Developing an implementation research proposal

Session 2:
Research design
Learning objectives

After completing this session, you will be able to:

• Develop a research design outlining your data collection and analyses procedures
• Identify the research methods (qualitative, quantitative or mixed) most effective in attaining your research objectives and answering the research question(s)
• Describe the participants in your research project
• Describe the quality management plan in place to ensure the quality of your research
• Explain the steps to ensure all ethical considerations and procedures will be addressed within your IR project
Research design includes the following sub-sections:

- Study participants
- Research methods
- Data collection
- Data analysis
## Research needs and design options

<table>
<thead>
<tr>
<th>Need</th>
<th>Design</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequacy</td>
<td>Before-after or time series</td>
<td>Introduction of health insurance in a resource poor setting, and examine the impact of health insurance on access to healthcare. Using before-after or time-series design to collect the data for the evaluation.</td>
</tr>
<tr>
<td>Plausibility</td>
<td>Comparison of intervention to control group pre-post; Cross-sectional studies</td>
<td>Introduction of a new approach to the improvement of maternal healthcare in selected districts. A number of districts with a similar socioeconomic development level were selected as control sites. The impacts or effects of the new approach were assessed by a comparison of “new approach – intervention” to “control” districts, using the method of differences in differences, for example.</td>
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<tr>
<td>Probability</td>
<td>Clusters RCT; pre-post interventions and control sites</td>
<td>Using mobile phones as a reminder to increase adherence to TB treatment. Each district is used as a cluster. Among ten districts, a cluster randomized controlled trial is employed to test the impact of using mobile phones as a reminder in the five districts randomly selected. The other five districts served as control sites.</td>
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<tr>
<td>Explanatory</td>
<td>Repeated measures on context and mechanisms</td>
<td>Using quantitative, qualitative or mixed methods to understand and examine change in use of health services by pensioners after retirement, and analyse main factors resulting in the changes.</td>
</tr>
</tbody>
</table>
Study design determines which methods you will use:

- Qualitative methods
- Quantitative methods
- Mixed methods
Study participants

• A full description of the subjects (sample) or participants involved in the research
• How participants will be selected
• Criteria for becoming a participant
• Discuss your study design
• Draft outline of your participants section
<table>
<thead>
<tr>
<th>Qualitative</th>
<th>Quantitative</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Social theory</strong></td>
<td>Action</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td>Observation, interview</td>
</tr>
<tr>
<td><strong>Question</strong></td>
<td>What is x? (classification)</td>
</tr>
<tr>
<td><strong>Reasoning</strong></td>
<td>Inductive</td>
</tr>
<tr>
<td><strong>Sampling</strong></td>
<td>Theoretical</td>
</tr>
<tr>
<td><strong>Strength</strong></td>
<td>Validity</td>
</tr>
</tbody>
</table>

Pope and Mays (1995). Reaching the parts other methods cannot reach: An introduction to qualitative methods in health and health services research. *BMJ*: 311; No. 6996
Research method: Qualitative

- Diversity in research design, researcher roles, and data gathering techniques
- Requires the use of a rigorous systematic scientific process
- Data are usually in the form of words (rather than numbers) are detailed, often including description and direct quotations
- Small number of purposefully selected participants or ‘cases’
- Used to explore values, attitudes, opinions, feelings, and behaviours of individuals
- Concerned with individuals’ perceptions of specific topics, issues, or situations and the meanings they assign to their lives
- Important for theory generation, policy development, improving educational practice, justifying change or a particular practice, and illuminating social issues
- Results are descriptive rather than predictive
Proposal should outline:

- Rationale
- Data collection
- Data analysis
- Trustworthiness
- Participants
If your research team decides to use qualitative methods in your study, your proposal should describe why qualitative approaches were chosen.
Qualitative data collection

- Preferable to ‘triangulate’ the data, adds rigor to the research
- Typically time-consuming and laborious
- Data collection process is emergent and flexible
Plan for qualitative data analysis

- Data collection and analysis are conducted simultaneously.
- Data analysis is an on-going process that begins with the first piece of data collected.
- Analysis consists of data management, reduction and coding.
- Goal is to identify patterns (themes) in the data and links between them.
- Software can help to manage data.
Stipulate how your research team will ensure scientific rigour

- If possible, have participants review interview transcripts
- Member checks
- Triangulate data
- Report "disconfirming" results
Participants

