Design and planning of epidemiological studies

The outline that follows is a checklist of issues which may require consideration in the planning and organisation of an epidemiological study. The list is not comprehensive; each different study is likely to present its own special problems; it will probably present aspects not covered in this list, while also not every item on the list here will apply to every study. The main section headings (Roman numerals) are in the order in which they might appear in a grant application.

Note that this list is intended basically as an aide-memoire; as has been said, you will not need to cover every item in the list by any means, but it is advisable to check with yourself that to decide that any of them is not relevant is reasonable.

I REASONS FOR STUDY (BACKGROUND)

Most important aspect of the design of a study.
Summarise (succinctly and with appropriate references) what is already known about the subject area to be investigated. Consult "experts", review literature.
Discuss only that which is directly relevant to the overall aims of the proposed study.
State why it is necessary to conduct the study and how it will add to existing knowledge.
A simple check list is-

- What are the immediate objectives?
- What are the long term goals?
- What specific hypotheses will be tested?

If the study cannot influence future action or research, question seriously whether it really need be done. Many studies have been conducted that should never have been started!

II OVERVIEW OF STUDY DESIGN

One must describe adequately:

1. Detailed specification of aims, objectives and specific hypotheses.

The more clearly stated and specific are the objectives, the easier it becomes to plan the study.

2. Type of study (Cross-sectional, longitudinal, case-control, etc).

Discuss suitability with other epidemiologists and statisticians. There must be a brief justification for the design chosen.

3. What is the population under study.

4. Outline of data to be collected.

III DETAILED DESIGN (METHODS)

This is the heart of the proposal, in which the methods and the techniques to be employed in the study should be clearly and unambiguously described.

1. Population to be studied

Appropriateness for study objectives - background information on the population
Representativeness (generalisability of findings)
Cooperation
Accessibility - travel time and cost
Availability of support facilities
Stability - implications for any follow-up or re-survey.

2. Sampling

Sampling units (study population) - persons, households
Sampling frame, study population.
Need, if any, for initial census
Sampling methods - sample random/cluster/stratified/etc.
Or, methods of selecting cases and controls
Precise specification of criteria for exclusion and inclusion - clear cut rules
Action in event of refusal or non-response
Detailed instructions to persons selecting sample (where relevant)
Randomisation procedures (where relevant)

3. Data requirements

Need for and scope of qualitative work.
For quantitative work:-
What items will be measured?
How measured? - scale used (continuous, categorical)
Essential minimum items - tolerable maximum (don't "overload" study)
Implications of errors and variation
Accuracy vs practicability

4. Sample size

What level of precision is required for estimates?
What is the expected size of differences to be measured?
What is the minimum difference we wish to be able to detect?
What is the expected variance of data'?
What power is required?

5. Data collection methods (for quantitative data)

Design of questionnaires (self or interviewer administered? How highly structured?)
Instructions to interviewers
Specification of methods of measurement, eg for anthropometry, blood pressure, etc
Blind, double blind?
Sources of error and variation (see also bias, below)
Design collection for data processing
Quality control - initially and during survey (equipment, people)
Variation between interviewers
Recording materials - forms, cards etc
Identity of individuals - registration cards, follow-up
Flow chart for data collection in field.
How many interviews per day?
Monitoring for unexpected effects (eg side effects of drugs)
Handling of specimens

When, where, how collected
Labelling and recording
Storage and transport - consult laboratory scientists
Processing - "blind" reading - batch analysis
checking by duplicate samples.

6. Sources of bias

Non-response - substitutions do not remove bias
Interviewer variation
Measurement errors
Non "blind" examination

IV LOGISTICS

Adequate staff with appropriate skills and time available
Flow charts and time charts
Equipment checklists
Anticipate action in event of illness, vehicle breakdown etc

V PILOT STUDIES

What aspects of study need pilot investigation
Anticipate design changes as result of pilot
Do not rush into main study too soon

VI DATA PROCESSING AND ANALYSIS

Involve statistician at the planning stage of study - not just for analysis
Processing and linking of forms and questionnaires
Coding - how? who? where? when?
Validation and data cleaning
Timing - during study or later - keep close to your data
Format of tables - mock tables

VII REPORTING

Detailed report for permanent record
Concise report(s) for publication
Authors

VIII LONG-TERM PLANS

Storage of questionnaires and data recording forms (with codes!)
Storage of specimens (eg serum)
Possible follow-up investigations

IX ETHICAL CONSIDERATIONS

1. Ethical committee review

2. "Informed consent"

3. Individual vs community considerations

4. Confidentiality - record anonymity/data storage

5. Political, social and economic considerations

X TIMING

1. Planning/organisation Prepare protocol Design forms

Recruit and train staff
Obtain equipment (tents, food, vehicles, spare parts, test tubes, drugs, printed questionnaires etc)
Get permission for study.
Ethical.
Local and/or national administration.
Potential participants (informed consent).
Obtain funding (often a long process!)

2. Pilot study

Train staff
Test methods - eg validate questionnaires
Adjust procedures as result of pilot

3. Final study

Complete preparations
Fieldwork and data collection.
Overall timing, including travel time, holidays, allowance for staff sickness.
Consider possible "disasters" (eg early rains, investigator sick)
Follow-up
Analysis (data preparation, computing)
Write up
Publication lag

XI STAFF

1. Definition of jobs

Number required - field, laboratory, office
Age, experience, qualifications
Salary

2. Recruiting and selection

Personal contacts

Advertising
Interview and other selection methods

3. Training

4. Duration of employment - careers structure

5. Consultants and Advisors

XII FINANCES

1. Source of funds

2. Complete budget - capital and recurrent costs

Salaries, Travel, Equipment, Petrol, Printing, Stationary, Postage, Telephone.
Fees for services - consultants, laboratory tests
Computing
Flexibility for unexpected additional costs.
Contingency (if allowed).
(All items require full justification)

3. Inflation, devaluation.