Conducting operational research in resource –limited settings

Patrice Tchendjou, MD, PhD

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Outline

- Generalities on research / operational research
- Research protocol content
  - Research Title - Background - Question / Hypothesis
  - Objectives
  - Methods`
  - Data collection & Management - Data analysis
  - Ethical considerations
  - Limitations - Timeline
- Conclusion on research / operational research

Generalities

What comes to mind when you hear the word ‘research’?

What comes to mind when you hear the word ‘evaluation’?

What comes to mind when you hear the word ‘operational research’?

Generalities

Research:

A systematic investigation, including research development, and testing and evaluation, designed to develop or contribute to generalizable knowledge.

Evaluation :

A systematic acquisition and assessment of information to provide useful feedback about some object / intervention

Generalities

Operational research:

"Use of systematic research techniques for program decision-making to achieve a specified outcome." [Population Council, 2006]

- Goal = find a best possible solution to improve performance of the organization and for the delivery of services
  - ➢ To assess the feasibility of new strategies or interventions in specific settings or populations
  - ➢ To improve program outcomes in relation to medical care or prevention
  - ➢ To advocate for policy change
- Often OR and Program Evaluation overlap

The M and E and R Continuum

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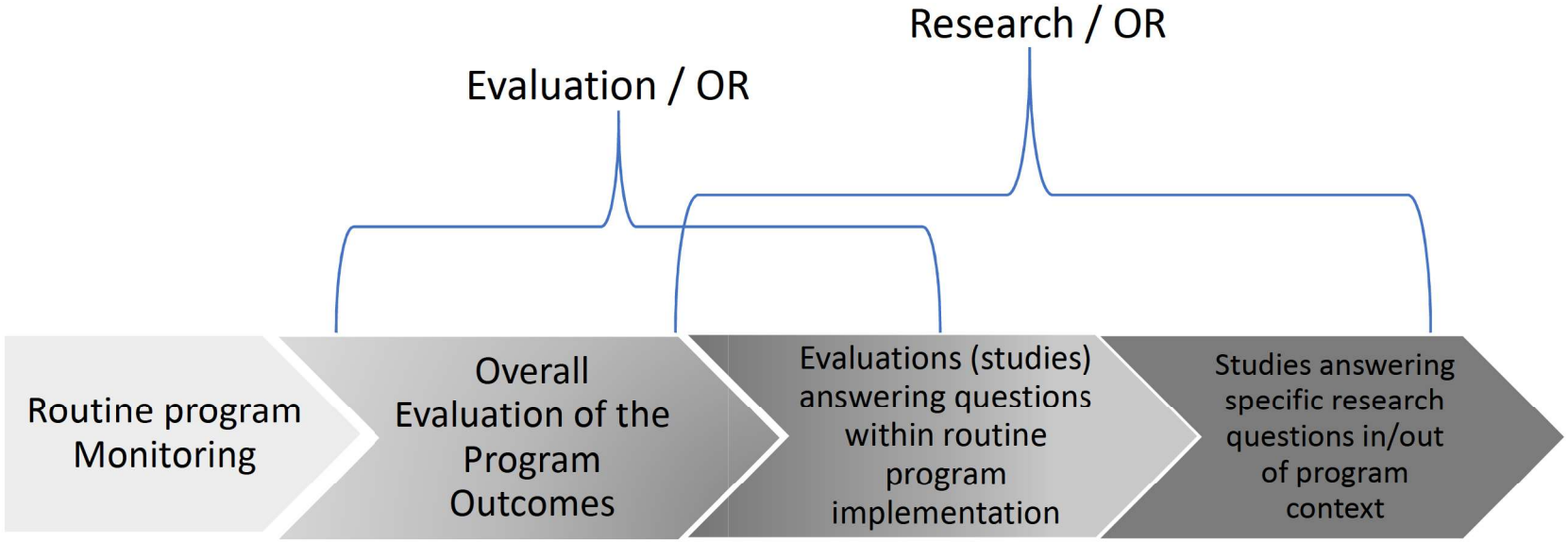

