





The Plan-Do-Study-Act

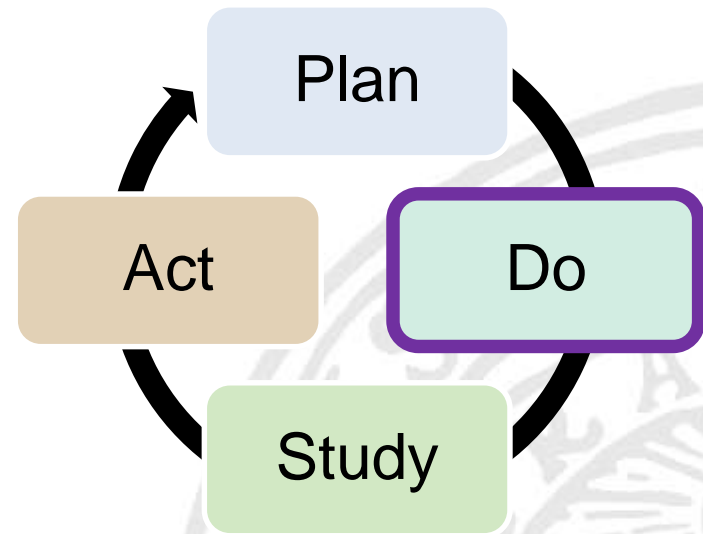
- **Plan:** make a clear plan for actions targeting a certain problem including assigning:
 - who is responsible
 - a deadline for undertaking the planned action
 - expected outcome of the action





The Plan-Do-Study-Act cont.

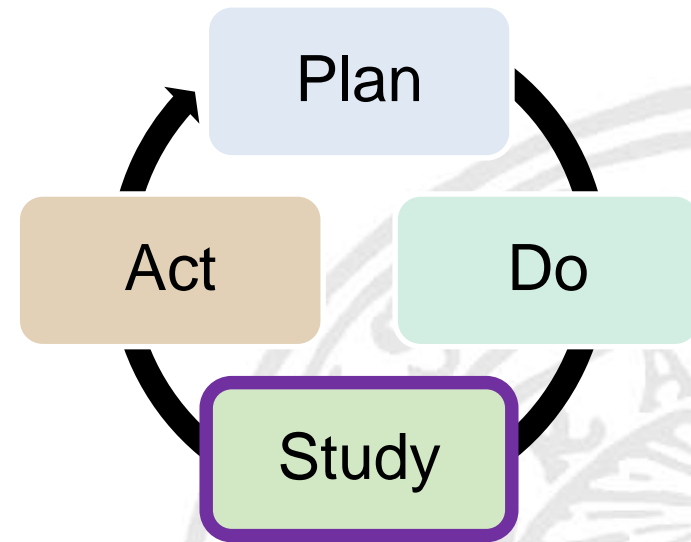
- **Do:** carry out the planned action.





The Plan-Do-Study-Act cont.

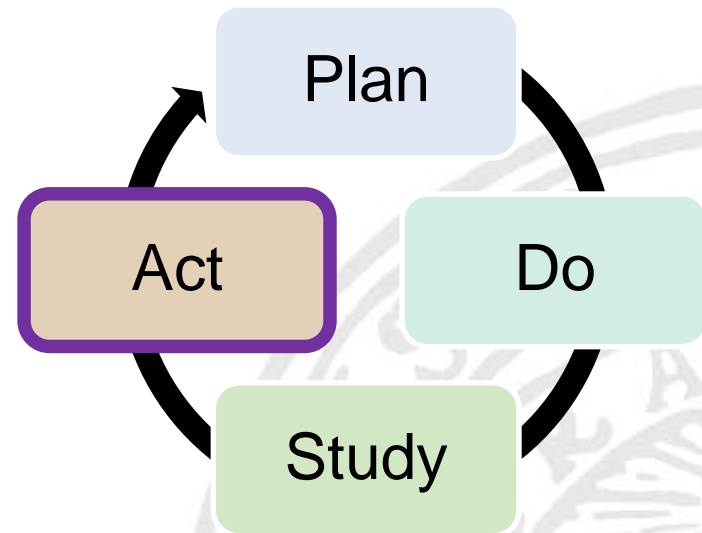
- **Study:** compare the expected outcome of action with the result of the action.





