

SCHOOL OF PUBLIC HEALTH

Designing a Study

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1. Developing and refining a research idea

Ideally your research idea should come from an area in which you have interest and expertise. Once you have an idea about which you are excited, it is essential to do a full literature search and read all available published and unpublished information relevant to the topic to ensure that the study has not been done previously and to find out what is known and what research questions still need to be answered. Select the major studies which have contributed to current knowledge. Note their strengths and weaknesses. Take note also of the deficiencies of other studies which have failed to deliver any useful information – you don't want to make the same mistakes! Discuss your ideas with others working in the area of interest and incorporate their comments.

Having formulated your idea, be prepared to justify it. Why is it a good idea? Support it by the published evidence you have found. Think about whether and why the research is worth doing. Consider the likely consequences if the outcome of your study is positive, negative or inconclusive. Will others be interested in your results? Think about the possible practical applications of your results. Are the results likely to influence others? Will they increase understanding of health related phenomena? Who will benefit and in what way? Is your research internationally relevant or concerned with local issues and problems?

2. Developing hypotheses and research questions

State the hypothesis, or the objective of the study. What are the research questions that need to be answered in order to support/reject the hypothesis or meet the objective? List the research questions, preferably in a form which can be answered by YES or NO, or by a 'figure' (eg. rate, relative risk). They should be expressed in sufficient detail so as to make the study strategy and analysis methods obvious. It should be clear from the objective whether you are concerned with describing the magnitude of a health problem, evaluating an intervention or testing a causal hypothesis. The magnitude of effect that it would be important to detect should be stated. Be suspicious if there are more than 3 research questions – it could mean that the hypothesis/objective of the study is too broad or vague.

3. Study strategy (type of design)

Decide on the most appropriate study strategy. This will be determined by the research questions, and influenced by available resources (time, money, people, equipment). Consider alternatives and list their advantages and disadvantages. Is your chosen strategy feasible?

4. Methods

i) Study subject selection and participation

Explore the conceptual basis on which study subjects are selected and decide on the appropriate methods. This step is especially important in case-control studies. Determine the eligibility criteria for inclusion in and exclusion from the study.

Detail the procedure for the enrolment/recruitment and follow-up of subjects. What is the anticipated response rate and what will be done to maximise response? Consider the likely sources of selection bias and how they will be dealt with. What will be done about non-responders and subjects lost to follow-up?

ii) Sample size

Determine the sample size required to have a good chance (power) of detecting as statistically significant the magnitude of effect specified in the research questions. Alternatively determine the sample size required for a confidence interval of the desired magnitude.

iii) Generalisability

Can the results be generalised to other populations? By what criteria can this study population be compared with others in the literature?

iv) Measurement techniques

List the variables to be measured, specifying the outcome and study factors, and potential confounding variables which need to be considered. How SHOULD the variables be measured? How CAN they be measured? Decide on the best alternative, based on the required validity and repeatability of the measures, the appropriateness to the study, and costs. Is an appropriate measurement method available or will one have to be developed? When measuring events (eg. cardiovascular death, work-related injury, episode of acute respiratory infection), define the criteria, and describe how the event will be detected.

Describe the measurement tools, giving details of who will administer them and when, where, and how they will be used. What are the potential sources of measurement error and how will measurement error be minimised? How will the validity of the measures be determined? What steps will be taken to minimise differential and non-differential measurement error?

5. Data analysis

How will the data be analysed to answer the research questions? What statistical methods will be used? How will adjustment be made for confounders?

Data to be computerised will need to be edited, coded, entered and cleaned. What facilities (eg. computer – mainframe or micro, which software) will be necessary, and where and by whom will the analysis be done?

6. Ethical Considerations

What ethical issues need to be considered? Are the subjects likely to benefit from the study, and, if not, are the risks to them negligible? Consider informed consent, freedom from assault, confidentiality, freedom to withdraw from the study without loss of care, and external monitoring of quality of care and emerging results. It is in the interests of ethics that the study will be well-designed.

7. Study procedure

Draw up a plan of the study, showing the different stages and indicating how much time is needed and which personnel will be involved at each stage. Define the role and tasks of each

team member. Consider the time necessary for selection and training of data collectors. How will you monitor the progress of the study, and how will quality control be ensured? What are the criteria for the success of the study? Other important preliminary activities are approaching the population and publicity of appropriate.

