Summary
Week 3 part 1:
Questionnaires and surveys design

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Questionnaire design

- Clarify the nature of the research problem and objectives.
- Develop research questions to meet research objectives.
- Define target population and sampling frame.
- Determine sampling approach, sample size, and expected response rate.
- Make a preliminary decision about the method of data collection.

A well designed questionnaire

- Good appearance (easy for the eye)
- Short and simple
- Relevant and logical

  ⇒ High response

  ⇒ Easier to collect
  to summarize
  to analyse

- Minimises potential sources of bias

Questionnaire design

Questionnaire Construction

- **Should be written after the analytic plan is developed and should be designed to collect the information required to perform the desired analyses**

- **Self-administered vs. interviewer administered**

- **Appealing to the eye and easy to complete and code.**

Questionnaire appearance affects response rate as well as the ease of data summarization and analysis

Broad Considerations:

- Sequencing of questions
- Identification of concepts
- How many questions are required to capture each concept?
- Question wording
- Overall length of questionnaire
- Placing of sensitive questions
- Ability of respondents
- Level of measurement
- Open-ended versus closed-end questions

Questionnaire Design – Typology of a Questionnaire:

- Determine the types of questions to include and their order.
- Check the wording and coding of questions.
- Decide on the grouping of the questions and the overall length of the questionnaire.
- Determine the structure and layout of the questionnaire.

Structure of a questionnaire

1. Identification
2. Interview introduction
3. Instructions on how to answer
4. Questions
5. Conclusion

2 – Introduction

- Covering letter/ interview introduction
  - Who are you / you work for
  - Why are you investigating
  - Where did you obtain the respondent's name
  - How and where can you be contacted
  - Guarantee of confidentiality
  - Length of interview (be honest)

⇒ usefulness of study should be clear to all respondents

3 – Instructions

- Minimise potential sources of bias
- Guide for Interviewers
- Guide for Respondents in self-administered questionnaires
  - Which questions can be skipped => where to jump to
  - Selection of multiple answers possible
- Use different fonts (e.g. **bold** or *italics*)
- **Interviewer guidance manual helps to reduce bias and to improve reliability**

Example: I will ask you a few questions about your family history of type II Diabetes Mellitus .

You will answer by yes or no

If no, go to question 27

Presentation and layout

- Clear and consistent
- adequate space to answer
  - large font size
  - appropriate page breaks
- avoid
  - messy layouts
  - too many and fancy logos
- printing questionnaire on coloured paper may help

4.2 – Question order

- Decide on the order of items/questions
  - easy → difficult
  - general → particular
- Group questions by topic
- Be aware of ordering effects
- Don't put the most important items last
- Where to place sensitive questions?

Order of Questions

- Most important questions go first
- Controversial questions should be positioned after less controversial questions

Starting questions

- “Door-opener”
- Simple
- Closed format
- Relevant to main subject
- Non-offending
- Demographic but personal questions

4.3 – Format of questions

- Adjust to responding audience
  - professionals vs. public
  - Educated vs. illiterate
  - Keep sentences simple and short
- Define key words (“fully vaccinated”)
- Remember options
  - “don’t know”
  - “don’t want to answer”

Steps to design a questionnaire:

1. Write out aims, objectives primary and secondary outcomes of your study.
2. Write out concepts/information to be collected that relates to these aims.
3. Review the current literature to identify already validated questionnaires that measure your specific area of interest.
4. Compose a draft of your questionnaire.
5. Revise the draft.
6. Assemble the final questionnaire.

Step 1: Define the aims of the study

- Write out the problem, aims, objectives, and primary and secondary outcomes using **one** sentence per point.
- Formulate a plan for the statistical analysis of each aim.
- Make sure to define the target population

Step 2: Define the variables to be collected

- Write a detailed list of the information to be collected and the concepts to be measured in the study. Are you trying to identify:
  - Attitudes
  - Needs
  - Behavior
  - Demographics
  - Some combination of these concepts
- Translate these concepts into variables that can be **measured**.
- Define the role of each variable in the statistical analysis:
  - Predictor
  - Confounder
  - Outcome

Step 3: Review the literature

- Review current literature to identify related surveys and data collection instruments that have measured concepts similar to those related to your study's aims.
- Saves development time and allows for comparison with other studies if used appropriately.
- Proceed with caution if using only a subset of an existing questionnaire as this may change the meaning of the scores. Contact the authors of the questionnaire to determine if a smaller version of the instrument exists that has also been validated.

Step 4: Compose a draft :

- Determine the mode of survey administration: face-to-face interviews, telephone interviews, self-completed questionnaires, computer-assisted approaches.
- Write more questions than will be included in the final draft.
- Format the draft as if it were the final version with appropriate white space to get an accurate estimate as to its length – longer questionnaires reduce the response rate.
- Place the most important items in the first half of the questionnaire to increase response on the important measures even in partially completed surveys.
- Make sure questions flow naturally from one to another.

