Designing Study Documents

Dr. Claire Collins
Director of Research
ICGP

Research

- More than simply asking someone a few questions
- It’s a multiple step process with a clearly defined protocol at each step

Bad research

- Failure can occur at a number of stages – planning, sample selection, data collection, data entry, analysis etc.

- Purpose here is to help avoid failure at data collection:
  - Poorly asked questions/Leading questions
  - Ethical issues due to consent/information

Minimize measurement error and reduce non-response by ensuring questionnaire constructed so that:

- Respondents are motivated to complete it
- Questions are clear and concise
- Respondents can easily understand how to complete each question
- Instructions re sections to complete/skip are obvious
- Returning the questionnaire is easy

Different Questionnaire Designs

- Different depending on use
  - Telephone interviews - short
  - Self administered - easy to follow & complete
  - Interviewer administered - longer, more detailed but need interviewer instructions

Before the Questionnaire

- Research Idea & Objectives
- Statement of the Research Problem
- Areas/Subjects
- Hypotheses
- Knowledge Required for each hypothesis
- Questions

The Questionnaire (1)

- Obtain all & only the relevant information
- Should be easily administered i.e. flow
- Clear and detailed instructions
- Format and sequence of questions is crucial
- The wording of questions is vital
- A pilot is always necessary

The Questionnaire (2) Wording of questions

- Easy to understand
- Ask one question at a time
- Should not be leading
- Avoid negatives
- Length of question
- Response categories
  - Exhaustive (all possible answers covered)
  - Mutually exclusive (no overlap)
- Avoid vague phrases

The Questionnaire (3)

- Mix of open and closed questions
  - Avoid too many open questions if possible
- Ease-in and Ease-out
- Sensitive questions to the middle
- Categories
  - Should they be called out
  - Prompt cards
- Scales/Composite scales

Need to consider

- Data coding
- Data checking/editing on receipt
- Missing and Inconsistent data
- Skips
- Reliability Checks
- Reverse Engineering (work back from tables etc. required for the write-up)

Consent Forms

- Must be clear what the respondent is consenting to
- Detail what involvement entails
- Specifically request access to additional information e.g. medical records
- Request future contact if necessary
- Give respondent a copy
- Adequate opportunity to read before signing
- Get a signature and printed name/label
- Researcher should also sign and date

Information Leaflets (1)

- Copy to be given to respondent

- Intro to Topic and Purpose of Research
- Who doing/funding the research
- What involvement entails
  - Procedures
  - Duration
  - Location

Information Leaflets (2)

- Identify any procedures which are experimental
- Disclosure or alternative procedures/courses of treatment
- Risks and Benefits
- Cost to respondent
- Compensation – participation/injury

Information Leaflets (3)

- Participation voluntary
- Right to withdraw
- Effect on usual care
- Sample size
- Confidentiality of records
- Treatment of questions
- Give contact details
- Results

Other Documents

- Covering Letters – which headed paper; who signs
- Return Envelopes
- Reply Paid/Freepost system
- Mark-Back List
- Response Record

Pretest and Pilot

- Pretest
  - Ask your colleagues to look at all forms and comment on them
  - Ask your colleagues to complete the forms
- Pilot
  - On a small sample of your population
  - Checks reliability and validity
  - Practice run and Test
  - Problems with wording or instructions / cost / response

Remember

- Remind yourself continuously of the research aim and objectives

- Pay attention to detail
  - Layout and Presentation
  - Spelling