folkehelseinstituttet

How to write a study protocol

Study protocol: What?

- Describes every step of a study
  - identification of the problem
  - application of the results

- Answers relevant questions
  - ✓Public health **problem**: Important?
  - ✓**Study question**: relevant to the problem?
  - ✓**Objectives**: consistent with the study question?
  - ✓**Study design**: achieves objectives?
  - ✓**Power of the study**: sufficient?
  - ✓Public health impact of the findings?

Study protocol: **Why?**

- To check if the objectives can be achieved
- To check the feasibility of the study
- Prevents failure to collect crucial information
- Lays down the rules for all partners
- To obtain approval of ethical committee(s)
- Application for funds
- Makes it much easier to write article

Study protocol: **How to start ?**

- Get good examples
- Get ideas from similar published studies
- Use a checklist of items to include
- Get the requested format
  (grant application)
- Share ideas with colleagues

Protocol outline

1. Presentation
2. Background and justifications
3. Objectives and research questions
4. Methods
5. Ethical considerations
6. Project management
7. Timetable
8. Resources
9. References
10. Appendices

1.Presentation

- Title
- Investigators
- Main centres
- (Steering committee)
- Summary of the protocol

2. Background and justification

- Statement of the problem, study justification
  - ✓Discuss importance of subject area
  - ✓Describe why study is necessary
  - ✓Describe the principal questions to be addressed
  - ✓Describe how study results will be used
- Review relevant literature and current knowledge

3. Objectives and research questions SMART

- **S**pecific - not “focus on ….”
- To **m**easure something (prevalence, incidence, risk increase…)
- **A**ction oriented – “in order to ….”
- **R**elevant
- **T**ime specified

Main objective

- Must be achieved
- Dictates design and methods

Secondary objectives

- Of interest, but not essential

Specific research questions

3. Objectives and research questions

Objective:

Measure the incidence of nosocomial infections in nursing homes in Norway between October 1 2004 and March 31 2005 in order to lay a foundation for improved prevention.

Research questions:

- Measure the incidence of nosocomial infections in general among residents of nursing homes
- Measure the incidence of each of the following nosocomial infections among residents of nursing homes: urinary tract infections, pneumonia and skin infections

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4. Methods

- Study design
  - ✓ what design will be used?
    (cohort, case-control, cross-sectional…)
  - ✓ brief justification
- Study population
  - ✓ selection and definition
  - ✓ appropriateness for study objectives
  - ✓ accessibility, co-operation, follow up, representativeness
  - ✓ criteria for inclusion and exclusion
  - ✓ description of mechanisms of recruitment

4. Methods

- Sampling design
  - ✓ Frame: district, household, persons,…
  - ✓ method: random, cluster, stratified,…
  - ✓ randomisation procedures
  - ✓ replacement procedures (in case of refusal)
- Sample size
  - ✓ sample size and power calculations based on principal objective
  - ✓ feasibility of recruiting the stated number

4. Methods

Data required

- Selection and definition
  - ✓ exposures: potential risk factors, protective factors, confounding factors
  - ✓ outcomes: definition of a case, definition of a control

  example:
  smoking: definition, quantification, categories
  lung cancer: case definition, definition of a control

- Items to be measured and how (scales used)

4. Methods

Data collection

- How?
  - ✓ Interview, observation, record review
- By whom?
  - ✓ interviewers: selection, training
  - ✓ level of supervision
- Tools?
  - ✓ questionnaires, recording materials (forms)
  - ✓ questionnaires: self or interviewer administered, face to face or telephone interview
- Blind data collection?
- Procedures for taking samples

4. Methods

Data handling

- Data coding
  - ✓ during data collection, afterwards?
  - ✓ by whom?
- Data processing
  - ✓ manually, by computer
  - ✓ software, hardware
  - ✓ data entry:
    - during the study, afterwards?
    - order of entry screen and structure of data base
    - single entry, double entry?

4. Methods

Data analysis

- Validation and data cleaning
  - ✓ timing: during study or later

- Data analysis plan
  - ✓ structured in terms of the specific objectives
  - ✓ dummy tables
  - ✓ from general to specific

Dummy table

Dummy-table 1. Incidence of nosocomial infections in five Norwegian nursing homes, 2004-2005.

Type	Number per month						Total	Incidence per 1000 person-days	95% ci	Proportion of all infections
	Sep	Oct	Nov	Dec	Jan	Feb				
Urinary tract infection	21	10	6	11	14	15	77	0.60	0.48-0.76	23 %
Pneumonia	4	8	8	8	8	12	48	0.38	0.28-0.50	14 %
Skin infection										
Other										
Total	54	48	53	61	39	82	337	2.6	2.4-2.9	100 %

Why a data analysis plan ?

- Prevents collection of data that will not be used
- Prevents failure to collect crucial information
- Better estimates of sample size for analysis of sub groups

4. Methods

Pilot studies, pre-testing

- No study should ever proceed without a test
- Describe how to test
  - ✓ Feasibility of sampling
  - ✓ Data collection, measurement methods
  - ✓ Questionnaire

4. Methods

Validity (limitations, weaknesses)

- Identification of potential sources of biases
  - ✓ confounding
  - ✓ selection bias
  - ✓ information bias
- How to deal with them
  - ✓ In design
  - ✓ In analysis

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5. Ethical considerations

- Informed consent
- Confidentiality, anonymity?
- Data storage and protection
- Ethical review committee
- Data protection inspectorate

6. Project management

- Participating institutes and persons
- Responsibilities and tasks of each partner
- Quality assurance
  - ✓ compliance with protocol
  - ✓ problem identification
  - ✓ distribution and maintenance of material
- Data ownership

7. Timetable

Planning/organisation of the study

- questionnaire design, recruitment, purchases
- permission
- obtain funding

“Pilot study”

- testing of methods and questionnaires
- adjust procedures as result of pilot

Final study

- data collection
- analysis
- presentation of results and write up

8. Resources

- Extent of this section will depend on target audience
- Specify
  - ✓ available sources
  - ✓ requested sources
- Keep budget
  - ✓ reasonable
  - ✓ detailed
  - ✓ well justified

9. References

- Limit number of references to key articles
- Follow recommended style

10. Appendices

- (Methodological appendices)
- Questionnaires
- Variable list with definitions
- Introductory letters to study participants
- Forms for informed consent

…..

Common problems

- Too ambitious: too many questions
- Insufficient attention to previous literature
- Poor justification
  - ✓ why is it important to answer this question?
  - ✓ what impact does it have on public health?
- **Poorly formulated objectives! Unspecific.**
- Inappropriate analysis
- Inadequate description
- Absence of pilot or test

Study protocol: and now….

- Good Luck !