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.





PeriKIP cont.

- 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



PeriKIP cont. Logic Model - Identify key uncertainties

Primary intervention components	Mechanisms of impact of primary intervention	Secondary interventions (examples)	Mechanisms of impact of secondary interventions	Outcomes	
Trained facilitators Supervisors PeriKIP groups at CHC, DH and PH level Monthly meetings PDSA Clinical guidelines	<p>Facilitators:</p> <ul style="list-style-type: none"> Support the group to identify problems and implement change Make sense of what is going on Deal with difficult issues Handle emotions in the group Help the group to work together in a structured way Create a climate where openness, integrity and personal values are respected Encourage use of innovations (e.g. clinical guidelines) Have dialogue with supervisor <p>Recipients (PeriKIP groups):</p> <ul style="list-style-type: none"> 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 <p>Innovation Use of clinical guidelines Other sources</p> <p>Context -inner (commune: CHC, district and province) -outer (national)</p>	Implementation of monthly occurring facilitated PeriKIP groups meetings carrying through PDSA cycles informed by clinical guidelines	<p>Outreach activities targeting community members:</p> <ul style="list-style-type: none"> Health promotion <ul style="list-style-type: none"> -Communication -Counselling -Mobilisation Health care <ul style="list-style-type: none"> -Distribute medication -Immunization <p>Interventions targeting all health care cadres:</p> <ul style="list-style-type: none"> Situation analysis to identify needs <ul style="list-style-type: none"> -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 <p>Interventions targeting health system and influential stakeholders</p> <ul style="list-style-type: none"> Mobilisation of support Mobilisation of resources Create a platform for dialogue between health system levels 	<p>Increased community awareness on pregnancy, maternal health and neonatal health issues</p> <p>Increased use of health care services</p> <p>Increased knowledge</p> <p>Improved quality of provided health care services</p> <p>Appreciation of the usefulness of locally derived data in quality improvement processes</p> <p>Mobilized resources to improve newborn health</p> <p>Strengthened linkage between levels of the health care system</p>	<p>Improved health outcomes for newborns</p> <p>Enhanced understanding of quality improvement processes</p> <p>Increased sense of accountability</p>

