Summary of sampling strategies

Weeks 3-4 | Sample Ridge: Selecting your study sample

Non-probability and probability strategies

Deciding on a sampling approach will be influenced by your:

- broad study purpose and specific study aim or question
- selected research methods and study design
- access to your desired study population

Probability sampling uses some form of *random* selection of study participants from the desired population of interest; all individuals in the population have an *equal chance* of being selected in the study sample.

Non-probability sampling is used when participant selection is based on the subjective judgement of the researcher.

See the differences in characteristics between *non-probability* and *probability* strategies below.

Sampling strategy	Ease of drawing sample	Risk of bias	Representativeness of sample
		Non-probability	
Convenience	Very easy	Greater than any other sampling strategy	Because samples tend to be self-selecting, representativeness is questionable
Quota	Relatively easy	Contains unknown source of bias that affects external validity	Builds in some representativeness by using knowledge about the population of interest
Purposive	Relatively easy	Bias increases with greater heterogeneity of the population; conscious bias is also a danger	Very limited ability to generalise because sample is handpicked

	Probability		
Simple random	Laborious	Low	Maximised; probability of non-representativeness decreases with increased sample size
Stratified random	Time-consuming	Low	Enhanced
Cluster	Less time-consuming than simple or stratified	Subject to more sampling errors than simple or stratified	Less representative than simple or stratified
Systematic	More convenient and efficient than simple, stratified or cluster sampling	Bias in the form of non-randomness can be inadvertently introduced	Less representative if bias occurs as a result of co-incidental non-randomness

What sort of people do you want in your study?

Inclusion criteria

A list of those characteristics that a participant **must** possess. These elements or traits are developed from your:

- research question
- study design
- concepts or variables of interest

Broad example

Everyone over the age of 18 years

Narrower example

- Women having their 1st baby
- Aged between 20-35 years
- Able to read English
- Live in certain postcode areas

Exclusion criteria

Those characteristics that cause a person to be excluded from the study. These criteria need to be carefully considered; the more you have, the less you can generalise to the target population.

Note:

- Stating the opposite of the inclusion criteria is not necessary
- List only any additional issues that would preclude this person from participating

Sampling: Some issues to consider

Weeks 3-4 | Sample Ridge: Selecting your study sample

What will you think about when selecting your sample?

- Clinical importance
- Participant availability
- Resource availability
- Statistical power
- Ethics
  - Balancing sample size against burden to participants

On the next page we will look at an example

Sample size

More important from a quantitative perspective

Needs to be:

- Large enough to ensure generalisability & accuracy of results
- Small enough to answer the question within available resources

For experimental / intervention studies,

- need to decide on: Power, Alpha level, Effect size …

https://clincalc.com/stats/samplesize.aspx

https://www.sealedenvelope.com/power/continuous-superiority/

Effect size

- Minimal (clinically) important difference between groups
  - Do you want to be able to detect a 5% or a 20% difference in the proportion of people who are in a bad mood
  - Do you want to be able to detect a 12 point or a 25 point difference in mood score between two groups?
  - If you opted for the 5% or the 12 point options, you will require a larger sample then if you had opted for the 20% or 25 point options

Study Power

For experimental studies

- The ability to demonstrate an association or difference between study groups that exists in reality
- Commonly set at 0.8 or 0.9
- product of:

  –significance level (a) [commonly a = 0.05]

  –effect size (ES) [small, medium, large]

  –sample size (n)

Alpha level

- α commonly set at 0.05 …
- a 5% chance the results occur by chance (error) – not because of the intervention, or …
- a 95% confidence that the difference you detected in this sample reflects a true difference in the population

Example: Sampling considerations applied

Weeks 3-4 | Sample Ridge: Selecting your study sample

Let's return to a previous example, to consider how the researchers decided on the required sample size.

Note:

This example relates to an intervention study, and therefore the issues of ***effect size*** and ***power*** are factors to be considered; these statistical concepts are not relevant for other quantiative designs, or any qualitative designs.

Study protocol: Home-based physical rehabilitation for survivors of a critical illness

(Elliott et al. 2006)

Summary

- Sample size calculated for SF-36 PF scale for a 2-sided hypothesis test with a Type I error rate of 0.05 and a Type II error rate of 0.20 (80% power)
- Clinically important difference, anticipate:
  - both groups have mean PF scores of 45
  - control group will improve by 5 points at 8 weeks, intervention group will improve by 15 points
  - giving a difference of 10 points between the two study groups
- n = 100 / group required

The effects of a sacrococcygeal pilonidal sinus wound on activities of living: thematic analysis of participant interviews

Stewart, Ann M ; Baker, Jacqueline D ; Elliott, Doug

Journal of Clinical Nursing, November 2011, Vol.20(21–22), pp.3174-3182

Methods	Key points
Purposive sampling	• Patients with postsurgical pilonidal sinus wounds • From community health database
Recruitment	• Contact by staff unrelated to study • Permission for researcher to then contact for informed consent
Ethical issues	• HREC approval • Confidentiality assured • Pseudonyms used in transcripts

Results	Key points
Participants	• 4 women, 7 men • Average age 23 years (range 17-39 years) • 7 acute wounds / 4 chronic wound history

Now consider your own proposed sample. What are the issues you need to address?

Let's develop your thinking further on the next page.

Developing a narrative description of your ‘sample’

Weeks 3-4 | Sample Ridge: Selecting your study sample

Questions

1. What is your (broad, general) 'population of interest'? (This should be explicit and clear in your study aim)
2. What is your 'sample'? *Who* and *how* many? (This should be specific and relate to your local study site/s)
3. List the specific 'inclusion criteria' for your study sample.
4. List any additional 'exclusion criteria' (Note, stating the opposite of the inclusion criteria is not necessary; list only any additional issues that would preclude this person from participating; see the 2nd example in #11 above for the delineation between inclusion and exclusion criteria)
5. What is your sampling method? (Based on your design, do you need a probability or non-probability sample? Is this reflective of your research paradigm? What is the specific sampling type you have selected?)
6. Describe your sampling approach (How will you access and recruit your desired participants?)