Logframe	Baseline assessment Mid line assessment End of project assess.	Assessing effect of new program activity on program outcomes (ie mobile units, support groups)	Qualitative studies Laboratory studies Quantitative studies Randomized intervention / trial

Generalities on Research – We want to maximize evidence generation

- Identify an important research/evaluation question
- Generate a research/evaluation protocol
  - Outlines critical steps in the evaluation/study
  - Provides a "Gold Standard" against which the conduct of the evaluation/study will be judged
  - Presents study components in logical, linear way
  - Identifies data to be collected and how to ensure data quality
  - Documents data analysis plan in advance
- Identifies ethical considerations and standards for the evaluation/study

Generalities on Research – level of proof of studies

evel of scientific proof	Recommended grades
evel 1 (NP1)	**High level of scientific proof A**
andomized control trial with high power	
Aata-analysis of comparative trials	
nalysis of informed-decisions from high level studies	
evel 2 (NP2)	**Presomptive scientific level of proof: average to high**
andomized trial with low power	
on randomized comparative sutdies	
ohort studies	
evel 3 (NP3)	
ase-control studies	
evel 4 (NP4)	**Low level of proof**
ross-cutting studies; retrospective studies	
ase study; Case serial	

Generalities - Documentation

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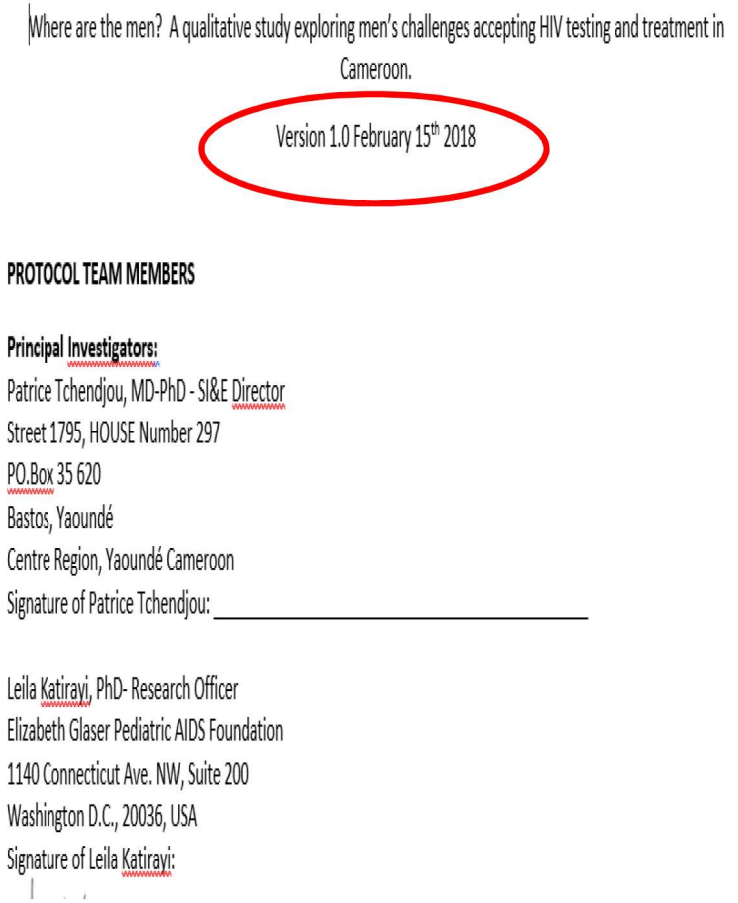


Where are the men? A qualitative study exploring men's challenges accepting HIV testing and treatment in Cameroon.