MRC	Process evaluation component	Process evaluation question	Data source	Procedures and tools
Context	Context	How does health workers perceive aspects of context influencing implementation of EBPs?	<ul style="list-style-type: none"> All health care workers in the intervention area (CHC staff, staff in district and provincial hospital involved in perinatal health) 	COACH
		Are there other MNH initiatives in Cao Bang?	<ul style="list-style-type: none"> Representatives from reproductive health center at provincial and district level 	<ul style="list-style-type: none"> Interviews and document analysis
		How does stakeholders from the inner context perceive PeriKIP	<ul style="list-style-type: none"> Representatives from Provincial health bureau, district health bureau and population committee at provincial and district level 	<ul style="list-style-type: none"> Interviews
Implementation	Reach	Are PeriKIP groups formed as intended?	<ul style="list-style-type: none"> Facilitators diary 	<ul style="list-style-type: none"> Document analysis
		What is the level of attendance in PeriKIP meetings?	<ul style="list-style-type: none"> Facilitators diary 	<ul style="list-style-type: none"> Document analysis
	Recruitment	How were members of the groups recruited?	<ul style="list-style-type: none"> Nga and Hoa/Hoa Cao Bang 	<ul style="list-style-type: none"> Interview
		How are representatives of stakeholders selected? (e.g. VHWs)	<ul style="list-style-type: none"> Nga and Hoa/Hoa Cao Bang 	<ul style="list-style-type: none"> Interview
	Dose delivered	How were facilitators trained?	<ul style="list-style-type: none"> Facilitators guide Notes from training of facilitators Facilitators 	<ul style="list-style-type: none"> Document analysis (Facilitators guide and notes) FGDs with all facilitators
		How was the intervention introduced to the PeriKIP groups?	<ul style="list-style-type: none"> Supervisors guide Supervisors Homogeneous representatives from the different stakeholder groups 	<ul style="list-style-type: none"> Document analysis Interviews with supervisors FGDs with homogeneous representatives
		Were PeriKIP meetings held once a month?	<ul style="list-style-type: none"> Meeting summary 	<ul style="list-style-type: none"> Document analysis
		Did groups apply PDSA and accompanying tools?	<ul style="list-style-type: none"> Meeting summary Facilitators diary Facilitators Homogeneous representatives from the different stakeholder groups 	<ul style="list-style-type: none"> Document analysis FGDs with all facilitators FGDs with homogeneous representatives
		Was supervision undertaken as planned?	<ul style="list-style-type: none"> Facilitators Supervisors Supervisors diary 	<ul style="list-style-type: none"> FGDs with facilitators Interviews with supervisors Document analysis
	Fidelity	How do facilitators perceive the functioning of the intervention?	<ul style="list-style-type: none"> Facilitators 	<ul style="list-style-type: none"> FGDs with facilitators
		How do PeriKIP members at hospitals perceive the functioning of the intervention?	<ul style="list-style-type: none"> PeriKIP group at hospital level 	<ul style="list-style-type: none"> FGDs with PeriKIP groups at hospital
		How do representatives of different homogeneous stakeholder groups perceive the functioning of the intervention?	<ul style="list-style-type: none"> Selection of sub-sample 	<ul style="list-style-type: none"> FGDs with homogeneous representatives
Mechanisms of impact	Dose received	Which problems and actions were identified?	<ul style="list-style-type: none"> Facilitators diary 	<ul style="list-style-type: none"> Document analysis
		Why were identified problems prioritised?	<ul style="list-style-type: none"> Problem identification list Meeting summary Homogeneous representatives from the different stakeholder groups PeriKIP group at hospital level 	<ul style="list-style-type: none"> Document analysis FGDs with homogeneous representatives FGDs with PeriKIP groups at hospital
		How did PeriKIP groups manage the ACT step?	<ul style="list-style-type: none"> Facilitator diary Homogeneous representatives from the different stakeholder groups PeriKIP group at hospital level 	<ul style="list-style-type: none"> Document analysis FGDs with homogeneous representatives FGDs with PeriKIP groups at hospital
		How were guidelines used when prioritising problems and selecting actions?	<ul style="list-style-type: none"> Problem identification list Meeting summary Facilitator diary Facilitators Homogeneous representatives from the different stakeholder groups PeriKIP group at hospital level 	<ul style="list-style-type: none"> Document analysis FGDs with facilitators FGDs with homogeneous representatives FGDs with PeriKIP groups at hospital
		How did supervision influence facilitators?	<ul style="list-style-type: none"> Facilitators Supervisors Supervisors diary Meeting summary 	<ul style="list-style-type: none"> FGDs with facilitators Interviews with supervisors Document analysis



PeriKIP cont.

- 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



Assignment (only a few examples!)

- 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

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2. Linnan L, Steckler A. **Process evaluation for Public Health Interventions and Research.** San Fransisco: Jossey-Bass; 2002.
3. Grant et al.: **Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting.** Trials 2013 14:15.
4. Medical Research Council: **Developing and Evaluating Complex Interventions: New Guidance.** London: Medical Research Council; 2008.
5. Hawe P, Shiell A, Riley T, Gold L: **Methods for exploring implementation variation and local context within a cluster randomised community intervention trial.** J Epidemiol Community Health 2004, 58:788–793.
6. Durlak J: **Why programme implementation is so important.** J Prev Interv Community 1998, 17:5–18.
7. Lewin S, Glenton C, Oxman AD: **Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study.** Br Med J 2009, 339:b3496.
8. Hulscher M, Laurant M, Grol R: **Process evaluation of quality improvement interventions. In Quality Improvement Research; Understanding The Science of Change in Healthcare.** Edited by Grol R, Baker R, Moss F. London: BMJ Publishing Group; 2004:165–183.
9. Cook T: **Emergent principles for the design, implementation, and analysis of cluster-based experiments in social science.** Ann Am Acad Pol Soc Sci 2005, 599:176–198. 31
10. Bonell C, Oakley A, Hargreaves J, Strange V, Rees R: **Assessment of generalisability in**