Allocation to study groups

(if applicable to your interventional design)

For some of you who have selected a quasi-experimental or experimental design (e.g. cohort or RCT), you will also need to describe how participants will be allocated to your study groups (e.g. 'control', 'intervention'). (If you are not evaluating an intervention, move to the 'Data Collection Approach' section).

1. If you haven't already, add a Section to your notes app, a Word document or ePortfolio called 'Intervention Canyon'.
2. Now add a new page called 'Allocation to study groups'.
3. Copy and respond to the following questions:

Questions

Note: some of these elements will form part of Assessment 4

1. Describe your group allocation process.
2. How will participants be assigned to the intervention / treatment group/s or the control / comparison group/s?
3. What are the strengths and limitations of this group allocation process?
4. Note your description of the intervention, including relevant references. It is also common to describe what participants in the 'control' or 'usual care' group will receive or experience.

Weeks 4-6 | Intervention Canyon

Description of intervention

Now that you have decided how your recruited participants will be allocated to your study groups, you need to describe what each group will receive, during the 'intervention' phase of your study.

The most common form of experimental or interventional studies is two groups:

- ***'Control'*** (or perhaps ***'usual care'***, or ***'placebo'***) group, and
- ***'Intervention'*** (or ***'Treatment'***) group.

There are of course many variations to this.

Note: this element forms part of Assessment 4

1. For your study proposal, write a clear and comprehensive description of:
    - the ***intervention***, including relevant references, to support the activities / interventions that participants in this group receive
    - what the 'control' or 'usual care' group participants will receive or experience.

Data collection rapids | Data collection approach

To-Do Date: Mar 22 at 9:00

Weeks 4-6

What, who, when and how?

This methods sub-section describes the plan and timing for collecting data from your study participants, and is commonly reported in some detail in published papers.

Data collection decision path

Weeks 4-6 | Data collection rapids: Data collection approach

Does your data collection approach match your selected paradigm?

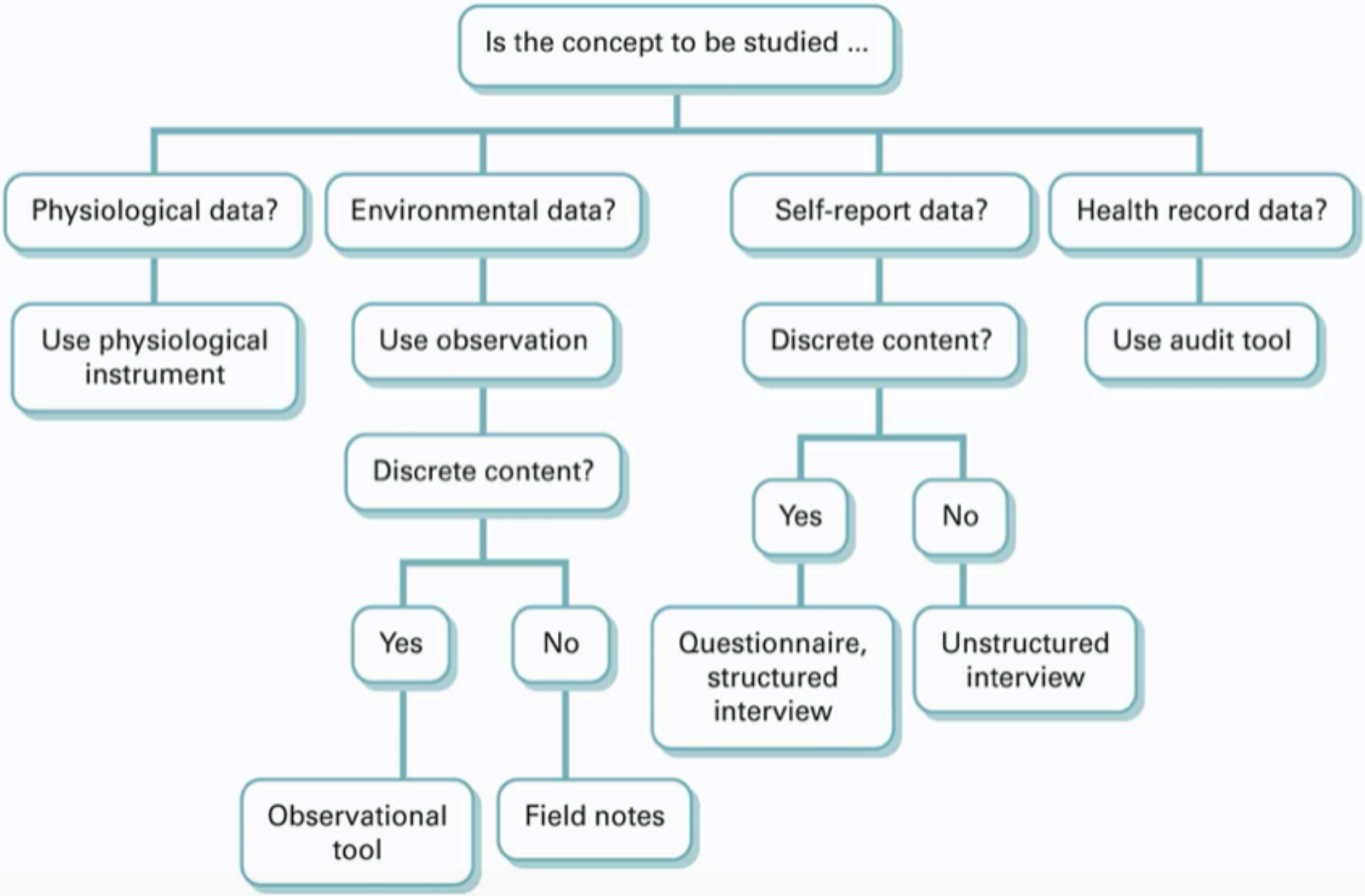
While you have already decided on your study methods and design, it is important that your data collection approach matches your selected paradigm.