Version 1.0 February 15th 2018

PROTOCOL TEAM MEMBERS

Principal Investigators:

Patrice Tchendjou, MD-PhD - SI&E Director
Street 1795, HOUSE Number 297
PO.Box 35 620
Bastos, Yaoundé
Centre Region, Yaoundé Cameroon
Signature of Patrice Tchendjou: _____

Leila Katirayi, PhD- Research Officer
Elizabeth Glaser Pediatric AIDS Foundation
1140 Connecticut Ave. NW, Suite 200
Washington D.C., 20036, USA
Signature of Leila Katirayi:

Research protocol content

Proposal ≠Protocol

- Proposal- broad range of information included
  - Includes details of study question, design, objectives, analysis etc
  - Puts study in context of the overall field, to convince a funder of the importance, feasibility, and impact of the study, experience of PI, site capabilities, etc- that it is worthy of funding

- Protocol- less broad, more focus on the study
  - Includes importance, feasibility, and impact of the study, but more as background info, not as part of study design and methods

Research protocol content

Protocol is like a contract

- Whatever you write in a research protocol is what you have to do once it is approved – it is like a contract
  - ✓If you write that everyone in a study must live within 15 km of a health care center then they really must live within that distance and not farther away
  - ✓You may want to write, participants should live within the catchment area of x health care center

Research protocol content

Considerations for Writing a Protocol

- Think carefully about what you write
- Write what you will do and do not write what you will not be able to do
- Avoid standard cut and paste protocol phrases that may not reflect site specific capabilities
- Include only study required activities in the study description/methods or clearly specify what activities are part of the study and what activities are not (ie what you will have control over/be responsible for in study and what you will not)

Research protocol content

Title page

- Project title
- Organization
- Name(s) of the principal investigator(s)
- Sponsor
- Version number
- Date of the version
  - The date and version number should also be included as a footer
  - Page numbers as “page x of y” in footer
  - Header or footer should include title of protocol

Research protocol content

Background/Rationale

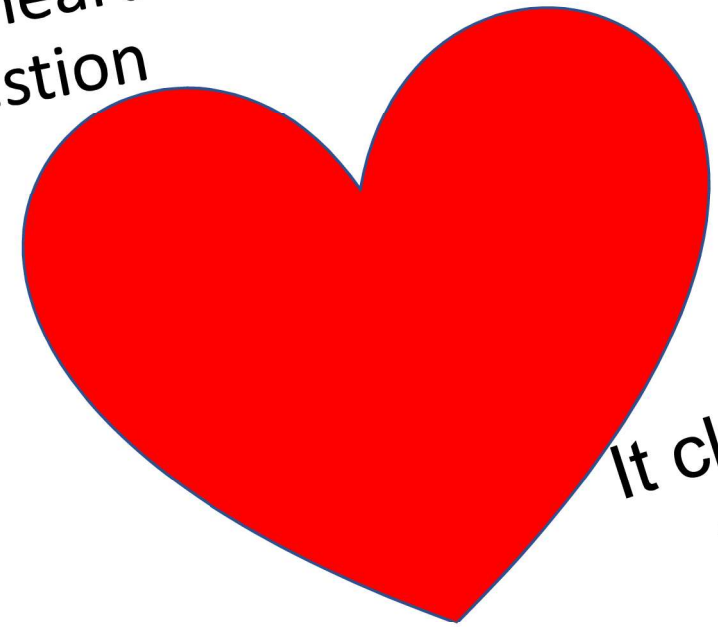
- *Background*
  - Relates the study to the literature about a topic, filling in gaps and extending prior studies.
  - Shares results of other studies related to the study being described.
  - Provides a framework for comparing the results of the study with other findings.

- Must clearly identify the problem you are studying
  - How widespread is the problem?
  - Who is affected by the problem?
  - How often does the problem occur?
  - What social or cultural practices are associated with the problem?

- *Rationale*
  - Why is the research important?
  - How it will contribute to the body of knowledge about the subject matter?

