Protocol design and critical appraisal of epidemiological studies

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- Pubmed search

Key steps in conducting medical research

- 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?

Key steps in conducting medical research

- Inform interested parties
- Write the protocol
- Obtain ethical approval
- Obtain funding
- Register under the data protection act
- Develop the data processing
- Pilot all stages
- Review the design

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

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

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1.Presentation

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

Background:

- Sets the scene for the proposed study
- Briefly describe work in the area
- Outlines the gap in knowledge which require further research
- It is not necessary to provide comprehensive literature review. Instead this section should explain why there is an urgent need for the new study

Aims and objectives

- Aims is subjective statement to describe what you wants to achieve by conducting this study

- Objectives: something you can measure or assess

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4. Methods

- Study design
  - ✓ what design will be used? (cohort, case-control, cross-sectional…)
  - ✓ brief justification

- Eligibility criteria:

Inclusion and exclusion criteria

- Study population

  - ✓ 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

  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

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

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