You will recall that we also spent some time earlier on identifying the key concepts for your study - what the major ***'concepts'*** or ***'outcome variables'*** are.

Have a look at this figure below.

What type of data are you proposing to collect?

You should be able to see what would constititute 'qualitative data' and 'quantitative data' ...


Is the concept to be studied ...
Physiological data?
Environmental data?
Self-report data?
Health record data?
Use physiological instrument
Use observation
Discrete content?
Use audit tool
Discrete content?
Yes
No
Yes
No
Questionnaire, structured interview
Unstructured interview
Observational tool
Field notes

Does the type of data you propose to collect 'fit' with your selected method?

Okay, let's now consider data collection approaches from either a qualitative or quantitative perspective.

Please select your ***'qualitative'*** or ***'quantitative'*** ***'track'*** here, to continue through ***Data collection rapids*** ...

Characteristics of qualitative research

Weeks 4-6 | Data collection rapids: Data collection approach

As you discovered at ***Paradigm Pass***, qualitative ('**QUALitative**') research has a distinct view of the world, and a series of related characteristics.

Review the statements below, and reflect on how this fits with your ***researcher position***, as you develop your qualitative research proposal. All of these statements should 'fit' with what you want to do ...

Characteristic	Description
Truth	There are multiple truths –generalisation is not sought
Purpose	Discovery and description; verification is also possible
Context	Attention to the social context in which events occur and have meaning
Emphasis	Understanding the social world from the view of study participants – an emic perspective (comes from the person within the culture)
Approach	Primarily inductive
Sample	Usually small in number; participants are able articulate their experiences
Relationships	Integration between researcher and participant/s; interactions are valued
Data	Words, diagrams; erroneously termed ‘soft data’

Data collection (common techniques)	Interviewing, participant observation, document analysis; procedures and tools for data gathering can be revised in the field
Analysis	Text as unit of analysis; differing approaches – qualitative descriptive, content, thematic
Findings	Presented mostly as narrative (rather than numerical form); use of some quantitative data to describe participants, other data not precluded
Trustworthiness	Credibility, auditability, fittingness (transferability) = Confirmability

Qualitative research approaches

'Qualitative research' is an umbrella term that encompasses a somewhat disparate set of methodological approaches. Characteristics or activities that are **common** across the approaches, as listed above include:

- context in which the data are gathered
- collection of text-based data
- determining trustworthiness of findings

Differences in methodological approaches between the 'types' primarily relate to the 'lens' (position and processes) for:

- researcher position and interactions with participants
- approaches to data collection
- data analysis

Descriptions of some common qualitative designs / methodological approaches are listed below:

Approach	
Qualitative descriptive	Use of qualitative approaches to collect text-based data, but with no defined use of a specific qualitative 'lens' for researcher position, data collection, or data analysis
Ethnography	Direct description of a group, culture or community
Grounded theory	Theory generation from data; or modify / extension of existing theory
Phenomenology	Deep description / interpretation / understanding / meaning of lived experience
Discourse analysis	Description / interpretation / counter-interpretation

If required, source some studies which used your preferred qualitative approach.

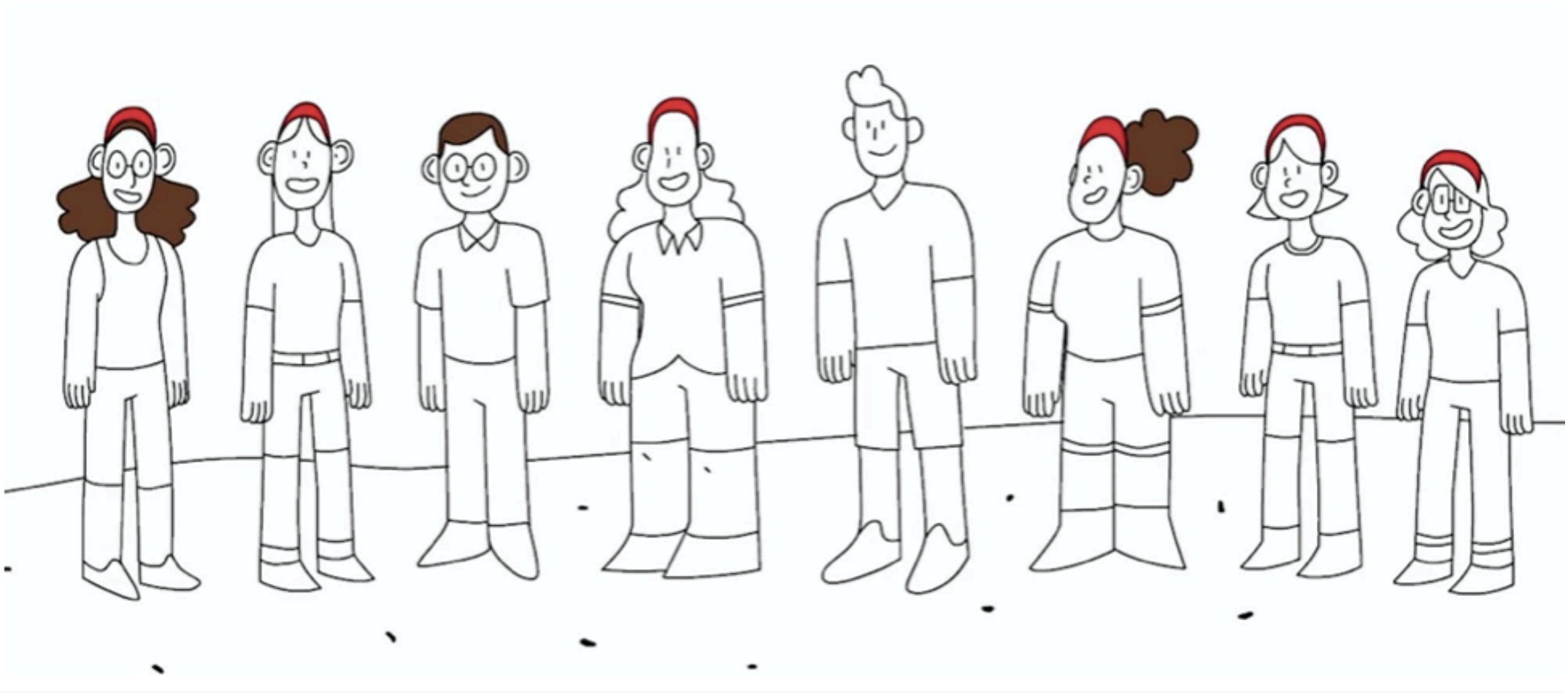
The papers do not have to be on your topic area; you are reading them to gain further insight and understanding into the research process or method, so the topic is irrelevant for your purpose.