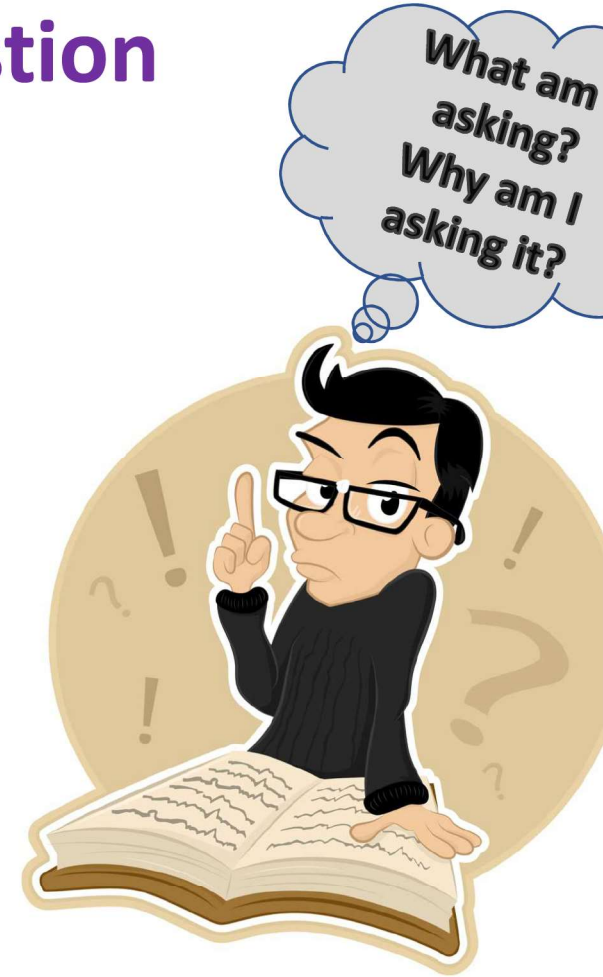
Research problem / research question

he problem is the heart
f the research question



It clarifies the goals
and directions of
your research

Research problem / research question



- Problem to study:
  - Want to study how effective it is to offer care and treatment services to HIV+ pregnant and lactating women in MNCH services
- Ask more detailed questions . . .
  - How do you define effective? What would you measure?
- Refine the problem statement:
  - Want to study how effective it is to offer care and treatment services to HIV+ pregnant and lactating women in MNCH services *to improve CD4 monitoring and ART initiation*

Research question

- Research question
  - How effective is offering care and treatment services to HIV+ pregnant and lactating women in MNCH services in improving CD4 monitoring and ART initiation*?*

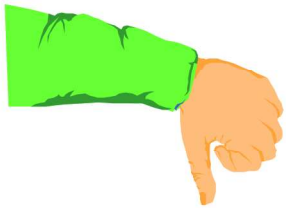
- Revised research question
  - How effective is providing HIV care and treatment services for pregnant and lactating women in MNCH clinics in increasing the number of women who are screened for HIV eligibility by CD4 count and if eligible are initiated on ART compared to referral to an HIV care center for screening and ART initiation?

Study Objectives and Specific Aims

- State your research objectives in clear and concise scientific language
  - include subject population, endpoint measurements, and research hypotheses, if any.
- State both the primary and secondary objectives.
- Be sure the research objectives are consistent with your research methodology and data analysis sections.

Study Objectives and Specific Aims

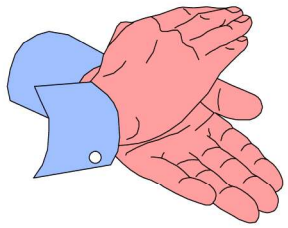
To determine the impact of zinc administered to children with acute diarrhea on its outcome.



Imprecise

determine the impact of 10 mg oral zinc administered as a single daily dose to children aged 6-24 months for 6 nths with acute diarrhoea on duration and severity of the episode

ool output, episode duration and need for intravenous fluids)



Precise

Methods – research design

- Different questions – Different design
- Depending on the research questions you want to answer, decide whether you want data in the form of:

.

Numbers and statistics (Quantitative)

Words, pictures and objects (Qualitative)

Methods – research design

- Non-intervention (Observational): observes, analyses; no interference
  - ✓ Exploratory ; Descriptive ; Analytical (comparative)

- Intervention (Experimental & Quasi-experimental): manipulates, tests, assign one or more variables to examine effects

.

Research protocol content

Methods – research design – Non-intervention : exploratory studies

Small scale, limited duration study, where little is known about the situation

May include *description* as well as *comparison*

Exploratory study examples –

- The program wants to improve counseling services for adolescents living with HIV. What specific needs for support do adolescents living with HIV have?
- Why are women not delivering in the health facility?