Step 5: Revise

- Shorten the set of questions for the study.
- If a question does not address one of your aims, discard it.
- Refine the questions included and their wording by testing them with a variety of respondents.
  - Ensure the flow is natural.
  - Verify that terms and concepts are familiar and easy to understand for your target audience.
  - Keep recall to a minimum and focus on the recent past.

Step 6: Assemble the final questionnaire [1]:

- Decide whether you will format the questionnaire yourself or use computer-based programs for assistance:
  - SurveyMonkey.com
  - Adobe Live Cycle Designer 7.0
  - GCRC assistance
- At the top, clearly state:
  - The purpose of the study
  - How the data will be used
  - Instructions on how to fill out the questionnaire
  - Your policy on confidentiality
- Include identifying data on each page of a multi-page, paper-based questionnaire such as a respondent ID number in case the pages separate.

Assemble the final questionnaire [2]:

- Group questions concerning major subject areas together and introduce them by heading or short descriptive statements.
- Order questions in order to stimulate recall.
- Order and format questions to ensure unbiased and balanced results.

Ethical issues

- Some service should be a part of any survey
- Informed consent-: Please leave the Institutional Review Board committee decided to have consent form or not.
- General statement: Only in cases of sensitive questions or permission to access medical database or investigations are required
- Confidentiality and the right place for the interview

- Remember…
- Each question in the survey needs to be justified and linked to the research objectives

5 – Conclusion

- Don’t forget to thank the interviewed persons
- Tell them when the results will be available and where

Summary: Questionnaire design

4- Pretesting: expert in the field, family member, friend, *colleagues*

More than one pre-test may be needed

Pretesting the Questionnaire

- Discover poor question wording or ordering
- Identify errors in questionnaire layout or instructions
- Determine if respondents were unable or unwilling to answer questions
- Suggest additional response categories
- Determine if questionnaire is appropriate length

Steps in questionnaire design

5. Pilot

- *Pilot it with the target group and as you intend to*

Evaluate and modify on basis of pilot

6. administer it

-Conduct survey, including protocol for maximizing response rates

Include manual

Assess response rate

A pilot test

- Is an evaluation of the specific questions, format, question
- sequence and instructions prior to use in the main survey.
- Pilot testing is a crucial step in conducting a survey. Even modest pretesting can avoid costly errors.

A pilot test

Questions answered by the pilot test include:

1. Is each of the questions measuring what it is intended to measure?
2. Are questions interpreted in a similar way by all respondents?
3. Do close-ended questions have a response which applies to all respondents?
4. Are the questions clear and understandable?

A pilot test

Questions answered by the pilot test include:

5. Is the questionnaire too long?
6. How long does the questionnaire take to complete?
7. Are the questions obtaining responses for all the different response categories or does everyone respond the same?

A pilot test

Always remember:
Even modest edits can avoid costly errors!

Pilot your questionnaire!

- Pilot with a group of people
  -> similar to your target subjects

Usually 30 subjects
If the whole population is 100 or smaller
You can do it on 10 potential participants

For multi sites study: One site is enough

- Highlight problems before starting
- Misunderstandings
- Look for alternative wording
- Evaluate for missing data, consistency, reasonableness of answers
- Ask pre-test participants for direct, feedback
- Use duplicate administrations to assess reproducibility

Final polishing

Steps in questionnaire design

6. administer it

-Conduct survey, including protocol for maximizing response rates

Include manual

Assess response rate

Questionnaire Design – Administering a Questionnaire

1. Identify the best practice for administering the type of questionnaire utilized.
2. Train and audit field workers, if required.
3. Ensure a process is in place to handle completed questionnaires.
4. Determine the deadline.

Conclusions

- You need plenty of ***time***!
  - Design your questionnaire from research hypotheses that have been carefully studied and thought out.
  - Discuss the research problem with colleagues and subject matter experts is critical to developing good questions.
  - Review, revise and test the questions Examine the questionnaire as a whole for flow and presentation.

Bias

Systematic difference in the response measurement

- Recall bias
  - Cases more likely to remember than controls
- Observer bias
  - Different interviewers – different interpretations
  - Different interpretation of similar questions
- Non-response bias
  - telephone interviews

How to reduce bias

- Structured questionnaire
- Ensure high response rate
- Pretesting and piloting
- Training of interviewers

Maximising the response rate

If you were sending out a questionnaire, what would you do to maximise the response rate?

In groups, 5 minutes

Non-responders

- Understanding the characteristics of those who did not respond to the survey is important to quantify what, if any, bias exists in the results.