Consider what the key issues will be for you in developing the data collection sections for your qualitative research proposal.

Now let's look at some sampling issues from a qualitative perspective.

Sampling issues | Qualitative research

Weeks 4-6 | Data collection rapids: Data collection approach



Sampling

Purpose of sampling in qualitative research

- Enables selection of **suitable** participants
- Sampling approach is guided by the selected specific qualitative design and related methods
- An appropriate **qualitative** sampling strategy:
  - Accesses individuals with the ability to provide information on the topic research interest
  - Highlights individual participant experiences, knowledge, understanding (the ability to generalise findings is not relevant)

Participant selection and sample size in qualitative research

- Selection based on intention (or philosophy) of specific qualitative approach
- Inclusion and exclusion criteria determine type of participant selected
- Usually no predetermined sample size (may provide a range in HREC submission)
- Adequacy of sample size judged by:
  - Ability to maximise 'richness' of data within context of the approach
  - Adding participants reveals no new information (**'data saturation'**)

Data saturation

When no new information / insights emerges from the data already collected; perhaps:

- > 15 participants if seeking heterogeneity of responses
- 5-10 participants if seeking homogeneity of responses

The number of participants may also vary depending on the methodological approach selected; for example:

	Interviews
Ethnography	30+
Grounded theory	10-30
Phenomenology	5-25

Data collection issues | Qualitative research

Weeks 4-6 | Data collection rapids: Data collection approach

Data collection

The specific qualitative design guides the approach selected fordata collection. The data can be derived as:

Direct data

- Direct from research participant e.g. words, writing, observable actions
- Collected from participant by talking, observing or reviewing written material

Indirect data

- Generated by another person or people relating an event e.g. documents, photos, songs
- Collected by searching archives or internet

Think about how you will describe your data collection approach in your proposal. You may also want to consider these issues listed below, as you work on developing your description.

How will you address these issues in your proposal?

Credibility of participant selection

Selection criteria used for accessing your participants?

- Heterogeneity of participants required?
- Groups of special interest requiring intense study?
  - Are key informants appropriate?

Researcher position

- Use of a reflexive diary / research journal?
- Where will you as the researcher be placed in the research?
- Does the researcher have proficiency in the 'language' / terms used?

Interview or oral narrative

Weeks 4-6 | Data collection rapids: Data collection approach

The interview or oral narrative

A common qualitative data collection method

- Usually a direct verbal encounter between researcher and participant
  - Can be conducted by telephone, email or video
- Usually audio taped or sometimes video recorded
- A complex and demanding task that requires skill and experience

There are two types of interviews:

1. **Individual in-depth interviews** using unstructured, semi-structured or structured questions.
2. **Focus groups** involves a group of participants engaging in a facilitated dialogue with each other on a specific topic.

Benefits & limitations of interviews

Benefits

- Offer the unique perspective of the participant
- Interviewer experiences participants' reflections
- Opportunity to offer support, clarification or counsel

Limitations

- Time consuming and resource intensive
- Dependent on interviewer skill e.g. imposing, coercing or biased
- Eliciting sufficient in-depth information

Techniques to elicit responses in interviews

Weeks 4-6 | Data collection rapids: Data collection approach

 Interview questions

In-depth detailed responses can be facilitated through a variety of interview techniques; for example:

- funnelling
- storytelling
- probing

Drag the best example that demonstrates the technique. There may be more than one example that matches to a technique.

Technique

Funnelling (open questions):

Storytelling:

Probing:

Paraphrasing

5Ws & H- What, Why, When, Who, Where and How

Tell, Explain, Describe (TED)

'Can you give me an example?'

'Tell me more about that [situation]'

probe; close (summarise / confirm)

'What I heard you say was...Is that what you mean't?'

Example: Focus group interviews

Weeks 4-6 | Data collection rapids: Data collection approach

Important elements of a focus group interview

- A collective set of values, experiences and observations
- Insight gained from interactions between participants
- Expertise required to elicit data while managing group dynamics

Example

Purpose

Experiences and views of clinical staff explored during brief semi-structured focus groups

Timing

Scheduled during shift overlap, staff development sessions and education forums to enable as many staff as possible to attend

Interview schedule

Guided discussion with items based on a review of the literature and from evaluations of early chart versions.

