Writing Study Protocol

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Writing Study Protocol

Essential Steps:

- Clear definition of research question
- Literature review
- Appropriate study design
- Source of funding or other means
- Write a study protocol.

Study Protocol

- Definition:

  A document describing a research study and summarizing the background , aim (s) and objectives, study design and methods, that will be used in the study.

- Should give sufficient details.

1.Background

- Needs to cover
  - What question will the study answer?
  - Why this question important?
  - What previous work has led up to the proposed study
  - Is the proposed study population appropriate to answer the question?
  - How will the results of the study contribute to knowledge or to the improvement of public health?

1.Background

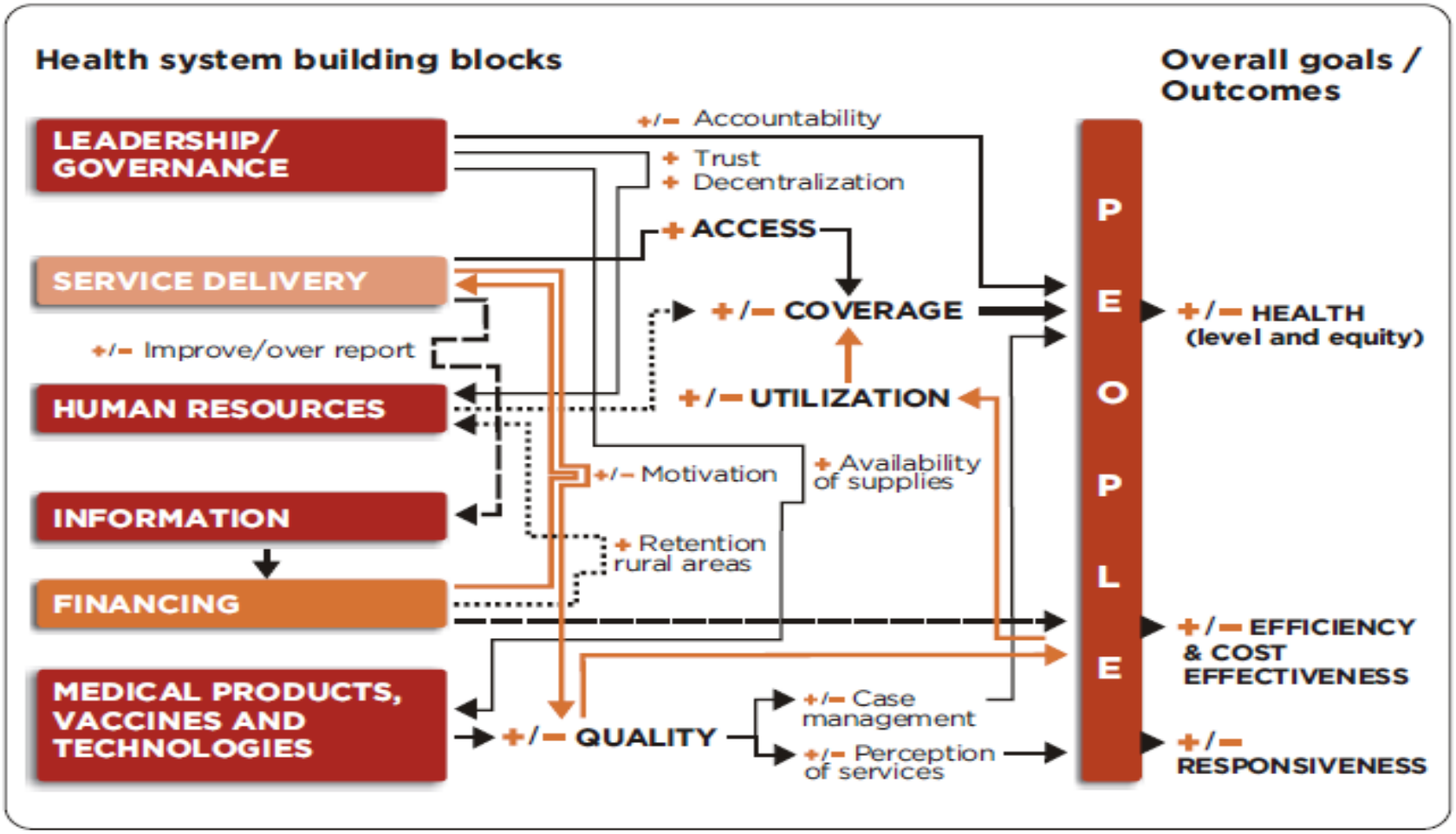
- The section should “tell a story”
- Start with justification and the work leading up to the proposed study
- Study question or hypothesis and how the results will contribute to knowledge or to public health
- Include information about the proposed site and population.

