# Developing an implementation research proposal

Session 2:

Research design

TDR For research on diseases of poverty
UNICEF • UNDP • World Bank • WHO

World Health Organization

# 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

**Research design includes the following sub-sections:**

- Study participants
- Research methods
- Data collection
- Data analysis

# Research needs and design options

| Need | Design | Example |
|---|---|---|
| Adequacy | Before-after or time series | 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. |
| Plausibility | Comparison of intervention to control group pre-post;<br><br>Cross-sectional studies | 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. |
| Probability | Clusters RCT; pre-post interventions and control sites | 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. |
| Explanatory | Repeated measures on context and mechanisms | 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. |

# Design informs methods

**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

# Group activity

- Discuss your study design
- Draft outline of your participants section

# Qualitative and quantitative approaches

| | Qualitative | Quantitative |
|---|---|---|
| **Social theory** | Action | Structure |
| **Methods** | Observation, interview | Experiment, survey |
| **Question** | What is x? (classification) | How many xs? (enumeration) |
| **Reasoning** | Inductive | Deductive |
| **Sampling** | Theoretical | Statistical |
| **Strength** | Validity | Reliability |

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

# Qualitative sub-sections of proposal

**Proposal should outline:**

- Rationale
- Data collection
- Data analysis
- Trustworthiness
- Participants

# Rationale

- 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

# Trustworthiness

**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

# Quantitative sub-sections of a proposal

**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
  - Considered valid if it measures what it purports to measure
  - 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

# Research method: Mixed methods

- 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

# Mixed-methods proposal sub-sections

**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

# Participants

- Ensure that your sample size, recruitment and selection criteria align with your mixed methods (see qualitative and quantitative participants sections)

# Group activity

- Discuss your research design
- Determine your research methods

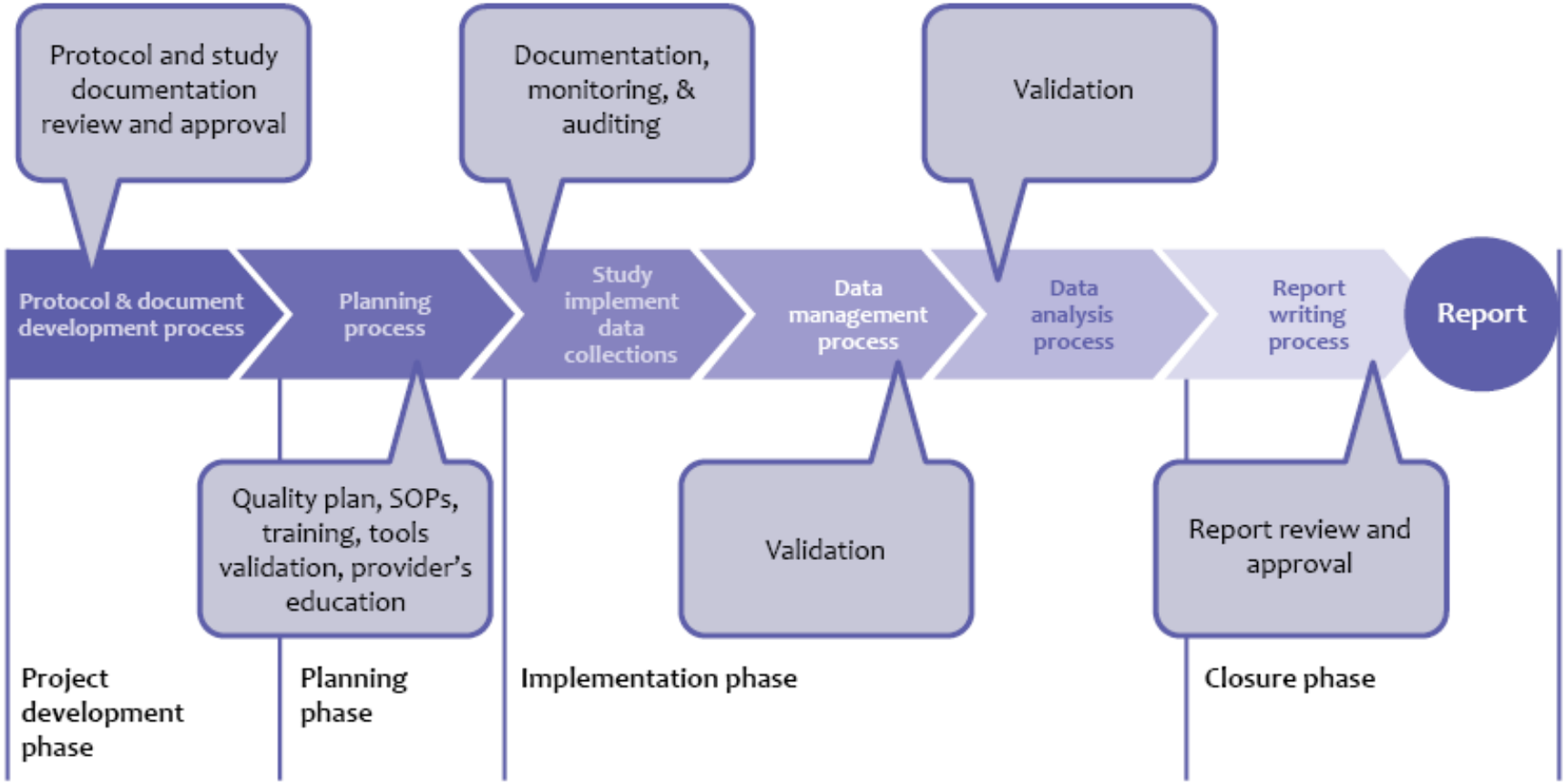
# Write-shop details

- **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

# 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



# 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

# Write-shop details

- **Develop the following components of your proposal:**
  - Data analysis plan
  - Research ethics
- **Revisit** the Introduction, Research Question(s), Research Method, Participants, Research Design, and Data Collection sections of your IR proposal.
  - Make any changes necessary to improve, update, or align all sections of your proposal