Types of evaluations

- **Effect evaluation**
 - Design
 - Primary outcome, secondary outcomes
- **Cost evaluation**
- **Process evaluation**





Studying implementation

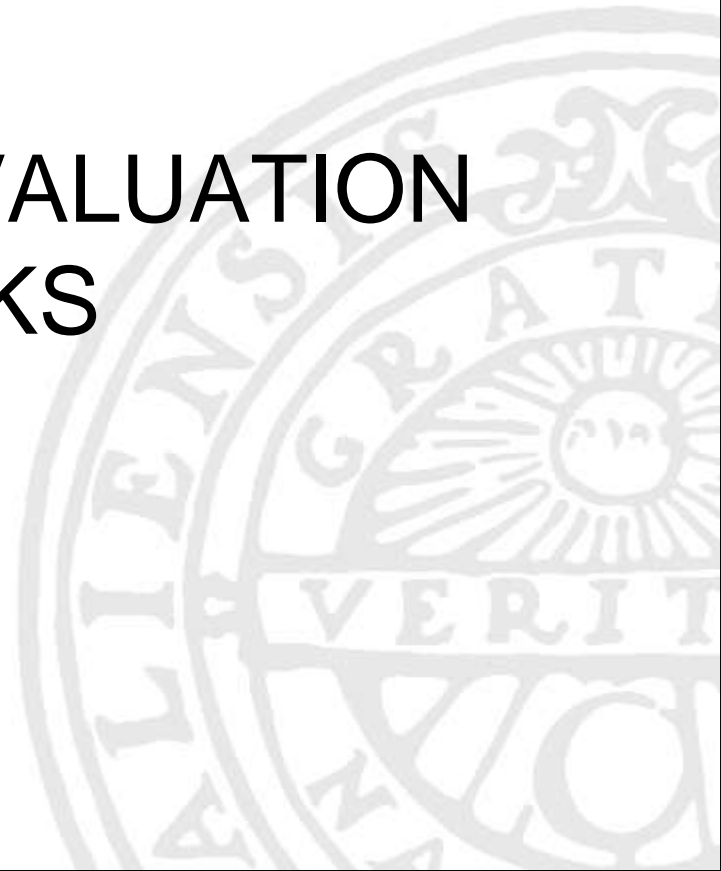
- Specific strategy (or a set of strategies)
 - e.g. reminders
- Being used in a specific domain of healthcare
 - e.g. rational prescription of antibiotics
- In a specific setting
 - e.g. amongst physicians in primary health care





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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



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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