Ways to Improve Response Rates

- Keep questionnaire short
- Ensure confidentiality
- Target the appropriate population
- Make it convenient for respondents
- Clearly communicate research purpose
- Give advance notice (advertising)
- Reward for completing the questionnaire

Techniques for minimising non-response

- Good design
  - Thoughtful layout, easy to follow, simple questions, appearance, length, degree of interest and importance, thank people for taking part
- Pre-notification
- Explanation of selection
- Sponsorship, e.g. letter of introduction / recommendation
- Cover letter

Techniques for minimising non-response

- Incentives
  - Small future incentives, e.g. prize draw
  - Understanding why their input is important
- Reminders
- Confidentiality
- Anonymity
- Pre-paid return envelopes

Week 3: Part 2
Ready to use questionnaires

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Ready to use questionnaires

- In general, for a tool to be validated for use in assessment, it should be:
- Valid
- ✓ Assess clinical important difference: smallest improvement considered worthwhile by a patient
- ✓ Tool sensitive for changes
- Reliable
- Precise
- Easy to administer
- Acceptable by the study population.

Definitions of terminology used in ready to use questionnaires selection

Instrument	**A questionnaire or interview or simple test (or some combination of these), used to measure and quantify health or disease status**
Domain	**An area or realm, one particular aspect within a broad assessment**
Measure	**A score, generally from a series of items designed to quantify some particular domain**
Item or indicator	**A single item, eg one question in a questionnaire**
Scale	**A simple test to quantify broad or single aspect of health using a numerical estimate from visual or numerical range**

Questionnaire needs to be adapted to study population

- Know the respondents
  - Language
  - Education
  - occupation
  - ethnic group
  - sensitive issues

Classification of ready to use questionnaires/scales

A. **Generic questionnaires:**

- Developed to be applied for a large range of populations and health care problems

- They permit comparisons between populations or other groups of people, and also in the same group before and after an intervention.

A. Generic questionnaires:

- In order to apply any instrument for generic use, it should be validated across different groups and should be acceptable by these groups.

Examples of generic ready to use questionnaires

1. Short Form Survey (SF-36)
2. General Health Questionnaire
3. Sickness Impact Profile

A. Generic questionnaires:

- It should be always considered that these measures are less responsive changes in health when compared with disease specific questionnaires.

- Therefore, if these are not used along with a disease specific questionnaire, it is advisable to choose a clinical outcome of direct relevance to the disease/health care problem under investigations.

A. Generic questionnaires:

Limitations:

- They may be insensitive to subtle but important changes in status with respect to a specific disease.
- They should be validated across a spectrum of different groups of people.

B. Disease or population specific questionnaires:

- They are designed to target particular population or patients group.

- Examples of disease specific questionnaires.
  Asthma quality of life questionnaire
  Arthritis Impact Measurement scales
  Rand Diabetes Mellitus Battery

B.Disease specific questionnaires:

- These quantify the severity of individual symptoms (such as angina pectoris) or the impact of a disease on a person's overall quality of life.
- They are well suited to detecting important changes (over time or following treatment) in an individual or within a population.

B. Disease or population specific questionnaires:

- More sensitive than the generic measures to minor impairments and changes over time.
- They also are expected to achieve a higher acceptability.

B. Disease specific questionnaires:

- They are not available for all diseases
- They may be lengthy and detailed.
- They have limited role in comparisons with other conditions or with the general population.

The European Organization for Research and Treatment of Cancer Quality of Life Questionnaires

- Cancer patients quality of life assessment through EORTC QLQ-C30
- Cancer site specific supplementary measures validated modules:

1. Lung (LC13)
2. Breast (BR23)
3. Bone Metastases (BM22)
4. Head & Neck (H&N35)
5. Oesophageal (OES18)
6. Ovarian (OV28)
7. Gastric (STO22)
8. Multiple Myeloma (MY20)
9. Cervical cancer module (CX24)
10. Oesophago-Gastric (OG25)
11. Prostate (PR25)
12. Colorectal Liver Metastases (LMC21)
13. Colorectal (CR29)
14. Brain (BN20)
15. Information module (INFO25)
16. Endometrial (EN24)

C. Dimension specific scales/questionnaires:

- These focus on particular aspects of health
- The Beck depression inventory is an example
- Some questionnaires measure functional ability; the Barthel index and Townsend's disability scale are examples.

How to select your questionnaire/tool?

- What is your research question?
- Who are the patients you are studying?
- What do you anticipate will happen?

How to select your questionnaire/tool?