Observational research

Weeks 4-6 | Data collection rapids: Data collection approach

Observational Research

- The process of watching daily life and behaviours of participants
- Occurs in a 'natural' (everyday life; real) setting
- Records aspects such as social role and function, actions and interactions

Observational Approaches

Can be used in qualitative or quantitative methods

Benefits

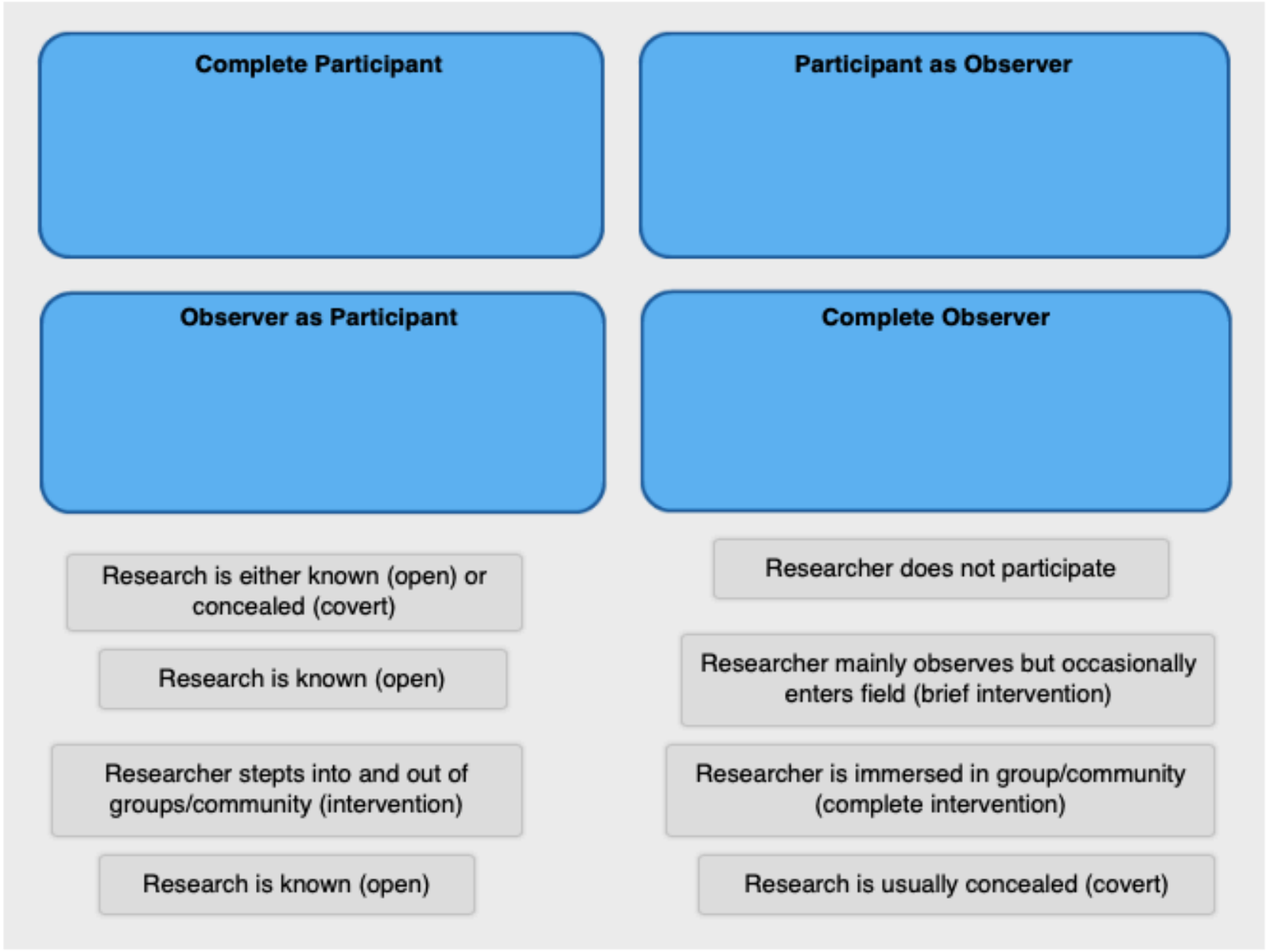
- Capture data in natural environment
- Identify influences from the physical or social context
- Explore or measure how participants behave under certain environmental conditions
- Suitable for complex clinical situations or social interactions
- Opportunity to interact with participants (qualitative)
- Permits participant observer to reflect on their own experience in the field (qualitative)
- Standardised systematic observation plan improves rigour (quantitative)

Limitations

- Requires training for identification of specific observations
- Possible Hawthorne effect
  - Unexpected environmental influences on objective and systematic process (quantitative)
- Subjective interpretation by observer

Roles of the observer in observational research

Identify the characteristics of each of the different roles of participation and observation.