Comparisons may be useful, i.e. compare extreme groups

Triangulation. Exploratory studies gain value through examining the situation from different perspectives/approaches

Research protocol content

Methods – research design – Non-intervention: descriptive studies

Describe the characteristics of the situation, event or case

Small scale descriptive studies. Describe in-depth the characteristics of one or limited number of cases

- Case studies, case series

Large scale cross-sectional surveys. Describe and quantify variables of interest at a point in time

Research protocol content

Methods – research design – Non-intervention: comparative studies

Cross-sectional comparative studies

Case-control studies (incident, prevalent cases)

Cohort studies (prospective, retrospective)

Cross-sectional comparative studies. Many cross-sectional studies focus on describing as well as comparing groups

Research protocol content

Methods – research design – Intervention studies

Experimental. Manipulation, randomization, control group

- Individual or cluster randomization
- Step-wedge

Quasi-experimental. Manipulation, **No randomization** may or may not have a control group

Research protocol content

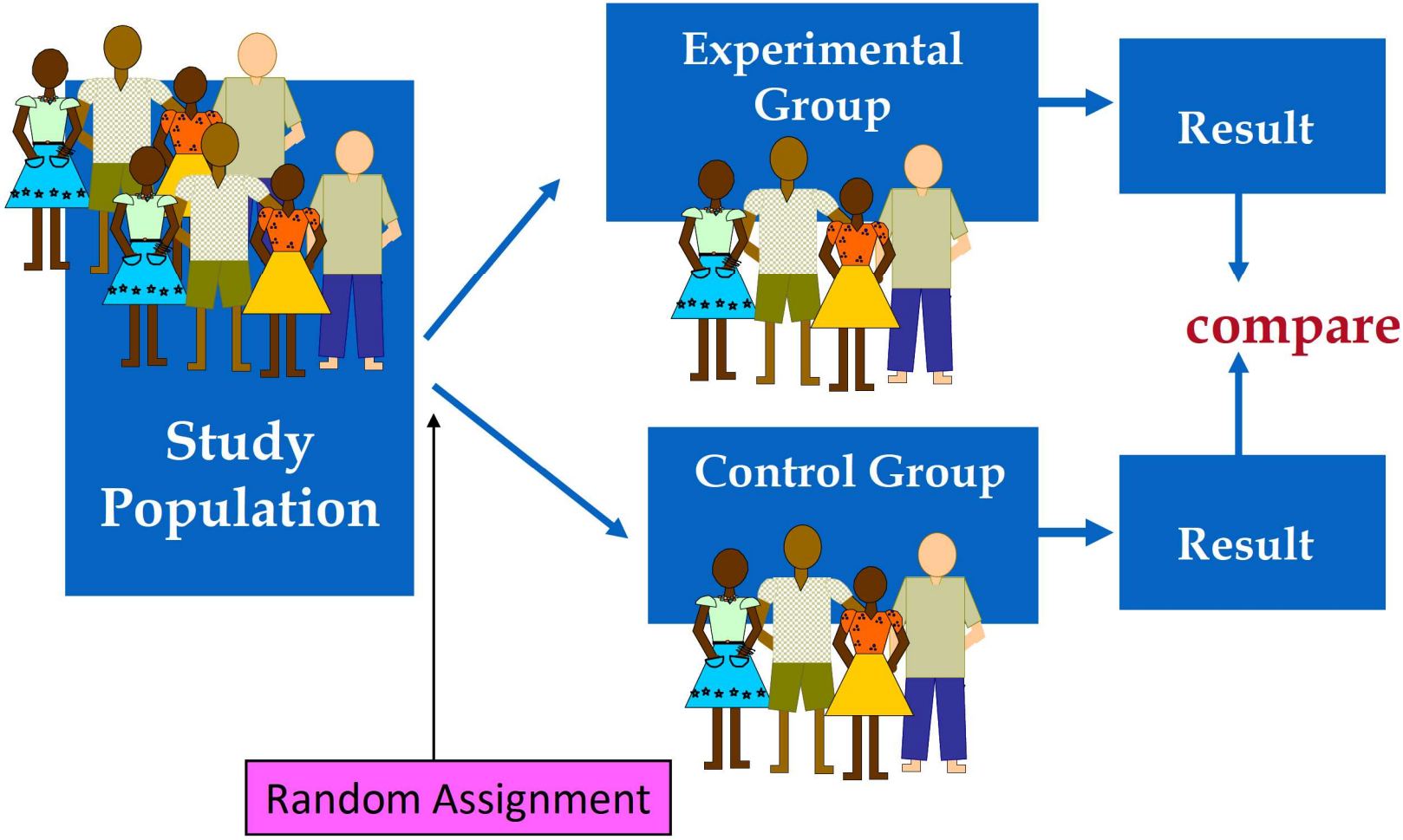
Methods – research design – Intervention Experimental Studies