- **Appropriateness**: of the measure to the question or issue of concern
- **Correspondence** between the content of the measure and goals of the study
- **Evidence** in relevant populations **of: Reliability, Validity, Responsiveness**

  If no previous evidence, you need to assess them
  For translated questionnaires, the **translated** version should be **validated.**
- Practical considerations

Practical considerations:

- Mode of administration
- Time to administer
- Language
- Respondent burden
- Availability of supporting materials

Practical considerations:

- Patients controlled on medications are expected to have a quality of life close to normal population
- Exclusion criteria: exclusion of subject with psychological conditions. Sometimes it is secondary to the condition.
  Examples:
- Depression secondary to hypothyroidism
- Anxiety and depression secondary to erectile dysfunction

Validity and reliability

- Validity: question measure what you claim it measures
- Reliability: results are reproducible or consistent with similar

Concept	Comment
1. Validity	Ability to measure what it supposed to measure.
a.Face validity	Refers to the investigators' subjective assessment of the questionnaire: a reasonable measure and items appears to be measuring what they intend to measure
b. Cotent validity	More systematic and comprehensive assessment than the face validity . It examines that extent to which items on a questionnaire covers all aspects that they intend to measure.
C.Construct validity	Construct: hypotheses are generated, then the questionnaire is tested to determine if it reflect these hypothesis. There two types of construct validity: 1. Criterion validity: the extent that the results match with the pre-existing tools..[3] 2. Concurrent: when the new measure is administered at the same time with the pre-existing one
D. Convergent validity	The measure is correlated positively with other methods that measure the same concept.
E. Sensitivity (detection rate)	Proportion of actual cases. For example patients with clinical depression who score positive on measurement tool for depression
F. Specificity	It is the discriminative ability of a measure. Ie the proportion of people w[illegible] not cases and test negative on the measure

Concept	Comment
2.Responsiveness	Ability of an instrument to be responsive to actual changes that occurs over period of time.
3. Administration	Easy
4. Length	Not too long or too short.
5. Cost	Not expensive to obtain or to administer
6. Precision:	Ability to detect small changes
7. Reliabiliy:	The extent to which a measure yields the same number or score each time it is administered.
a.Internal consistency	A test for the homogeneity and extent to which items are correlated within the same scale or domains in the scale. Cronbach's alpha gives an estimate of reliability based on all possible correlations between all items in the scale. Researchers have regarded that 0.7 is the minimum acceptable level for internal consistency. [1,2]
Test-retest reliability	Relationship between scores obtained by the same person on two or more separate occasions. Kappa coefficient is used to test nominal data (ranging from -1 to 1,(0) if the agreement is not better than chance, negative if worse than chance and (1)if there is perfect agreement.

Measures of *validity* of a new instrument

Measure	Concept measured	How measured
Face validity	The investigators' subjective assessment of the instrument; whether it appears to be measuring what it is intended to measure and whether each indicator is a reasonable one	Judgement (superficial)
Content validity	The extent to which the items in an instrument covers all aspects of the attribute to be measured. More systematic and comprehensive assessment than face validity	Judgement
Criterion validity	Validating an instrument by comparing it with a currently accepted reference measure[6]	Correlation coefficient, correlating the measure with some other accepted "criterion", ideally a gold standard[6]
Concurrent validity	Term for criterion validity when the two scales are administered at the same time; used when attempting to replace an existing scale with a new one that has some advantage (eg simplicity)	

Measures of *reliability* of a new instrument		
Measure	**Concept measured**	**How measured**
Internal consistency	**A test for the homogeneity, the extent to which the items within a domain (which broadly should measure the same thing) are correlated.**	**Cronbach's alpha, an average of the correlation coefficients between all items. Takes values between 0 and 1. A low value (<0.50) indicates that an item does not come from the same conceptual domain[5], a value of 0.7 has been judged the minimum acceptable level for internal consistency[6].** **Split half reliability: correlation of two summary scores (for example from odd- and even-numbered questions in a questionnaire)**
Test-retest reliability	**Relationship between scores obtained by the same person on two or more separate occasions.**	**Kappa correlation coefficient: Takes values between -1 and 1. A score of 1 indicates perfect agreement, 0 is the extent of agreement expected from chance, a negative score indicates worse agreement than would occur by chance**

Measures of *validity* of a new instrument

Construct validity	**Validating a new instrument by developing a hypothetical prediction of its performance, relevant where the variable of interest is abstract and cannot be directly observed[1]**	**For example a questionnaire for use in jaundice, measuring the extent of itching and excoriation, should show improvement when serum bilirubin decreases[1]**
Two subtypes:		
Convergent validity	**The measure is correlated positively with other methods accepted as measuring the same concept**	**Correlation coefficient**
Divergent or discriminant validity	**Lack of correlation with variables that measure a different unrelated topic**	**Correlation coefficient**