

How to Prepare a Research Protocol for WHO?

Shyam Thapa, PhD
Scientist

Department of Reproductive Health and Research
World Health Organization

E-mail: thapas@who.int

30 July, 2010

Geneva Foundation for Medical Education and Research

Training Course in Sexual and Reproductive Health Research
Geneva 2010

Protocol

the *plan* of a scientific experiment

Format may vary between organizations, but the basic principles and key components remain the same

Clinical v. Non-clinical

A competitive research protocol should be

- **Complete**
- **Robust**
- **In conformity to rules, procedures, specifications, and standards**
- **Credible, manageable, doable**

Yet, often many proposals are not ...

Take-home message

**Bright research ideas are essential,
but not sufficient to win a proposal/grant.**

Opportunities for Research with Financial and Technical Support from WHO

Call for Proposals

- **Implementation research**
- **Medical abortion**
- **Injectable contraception**
- **Capacity strengthening**
- **Country and region level call for proposals**
- **Tropical Diseases Research Institute**
- **Patient Safety**

Re-entry grant

Unsolicited proposals

Opportunities for Research with Financial and Technical Support from WHO

□ *How to make it a winning (complete) proposal?*

What are the basic essentials?

What are the open secrets?

Perspectives from the receiving of the proposals at WHO HQ

Diversity in Backgrounds of the Online Course Participants

- A. Experienced with WHO policies and procedures, and been successful – either completed a research or ongoing**
- B. First time aspirants**
- C. Future aspirants**

Reference Materials

- **Preparing a Research Project Proposal (WHO, 2003, 4th Edition)**
- **Format for a Research Protocol (In Brief)**
- **Research Project Proposal Template (for submission)**
- ***A Practical Guide for Health Researchers* – M.F. Fathalla, prepared for for WHO Regional Office, 2004**
- **Habicht et al., *Int'l J of Epi* (1999) on three levels of evidence generation**
- **Ethics section (S Thapa's session on 18 June, 2010) – *not included***
- **Tomas Allen's lecture on lit search– *not included***

Additional Reference Materials *(Google, 29 July 2010)*

- *How to write a business proposal and business proposal writing tips*
www.captureplanning.com
- *Tips on How to Write a Proposal*
www.usistf.org/download/RFP/
- *Writing a good grant proposal*
research.microsoft.com/en-us/um/.../proposal.html
- *12 tips for writing a winning proposal*
office.microsoft.com/.../12-tips-for-writing-a-winning-proposal
- *Get Started – Tutorials – Proposal Writing Short Course*

Components of a Research Protocol, Part I

**Project Summary
General Information**

Rationale & Background Information

References (of literature cited in preceding sections)

Study Goals and Objectives

Study Design

Methodology

Safety Considerations

Follow-Up

Data Management and Statistical Analysis

Quality Assurance

Expected Outcomes of the Study

Dissemination of Results and Publication Policy

Duration of the Project

Problems Anticipated

Project Management

Ethics

Informed Consent Forms

Components of a Research Protocol, Part II

Budget

Other support for the Project

**Collaboration with other scientists or
research institutions**

Links to other projects

Curriculum Vitae of investigators

Other research activities of the investigators

Financing and Insurance

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✓ Why the study?

✓ What do you know about the study globally and locally?

✓ Why do you want to conduct the research? That is, what goals do you hope to accomplish, if you completed the study and obtained the results you hoped to obtain?

✓ What are the main objectives of the study?

Steps (Illustrative)

- ❑ **What is the problem and the research question?**
 - Actual problem encountered / observed?
 - Discussion with peers or colleagues

- ❑ **What do we know about the research question in the country and globally?**
 - Literature search – published / unpublished

- ❑ **How to conduct literature search?**
(Online session by Tomas Allen, WHO Library & Information Networks for Knowledge)

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✓ **Ethics**

✓ **Informed Consent Forms**

Study Design / Methodology

- Study design
- Study sites
- Study participants (exclusion and inclusion criteria)
- Treatment Regimen, if applicable
- Sample Size
- Data Collection Instruments
- Data analysis plan

Definition

Methodology

A systematic description of how certain tasks are carried out from beginning to end. A methodology may include procedures/techniques, protocols, norms, and standards.