- Describe sampling of the study population
- Define the number of participants
- Participant criteria
- Describe selection (age, gender, ethnicity, income bracket, etc.), characteristics related to the disease of interest, etc.
- A full description of the participants involved in the research
Research method: Quantitative

- Determine the relationship between variables or explore differences between two or more groups
- Involves the collection and analysis of objective data, often in numerical form
- Research design and methods are determined prior to the start of data collection and are not flexible
- Types of quantitative research design include:
  - Quasi-experimental research
  - Correlational research
  - Monitoring evaluation
Proposal should outline:

• Rationale
• Data collection
• Data analysis
• Reliability and validity
• Participants
Quantitative data collection

- Instrument used (e.g. questionnaires, checklists)
- Instruments may be one developed by the researcher or, one that has been previously developed
- Instruments need to be tested through pilot studies, for example
- Enumerators need to be trained for data collection
Plan for quantitative data analysis

- Data presented in numerical form
- Analysed using descriptive or inferential statistics
- Data can be either quantitative or categorical
- A variable is measured along a scale and reported in terms of scores
- Quantitative data differ in degree and amount
- Categorical data differs only in kind,
  - indicates the number of instances in each category,
  - are reported as frequencies or percentages
Reliability and validity

• Tools should be valid and reliable
  o Considered valid if it measures what it purports to measure
  o Reliability, refers to the consistency and reproducibility of the results
• Internal consistency is the degree to which all items in a domain reflect the same construct
• Content, criterion and construct validity
Participants

- Describe the study population
- Define the sample size, unit of analysis, number of units
- Documents how participants will be selected and criteria for becoming a participant
- Describe selection (age, gender, ethnicity, income bracket, etc.), characteristic related to the disease of interest, study site, or other factors
- Indicate whether variables are dependent or independent
Most IR proposals use mixed methods

- Qualitative and quantitative techniques are combined
- Under the right circumstances, a mixed methods approach can provide a better understanding of the problem than either a quantitative or qualitative research approach
- It could be challenging to create the optimal combination and sequence of both approaches
- Appealing for interdisciplinary projects which deal with complex problems
Since mixed-methods involve both qualitative and quantitative methods, components must be included in the proposal:

- Rationale (including methods used)
- Data collection
- Data analysis
- Reliability and validity
- Trustworthiness
- Participants
Mixed methods data collection and analysis

Elements related to mixed methods that need to be considered in research design:

• Timing
• Weighting
• Mixing
• Visual diagrams
Data collection and analysis

- Indicate data collection strategies and tools you intend to use and why
- Outline a plan of data management and analysis
Trustworthiness, validity and reliability

- Explain how you will address issues of trustworthiness, validity and reliability with data collection and analysis
• Ensure that your sample size, recruitment and selection criteria align with your mixed methods (see qualitative and quantitative participants sections)
• Discuss your research design
• Determine your research methods
Develop the following parts of your proposal:

- Research design
- Research methods including:
  - Step-by-step procedures for your data collection
  - Data analysis
  - Trustworthiness, validity, reliability
  - Participants

Write-shop details
Quality management

- Ensure the research process will meet or exceed scientific, ethical and regulatory research standards
- Should be embedded into all research activities
- Quality management plan is NOT optional
Activities to address quality issues

- Protocol and study documentation review and approval
- Documentation, monitoring, & auditing
- Validation

Phases:
- Project development phase
- Planning phase
- Implementation phase
- Report writing process
- Closure phase

Processes:
- Protocol & document development process
- Planning process
- Study implement data collections
- Data management process
- Data analysis process
- Report review and approval
Quality management

Some of the activities you can integrate into your proposal to manage quality include:

- Protocol review and approval
- Documentation of standard operating procedures (SOPs)
- Validation of research instruments
- Training the project team
- Quality control and monitoring
- Evaluation of services provided
- Evaluation of the performance of service providers
- Review of reports
Research ethics

- Research that collects data from human subjects must undergo an ethics review
- Describe how you will ensure the protection, dignity, rights and safety of all research participants
• **Develop the following components of your proposal:**
  o Data analysis plan
  o Research ethics

• **Revisit** the Introduction, Research Question(s), Research Method, Participants, Research Design, and Data Collection sections of your IR proposal.
  o Make any changes necessary to improve, update, or align all sections of your proposal