Experimental. Manipulation, randomization, control group

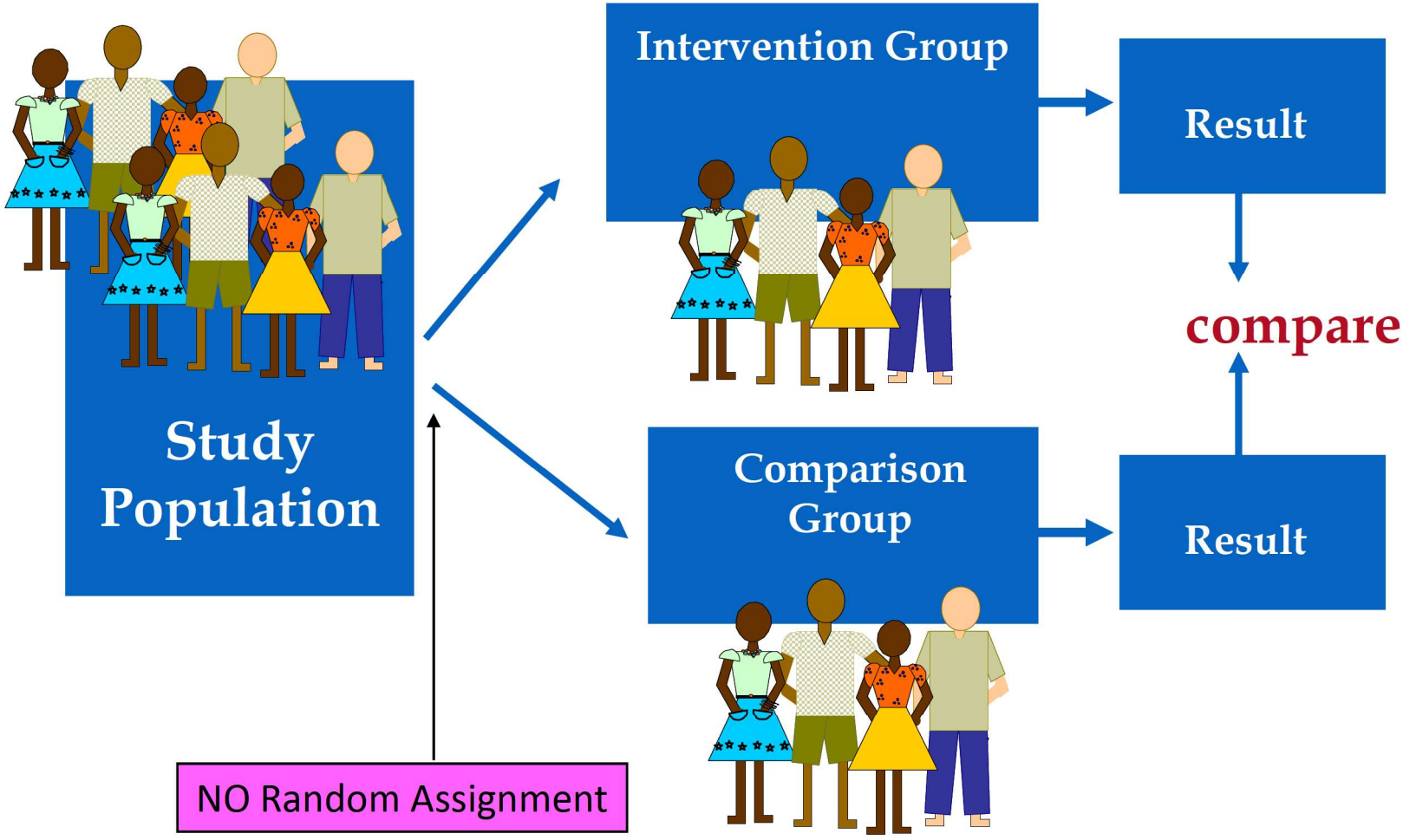
- Individual or cluster randomization
- Step-wedge