Determine what pilot studies need to be done? Each pilot study should have specific objectives. For example several pilot studies may need to be done when developing measuring instruments (eg. questionnaires). Pilots may be necessary for each of the following:

- qualitative testing of how subjects perceive the issues we wish to measure
- testing readability and acceptability
- excluding redundant items
- testing methods of reducing non-response
- 'dress rehearsal' of final procedures

8. Budget and administration

List the major budget items – personnel, equipment, maintenance, data analysis, transport and communications, stationary and printing, etc. Allocate costs and be able to justify each item. Add a safety factor to take account of extra time and unanticipated costs. Consult someone experienced in drawing up budgets for advice. Who will be responsible for co-ordination and supervision of the study – overall and on a day-to-day basis?

SOME OTHER ISSUES

1) Research protocol writing is a cyclical process

THIS IS A VERY IMPORTANT THING TO REALIZE

You will find that you often go 'back to the drawing-board' during the development of a study protocol. For example, you may find your idea has been adequately addressed in the literature, or is infeasible because of extravagant sample size requirements, absence of measuring instruments, costs, anticipated poor response rates, etc. You should expect this and be prepared to cycle back to prior steps many times during the process before you finally reach a satisfactory research objective and a method of achieving it. In some cases, you may not reach this outcome and will have to 'abandon ship' and explore alternative ideas. This cyclical process is encompassed in the flow-diagram on page 6. When the protocol is complete, continue this cyclical process of development by checking that all items you propose to measure relate clearly to the research objective/questions.

2) Use consultants

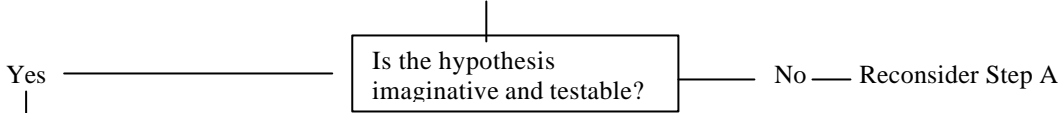
You should think about whether you need to consult an expert at each stage during the development of your research study, perhaps for general comments, or for advice and guidance on a specific methodological or technical issue. Let the consultant know in what area you are seeking advice and the time-deadline to which you are working. State whether you are at the 'early ideas' stage or close to finalising the protocol. If the consultant suggests meeting, find out if you should send a copy of some material or if there is anything that you can do beforehand to make the most efficient use of both your and the consultant's time.

ITERATIVE PROCEDURE

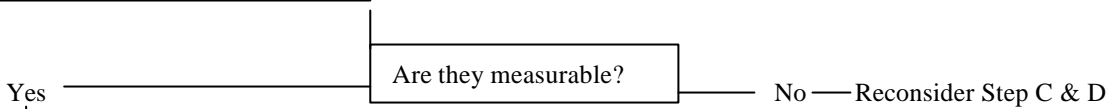
A Decide on the research problem

B Examine existing data

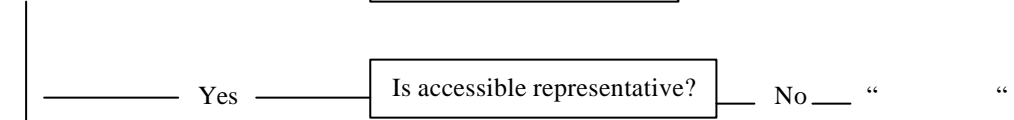
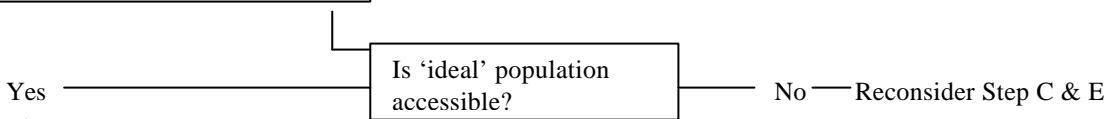
C Define study objectives and hypothesis



D Define variables to be measured



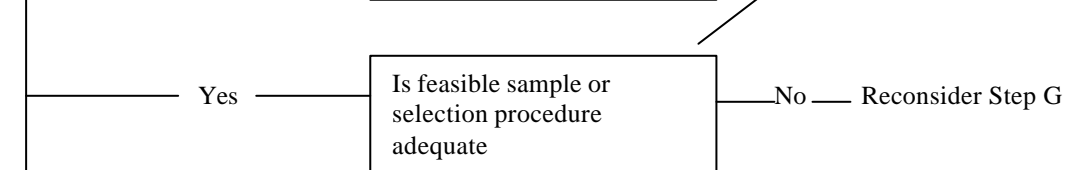
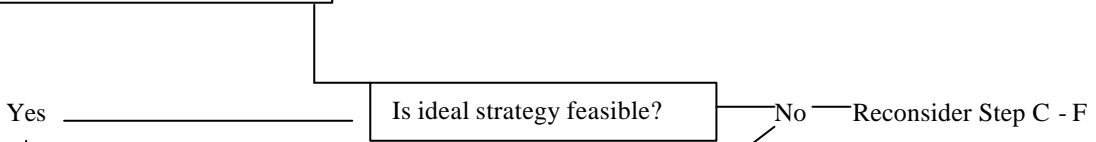
E Decide on target population