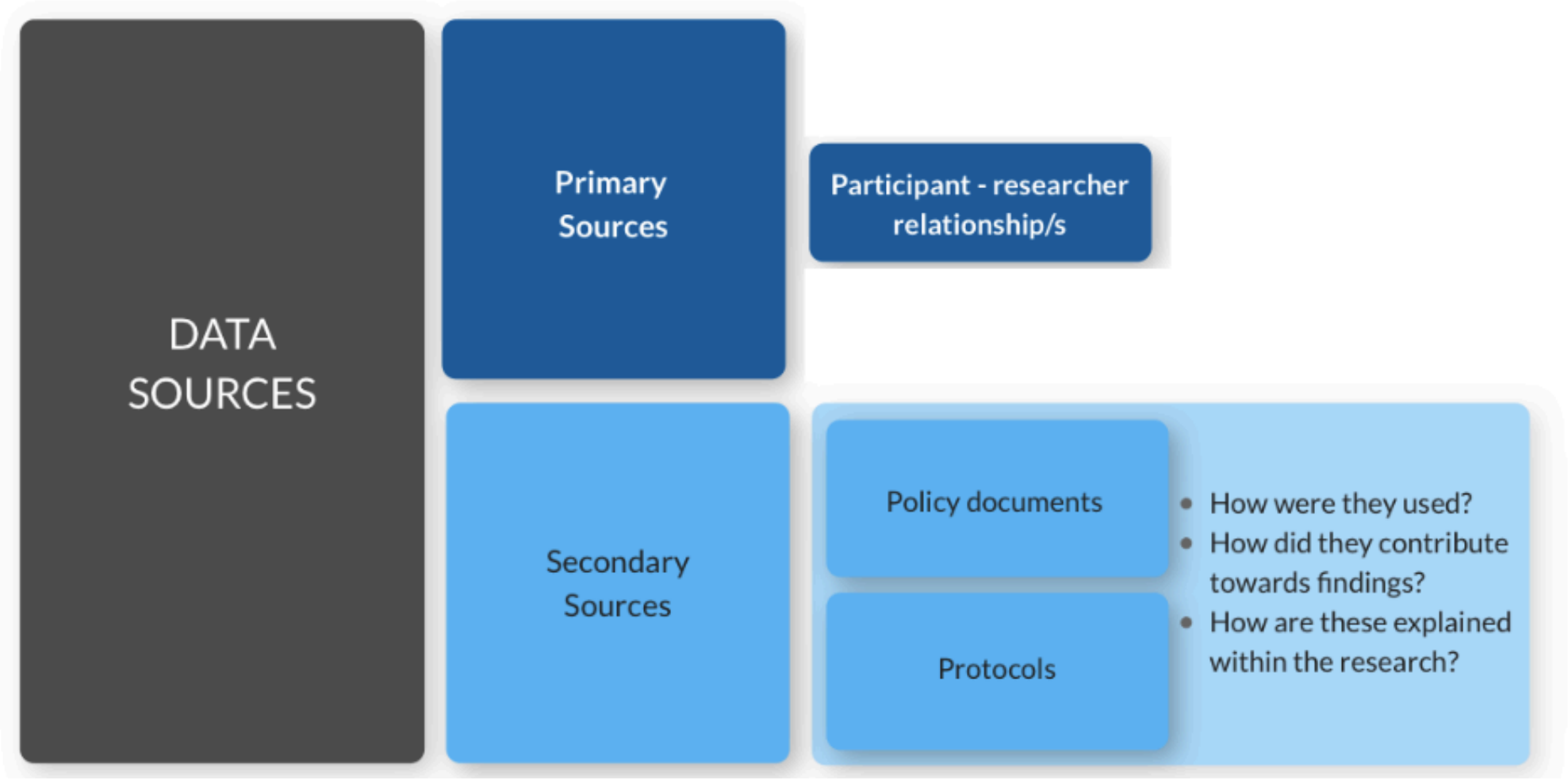


Other data sources

Weeks 4-6 | Data collection rapids: Data collection approach

For some qualitative studies, additional data may be collected from documents as ***secondary sources*** to support the primary data collection.

Consider whether your study aims require both primary and secondary sources of data.



Qualitative data collection | Application to your proposal

Weeks 4-6 | Data collection rapids: Data collection approach

Characteristics of quantitative research

Weeks 4-6 | Data collection rapids: Data collection approach

As you recall from ***Methods Fork*** and ***Design Bluff,*** quantitative designs have common elements; that is:

- representative sampling
- reliable, valid, responsive instruments
- consistent data collection
- ***control over study environment***
- ***randomisation***
- ***manipulation of study***

The last three are key chacteristics of RCTs.

The last three are key characteristics of RCTs.

Some quantitative designs are purely ***observational***, with no researcher influence on study variables.

Other, ***interventional*** designs, particularly need to address:

Control

Control of environment

- Consistency of data collection
- Control – methods / analyses
  - Control for ***confounding*** variables (co-variates; other factors that may influence your selected outcome variable)
  - Consider other ***extraneous*** variables

Causation

Based on study intent and resulting 'Design' (for Quasi-experimental and Experimental designs - RCTs)

- 'Intervention' / 'Treatment'
  - ***'explanatory'*** / 'independent' variable has a measurable effect on the
  - ***'outcome'*** / 'dependent' variable

Steps in quantitative research

Weeks 4-6 | Data collection rapids: Data collection approach

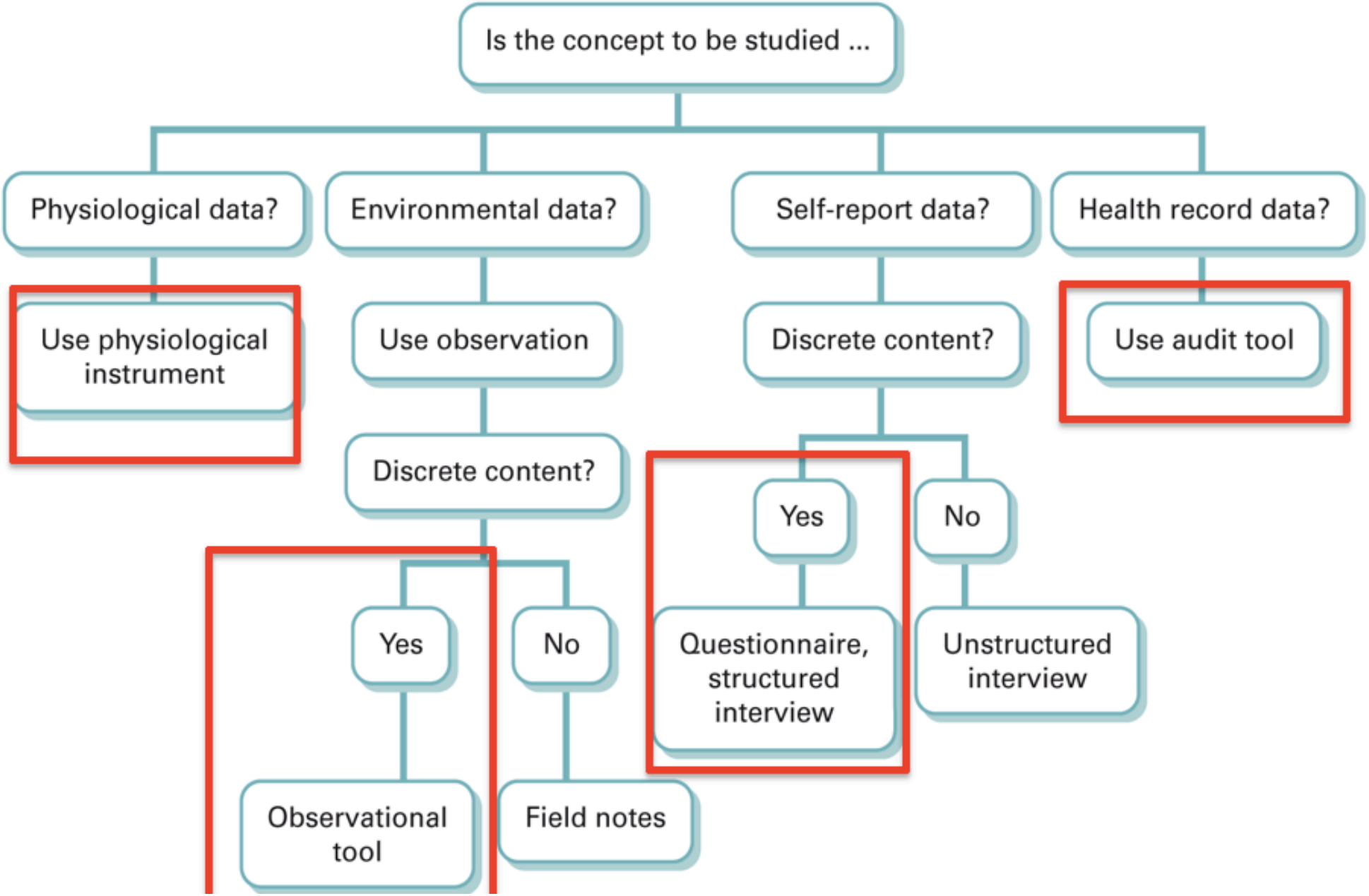
As you now appreciate, quantitative methods follow a sequential approach:

1. Determine the research problem (question, objective, hypothesis to be tested)
2. Select primary and secondary outcomes to be measured, and other variables to be collected
3. Collect the data
4. Analyse the data
5. Interpret the results

Let's have a closer looks at ***outcome variables*** and ***collection of data***.

Data collection methods decision path

The common approaches to data collection are highlighted below:



Have a think about the link between your study aim(s), your major ***variables of interest***, and you propose to collect relevant data.

How will you collect the data of interest?

Data collection approaches

Consider:

- **Physiological measurement**
  - Routine use in setting? Measurement precision?
- **Observations**
  - Observation tool?
- **Self-report / surveys from participants**
  - Use of previously developed questionnaire / instrument?
  - Reliability, validity and responsiveness testing?

Collecting & managing data

Weeks 4-6 | Data collection rapids: Data collection approach

Data Collection

Data are collected to:

- Describe the sample
  - can you generalise the sample characteristics to a broader population of interest?
  - are participants in the study groups similar?
- Collect information from participants
  - Did the intervention make a difference on the outcome variables of interest?

Managing & analysing data

- Develop a study protocol for collection of all relevant data
  - Standardised data collection especially if a number of collectors used
- Develop a database (+ a data dictionary?)
- Time needed to collect and enter data and check for errors
- Conduct 'pilot study' to check feasibility and data collection forms

Consider data analysis early and often

- Outcome variable(s)
- Other important data fields (r/t question/s)
- Data analysis plan
  - Descriptive tests?
  - Inferential tests?

Data definitions

Weeks 4-6 | Data collection rapids: Data collection approach

Variables need to be clearly defined before data collection commences. This is particularly important if there are multiple data collectors.

You may therefore need to develop a data dictionary, which outlines each variable to be collected, with clear descriptions, of type and format of permissible variables.

Common, explicitly defined variables can be found in the National Health Data Dictionary.

Example of explicitly defined variable

Here is an example ...

Body mass index - adult (measured)

Identifying and definitional attributes

Metadata item type:	Data Element
Technical name:	Adult—body mass index (measured), ratio NN[N].N[N]
METeOR identifier:	270084
Registration status:	Health, Standard 01/03/2005
Definition:	A measure of an adult's weight (body mass) relative to height used to assess the extent of weight deficit or excess where height and weight have been measured.
Data Element Concept:	Adult—body mass index

Value domain attributes

Representational attributes

Representation class:	Ratio
Data type:	Number
Format:	NN[N].N[N]
Maximum character length:	5
Supplementary values:	Value Meaning 888.8 Unknown 999.9 Not reported

Data element attributes

Collection and usage attributes

Guide for use:	Formula: BMI = weight (kg) divided by height (m) squared. Body mass index is a continuous variable. Code body mass index to one or two decimal places (i.e. 99.99 or 99.9). If any component necessary for its calculation (i.e. weight or height for adults) is unknown or has not been collected, code to 888.8, 999.9.
Collection methods:	NN.NN for BMI calculated from measured height and weight. BMI should be derived after data entry of weight and height. It should be stored on the raw data set as a continuous variable and should not be aggregated or rounded.

Data collection forms

Weeks 4-6 | Data collection rapids: Data collection approach

- Essential for recording data
- Development of 'case report form' (CRF)?
- Forms must be:
  - Practical
  - Simple
  - Logical
  - Clear
- Data are commonly recorded in numerical form …