Quasi-experimental. Manipulation, **No randomization** may or may not have a control group

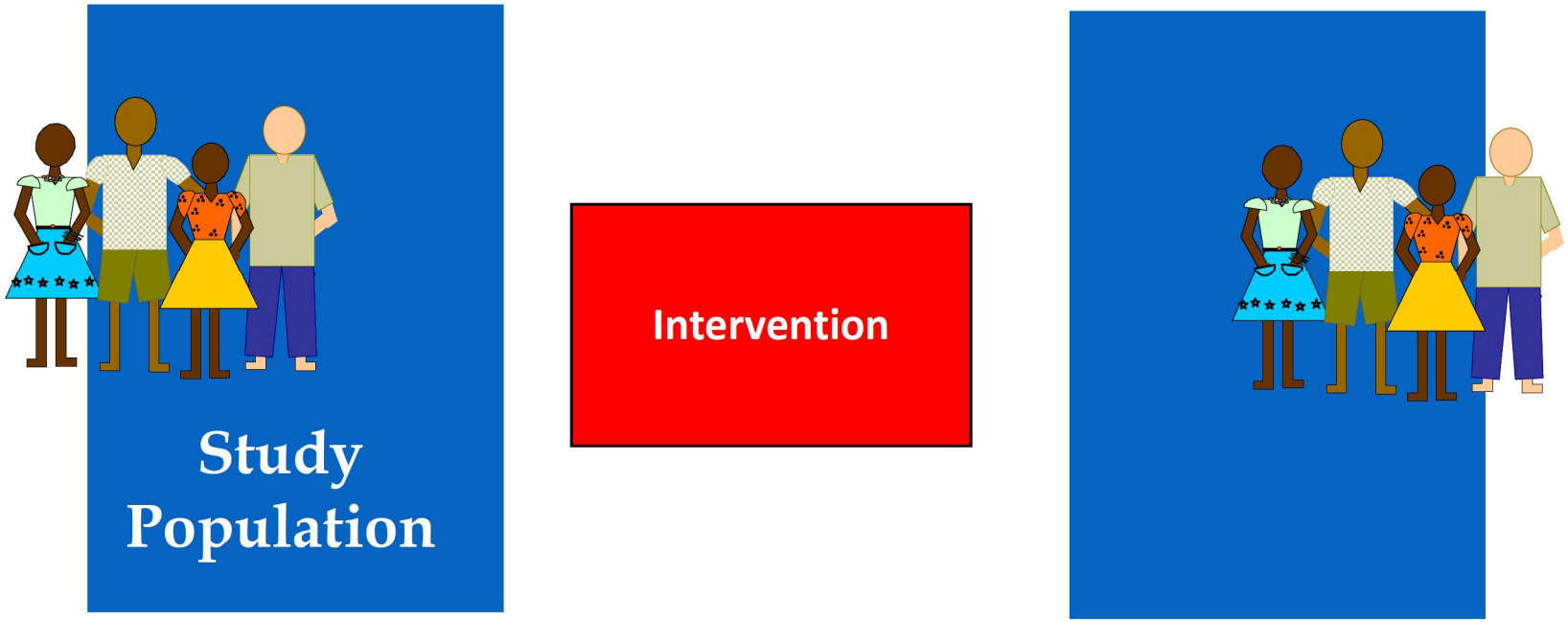
Experimental studies



Quai-Experimental studies / Non-randomized studies



Pre-Post test design



Research protocol content

Methods – research design – Impact Evaluation

Measures effectiveness of an intervention(s) or program(s) at a community or population level

Goal- causal attribution of measured outcomes to the intervention or program

Key- good counterfactual (what would have happened in the absence of your intervention)

Gold standard: Experimental design with good randomization

Research protocol content

Methods – Study population

Population

—Describe the subject population, including age, gender, and any other defining characteristics used in selecting the population.