2.Aims and Objectives

- Aims
  - Statement of the overall purpose of the study (General)
- Specific Objectives
  - Make the purpose more specific
  - Give more detail about exactly what the study proposes to investigate
  - Should have a measurable outcome

Conceptual framework (optional)

Figure 3.2 Conceptual pathway for the P4P intervention using a systems perspective



3.Methods

- Outline
  - Type of study design
  - Site of study
  - Study population
  - Description of intervention
  - Main exposure(s), and/or confounders and/or outcome(s) to be measured

3.Methods

- Study population
  - Inclusion and exclusion criteria
  - Sampling
  - Randomization
- Study Procedures
  - Procedures at enrolment (inclusion and exclusion criteria)
  - Follow-up
  - Measurement of exposures and confounders
  - Measurement of outcomes
  - Laboratory methods

3.Methods

Examples

- Case control (Association between Breast feeding and risk of pneumonia)
  - Exposure (duration of BF, type of feed received..)
  - Confounders (age, educational level, type of water available..)

- Cohort Study (Effect of cigarette smoking on mortality)
  - Exposure (type of Tobacco smoked, duration of smoking..)
  - Confounders (age , socioeconomic status..)
  - Outcome measure (deaths due to lung cancer and cardiovascular disease..)
- Intervention study (Comparison of new antimalarial drug to standard treatment for falciparum malaria)
  - Main outcome measure (Mortality due to Malaria, Proportion of cases cured..)
  - Secondary outcome measure (time of clearance of parasites, time to clinical recovery..)

3.Methods

- Sample size
  - key factor with major consequences
  - Determines which outcome measures are feasible
- Data management
  - Procedures that reduce the risk of errors
  - Methods used to ensure the confidentiality of data

3.Methods

- Proposed Analysis
  - Analysis method to be used
  - Description of the analyses

Statistical tests to be used

PREDICTORS (VI)	OUTCOME (VD)		
		Categorical	Continuous
	Categorical	- Chi carré - T Test - Regression Logistique - Loglinear Analysis	- Linear regression - Discriminant analysis
	Continuous	- T Test - ANOVA - Linear regression - Multivariate Analysis of Variance (MANOVA)	- Pearson Corrélation - Linear regression - Canonical Correlation

Analysis plan for multivariate analysis

DEPENDENT VARIABLES					
INDPT VARIABLES		Dichotomous	Nominal	Ordinales	Interval ou Ration
	Dich, Nom et Ordi	Regre. Logistic	Multinomial Logistic Regr	Multinomial Logistic Regr	Multiple regression
	Interv ou Ratio	Regre. Logistic	Multinomial Logistic Regr	Multinomial Logistic Regr	Multiple regression
	Mixed	Regre. Logistic	Multinomial Logistic Regr	Multinomial Logistic Regr	Multiple regression

4.Ethical consideration

- Confidentiality
- Informed consent
- Ethical approval

5.Logistics

- Distribution of responsibilities
- Timetable
- Budget

Outline ctd…

6. References

7. Appendices

- Sample size calculation
- Patient information and consent form
- Questionnaire

Summary

- All epidemiological studies aim to answer a **main question**; the question must be clearly defined
- **Literature review** is necessary in order to establish whether or not the question has already been addressed, and if so to discover how other investigators have approached the problem
- An **appropriate study design** must be found and possible study sites chosen. Sample size should be taken into consideration
- The **source of funding** may affect the nature or design of a project.

THANK YOU.