Technique

A specific procedure applied to a specific task.

Study Design / Methodology

- ❖ **Randomized Controlled Trials (RCTs)**
- ❖ **Non- Randomized Controlled Trials (Observational Designs)**

Basic, Intermediate, Advanced Levels

Reference on clinical research, particularly randomized controlled trials (RCTs)

- **The Lancet Handbook of Essential Concepts in Clinical Research** -- Kenneth Schulz and David Grimes (Elsevier, 2006)

“Clinicians are *medical detectives* by training. ... The handbook speaks to two audiences: those who read and those who conduct research. ... not another introductory text in biostatistics, medical statistics or epidemiology. ... focus is on the *elimination of bias*...”

Basic Non-RCT Designs in Research

Observational Designs

Cohort Study

Design: Often referred to as a panel study; longitudinal where individuals are followed through time. May involve comparison groups subjected to different treatments or exposed to different conditions.

Cross-sectional Study

Design: Often referred to as a survey study; a random sample. Design allows statistical control of variables during analysis.

Case-Control Study

Design: For a given outcome measure, compares a group in which members have some characteristics of interest with one or more groups in which the characteristics of interest is absent. Assumed that both groups come from the same underlying population.

Static-Group Comparison

Design: A variant of cross-sectional design in which a treatment group is compared with a comparison or control group whose members are not exposed to the variable of interest.

Basic Designs in Research

Quasi-Experimental Designs (RCT—Yes/No)

One group posttest only design

Design: Pretest observations are made on a single group. The group receives a treatment and posttest observations are made.

Posttest only nonequivalent groups design

Design: Experimental or control group are determined without random allocation of group members. Posttest observations are made and groups are compared.

Pretest/posttest nonequivalent groups design

Design: Experimental and control group are determined without randomization. Pretest observations are made on both. Posttest observations are made on both.

Interrupted time series design

Design: One experimental group in which a series of observations is made both prior to and after the treatment.

Methodologies for Collecting Data

Quantitative

- ◆ **Structured interviews**
(with clients, participants, service providers, and others)
- ◆ **Service Statistics (or other program data)**

Qualitative

- ❖ **Focus Group**
- ❖ **In-depth interviews**
- ❖ **Observation**
(direct observation, mystery client, or ethnologic techniques)

Study Samples

Types of sample –

Non-probability (convenience, quota), and Probability

Probability sample

- Simple random sample
- Systematic sampling
- Stratified sampling
- Cluster sampling

Sample size – desirable v. feasible

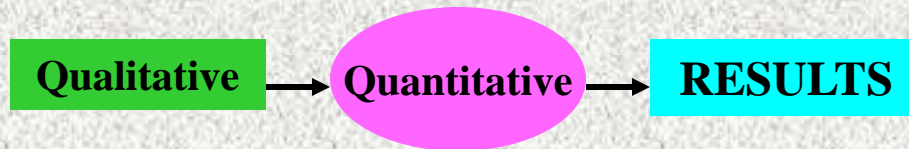
Sample size formulae

- Precision – means, rate
- Significance – difference between groups

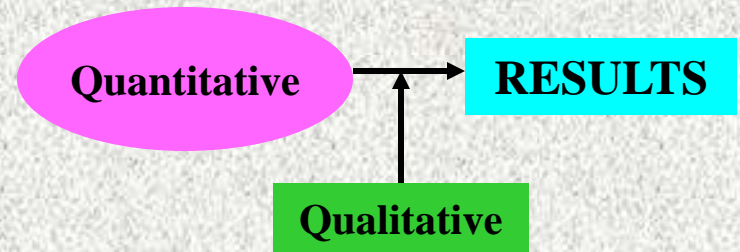
Call for help / consultation!