—Explain why you have chosen this population- why is this group relevant?

— Consider how studying this population will effect interpretation of study results- generalizability, bias etc

Inclusion and Exclusion Criteria

—List the inclusion and exclusion criteria separately.

—Exclusions should not just be opposite of inclusions

—If the inclusion and exclusion criteria differ for each study group, provide them separately under a subheading or in a summary table.

Research protocol content

Methods – Study population

Overall population

- HIV+ adult men and women in care and not yet eligible for ART in resource-limited settings

Target population

- HIV+ adult men and women in care and not yet eligible for ART in the littoral region

Study sample

- HIV+ adult men and women in care and not yet eligible for ART attending services during the study period in 5 facilities in 2 districts in Douala

Research protocol content

Methods – Study location / sites

Where will the study will be conducted (country, province, city, clinic, etc.)

What are the characteristics of the sites

Why were the sites selected

How were the sites selected

Research protocol content

Methods – Study recruitment

Need to think through at protocol development- avoid bias

Recruitment strategies should be developed with local input

Need to be specific on who is introducing/ recruiting participants

If recruitment script is used, must be IRB approved!

Are there Incentives given to participate?

Recognize the challenges

- Risk of stigmatization from study association
- Risk of confidentiality
- General unwillingness or lack of time to participate

Research protocol content

Methods – Study recruitment – enrolment procedures

Describe the process for enrolling participants into the study.

Describe procedures for tracking the number of persons (records) referred, screened, and enrolled.

Explain the procedures for assigning participants to different groups, if applicable.

Describe the consent process, whether it will be written or verbal and who will conduct the consent process. Request waiver of consent if applicable.

Research protocol content

Methods – Statistical considerations

Explain how many participants you plan to recruit with an explanation of your sample size calculations for quantitative data collection.

Provide power analysis, where applicable.

Sample size estimation should also account for withdrawals and dropouts.

Qualitative studies do NOT have statistical section, but the number of subjects may be justified

Research protocol content

Data collection / Management

- What data will be collected including the measurement time points.
- How data will be collected, by whom (paper based, electronic via phones, tablets, laptops etc)
- Procedure for data entry, if applicable.
- Who will send and/or receive data and how
- What are the processes and procedures to ensure data quality.
- What is the data management system
- Who has access to the data, where will it be stored
- How will data be backed up and stored

Research protocol content

Data management & Analysis

Critical area that often is not adequate or emphasized sufficiently

- most common donors reviewers response is lack of detail in this area

During protocol development, you must plan for your data collection and analysis to ensure that you can answer your research question

Data analysis plan is important to work out prior to the analysis of data to direct the analysis, minimize bias, or data "fishing"

Need to consider any variables or factors that may impact the reliability and validity of the data, and what can be done to strengthen reliability and validity of the data.

Research protocol content

Data Analysis

Describe how the data will be analyzed / Which statistical programs will be used

Who will be doing the analysis, What is the timeline for the analysis, interir analyses?

Address statistical analysis for each objective or specific aim and include ar sub-group analyses (e.g., sex or age group).

- Specify statistical methods and variables for each analysis.
- Discuss how potential confounding variables will be controlled in the data analysis.

Research protocol content

Ethical considerations

Need to understand the requirements of the IRB(s) that will be responsible for study oversight

Outline key issues in protection of study participants

Risks/ benefits to participation

Informed consent

Confidentiality

Adverse Event documentation

Research protocol content

Standards Operational procedures

Serve different purposes

Different degree of “commitment”

Vary in content and format

Vary in length and detail

MOP = Many different SOPs

Research protocol content

Others

Limitations

Timeline

Budget

Conclusion

Operational research is an opportunity for resources limited-settings; this help to generate data that inform public health program

There is no excuse for absence of research culture ; as this is an opportunity to improve our practices

Research has non negotiable steps; this must be followed

Operational research is a great opportunity for HCW to communicate about their work conditions, advocate for better work conditions on behalf of their “patients”