F Select appropriate research strategy

Define time frame

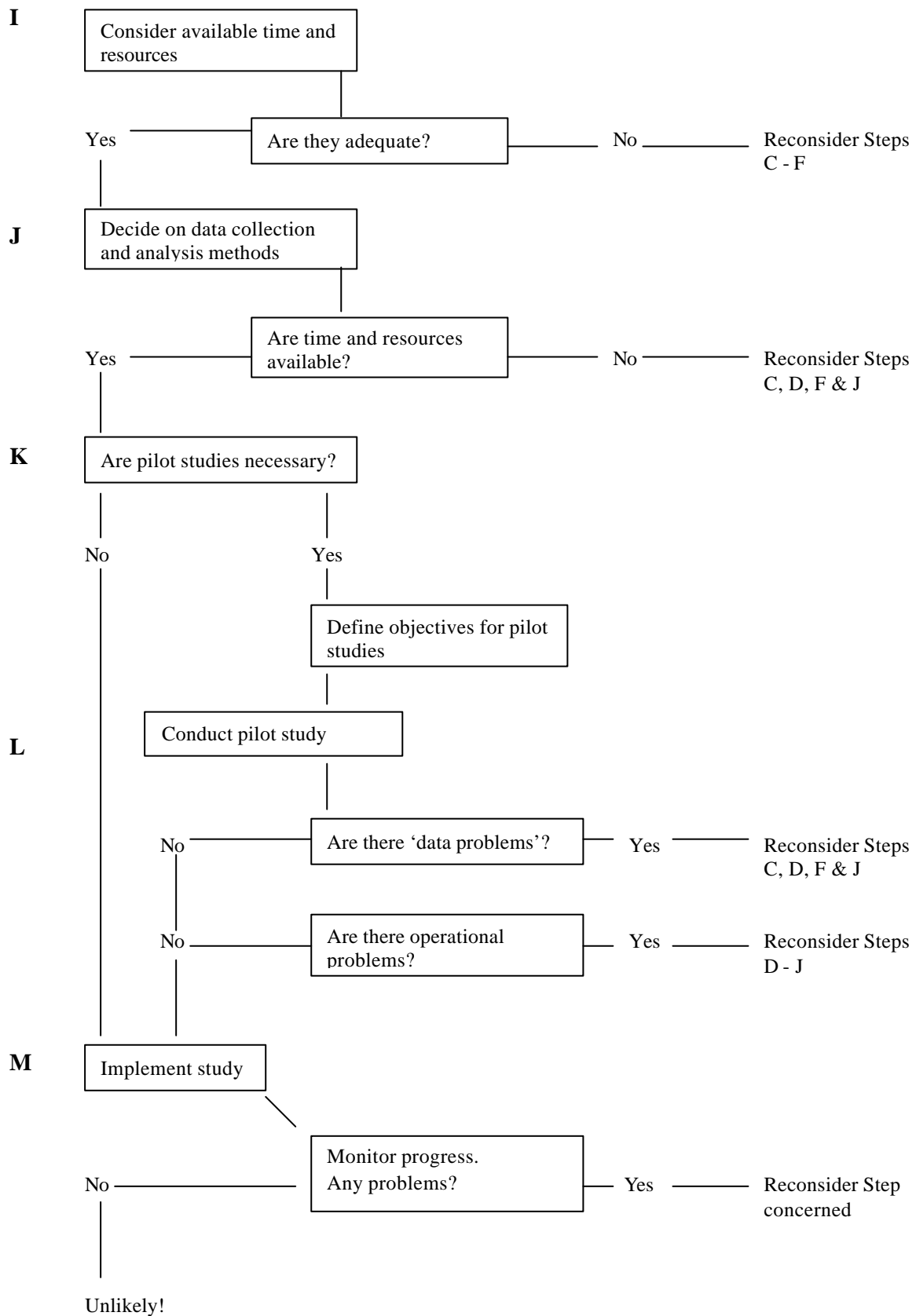
G Define sampling or selection strategy



H Calculate required sample size

Are the resources adequate to cope with this? — No — Reconsider all previous Steps





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