Cluster randomized controlled trials

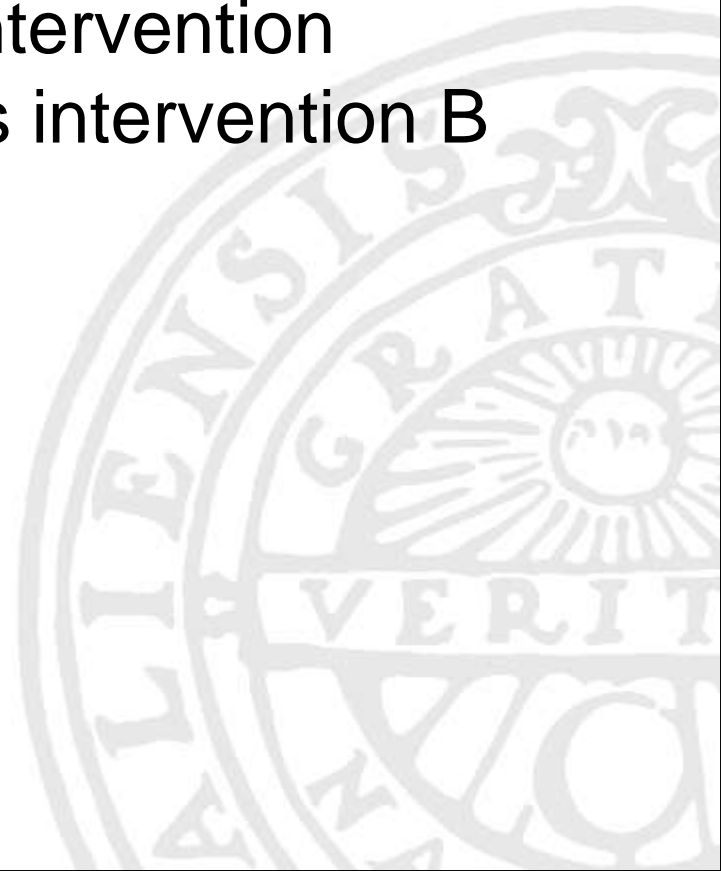
Types of analysis

- **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 working experience
 - Nested within practices (level 3) – covariates as size of the hospital



Cluster randomized controlled trials cont.

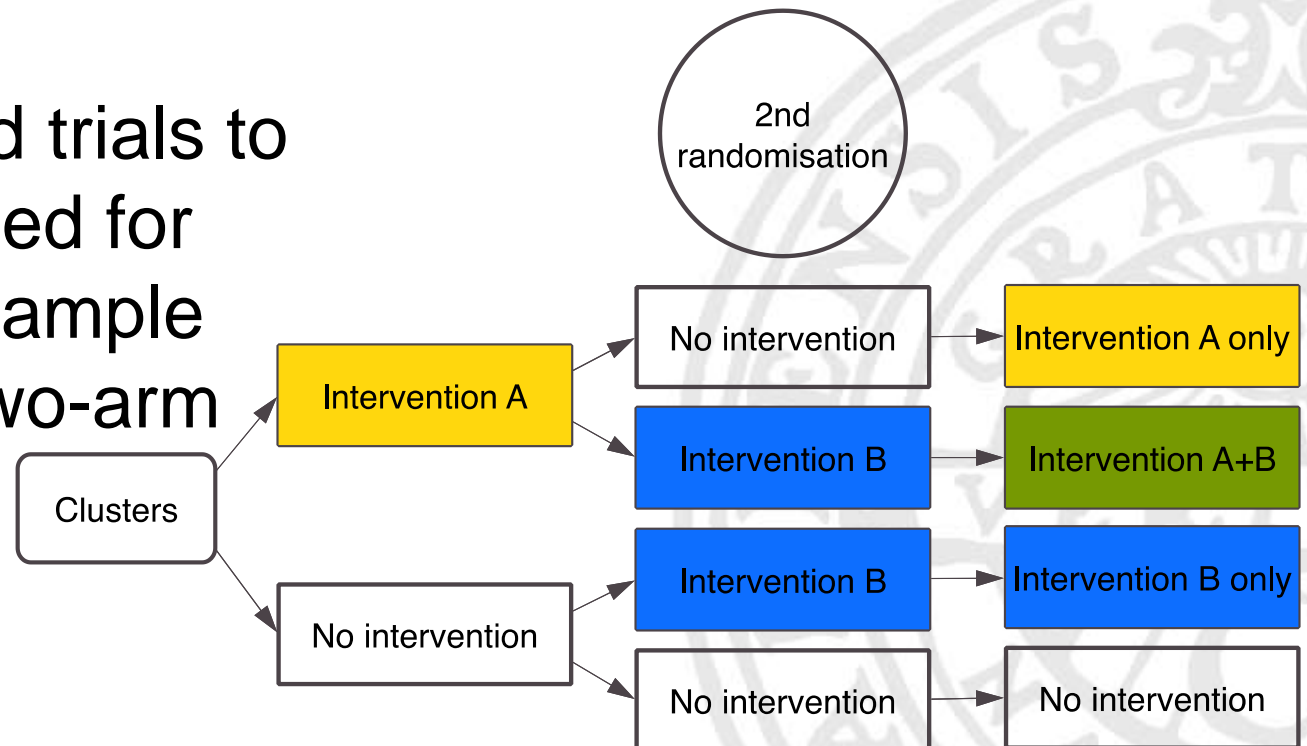
- Two-armed trials: control vs intervention (/implementation strategy)
- Multiple arm trials: control vs intervention (/implementation strategy A) vs intervention B (/implementation strategy B)





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.