Illustrations of Different Scenarios for Combing Qualitative and Quantitative Methods

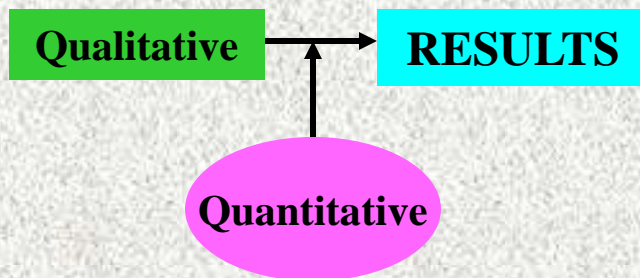
Qualitative Measures to Develop Quantitative Tools



Qualitative Methods to Explain Quantitative Results



Qualitative Measures to Enlarge on Quantitative Study



Qualitative and Quantitative Methods Equal and Parallel



Points not always appreciated by those using Focus Group Discussions research

- **FG methodology involves fairly specific procedures**
- **FG approach (including through analysis) requires considerable time, effort and fund**
- **FG analysis is very demanding on principal investigators – relatively little can be delegated to assistants**

Comparing Methods

Group Interview <i>(e.g. to gather community –level data)</i>	Highly structured data defined entirely by researcher
Focus Group Discussion (FGD)	Semi-structured data, researcher defines topic but discussions open-ended
Participant Observation of natural group (e.g. joining a “drinking circle”)	Largely naturally emerging data defined by respondent but modified occasionally by pointed researcher inquiries
Passive observation of a natural group	Naturally emerging data defined entirely by respondents

Deficiencies of Monomethods

“Social science methods should not be treated as mutually exclusive alternatives among which we must choose. ... Our individual methods may be flawed, but fortunately the flaws are not identical. A diversity of imperfection allows us to combine methods ... to compensate for their particular faults and imperfections.”

*J. Brewer & A. Hunter, **Multimethod Research: A Synthesis of Styles** (Sage, 1989)*

Mixed Methodology

Combining Qualitative and Quantitative Approaches

- *Rapidly growing area of interest in research methodology: mixed method and mixed model*
- *QUAN-QUAL application and analysis*

Purposes of Mixed Methods Studies

- A. Triangulation, or seeking convergence of results;
- B. Complementarity, or examining overlapping and different facets of a phenomenon;
- C. Initiation, or discovering paradoxes, contradictions, fresh perspectives;
- D. Development, or using the methods sequentially, and
- E. Expansion, or mixed methods adding breadth and scope to a project/study.

J. C. Greene et al. "Toward a conceptual framework for mixed-method evaluation designs" *Educational Evaluation and Policy Analysis* (11, 1989).

Reference on Mixed Methods

- **Mixed Methodology: Combining Qualitative and Quantitative Approaches** – A. Tashakkori and C. Teddle (Sage, 1998)
- **Handbook of Mixed Methods in Social and Behavioral Research** – Edited by A. Tashakkori and C. Teddle (Sage, 2003)

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Preparing a CV – Key Elements

- ✓ **Standardize the format for all staff on the team with the main elements**
- ✓ **Avoid acronyms and abbreviations**
- ✓ **Ensure information is complete**
 - **Name**
 - **Contact information**
 - **Education**
 - **Training**
 - **Employment and Work experience**
 - **Professional organization/s**
 - **Professional credentials**
 - **Publication**
 - **Other research activities**
 - **Language**
 - **Reference**

Bright research ideas are essential, but not sufficient to win a proposal/grant

Tips

- **Follow the template/format, make sure to fully understand what is asked for and required, and address each section/sub-section (component).**
- **Do not assume that each reviewer is an expert on all aspects / components of the proposed study.**
- **Use acronym / abbreviations only where necessary, but have a page with details.**

Tips

- Importance of balance and proportionality in different sections/components
- Give equal attention to each section/component
- Pay attention to specific policies (e.g., budget)
- Project should be feasible, doable, and manageable
- Identify appropriate people to work in the research team
- Remember, the abstract and summary are prepared the last, but read the first!
- Plan ahead, preparation and review processes take time

Assignment

✓ Review the protocol development guidelines

If any questions / comments or would like to know more about specific topics or areas related to the materials in this session, email me at

thapas@who.int

If you are working on a proposal / protocol or plan to work on one, feel free to share for comments / feedback

Thank you and happy reviewing the materials!