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



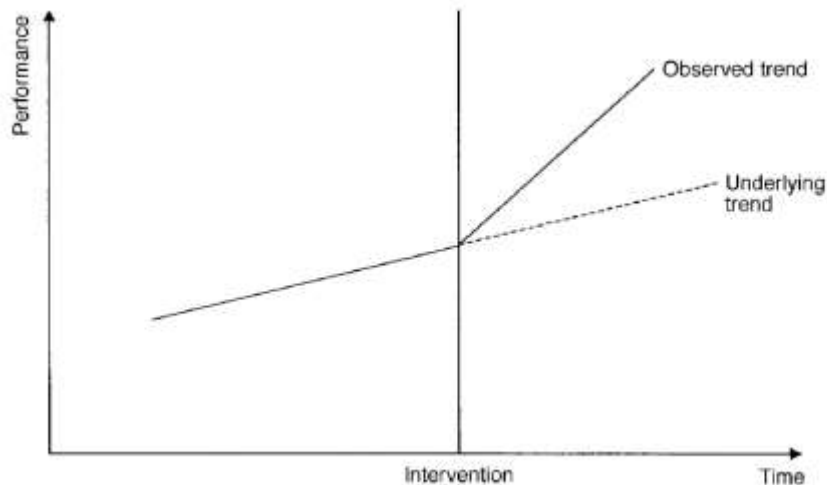
Time series designs

- 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.



Time series designs cont.

- 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)





Time series designs cont.

- 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.

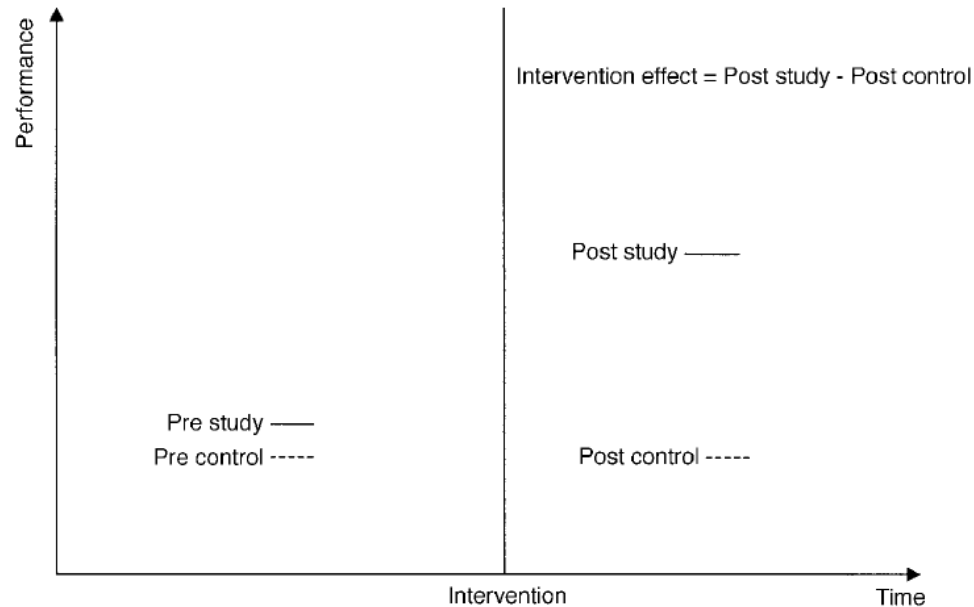


Controlled before and after studies

- 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



Controlled before and after studies cont



- 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