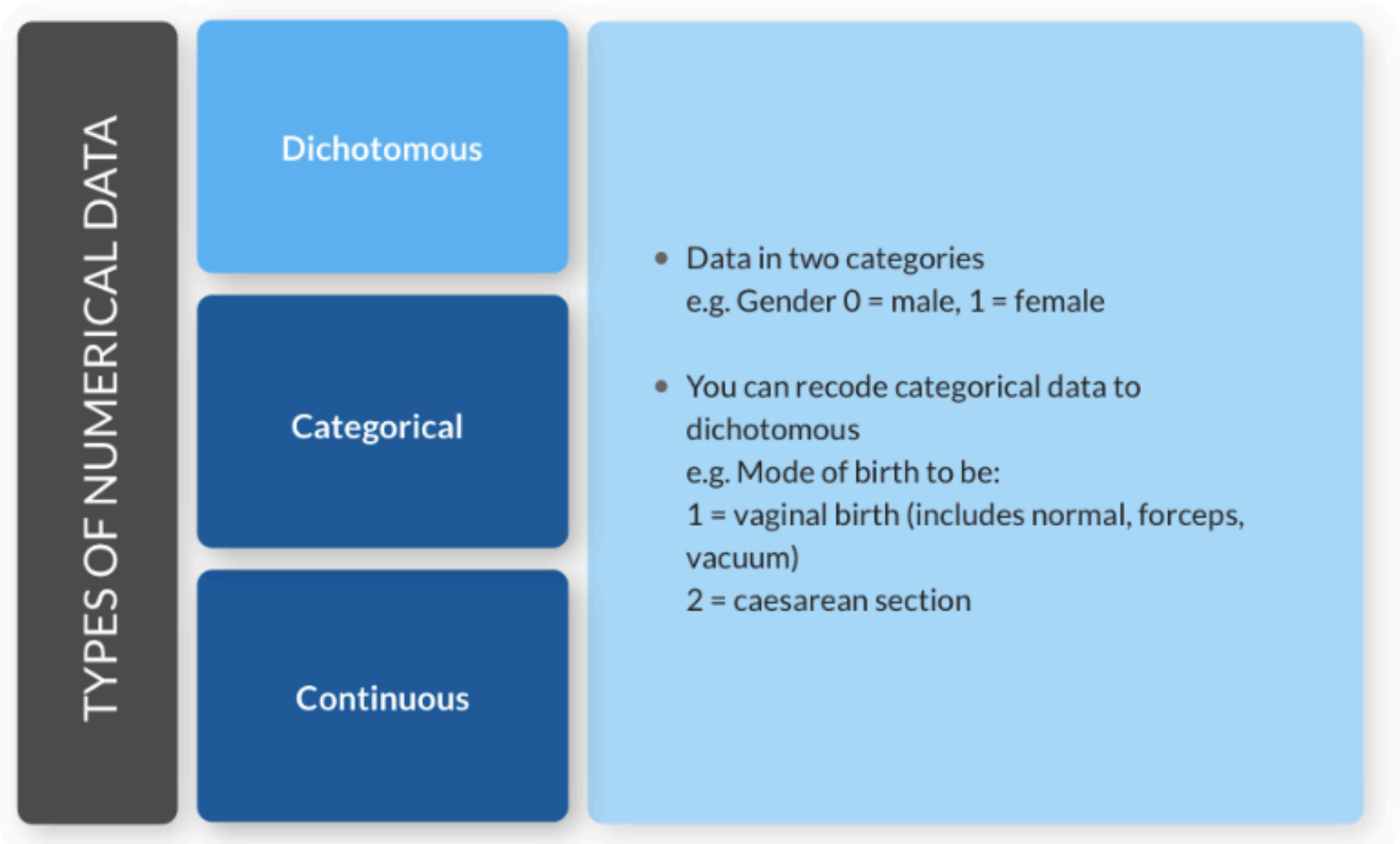
Data abstraction from records or documents: Case report from (CRF) example

Patient comfort in the intensive care unit: a multicentre, binational point prevalence study of analgesia, sedation and delirium management, *Crit Care Resusc* 2013; 15: 213–219

Element	Description
Data collectors	completed a CRF for each patient in the ICU at 10 am on the point prevalence day, using a prepared data dictionary
retrospective note and chart review	• of the previous 4 hours • included clarification with the patient's nurse
contemporaneous independent assessment	◦ analgesic and sedative needs ◦ delirium scoring using the intensive care delirium screening checklist (ICDSC)

Classifying numerical data

Weeks 4-6 | Data collection rapids: Data collection approach



Levels of Measurement

Measurement	Description	Measures of central tendency	Measures of variability
Nominal	Classification	Mode	Modal %, range, frequency distribution
Ordinal	Relative rankings	mode, median	Range, percentile, semi-quartile range, frequency distribution
Interval	Rank ordering with equal intervals	Mode, median, mean	Range, percentile, semi-quartile range, standard deviation
Ratio	Rank ordering, equal intervals & absolute zero	Mode, median, mean	All

Consider your proposed data variables. What ***level of measurement*** are each of the variables?

As you can see from the right-hand column above, a variable's level of measurement dictates the type of statistical tests than can be performed.

You will develop your application and understanding of variables and levels of measurement later in ***RiH Island***, at ***Date management and analysis ravine***. I know you are looking forward to that part of the journey.

Measuring instruments

To-Do Date: Mar 22 at 16:00

Weeks 4-6 | Data collection rapids: Data collection approach

Are you using a questionnaire or survey?

For those of you still here, let's have a look at the key issues when using a measuring instrument in your proposed research.

A ***Measuring instrument*** is a standardised set of items that purport to measure a defined concept or construct, such as pain, anxiety or mental health.

Physiological measures also fit this definition, but our focus here is on ***psychological*** instruments, and their accuracy in measuring the concept of interest.

Considering psychometric assessment of your selected measuring instrument/s

If your quantitatively-based study proposal includes use of a measuring instrument(s), such as a questionnaire or survey, then you need to understand ***'psychometric'*** properties; the reliability, validity and responsiveness of your instrument(s).

First, let's have a look at some underlying theory.

Measurement theory

Your selected measuring instrument was designed by somone else previously to measure a specific variable. How accurate it is though, in truly measuring a particular concept?

The instrument will measure the ***observed*** score, but how close is that to the actual ***true*** score? There may be other factors at play here - the concept of ***measurement error*** - see below for two types of error

How to account for ***measurement error*** is important for researchers to consider when developing the description of methods in their proposal. Let's now looks at the issues for instrument developers, and by extension, researchers who used existing, available instruments.

Conceptual base for instrument development/assessment

- Theoretical constructs (from literature) compatible with operational definitions of concept and item development
- Instrument designed to operationalise:
  - Existing or original concepts in health disciplines
  - Concepts / models from other disciplines

Operational definition

- Translated into a defined or measurable outcome of interest
- Informed by reviewed studies and related methodological literature

Example: Questionnaire use to measure concepts

Weeks 4-6 | Data collection rapids: Data collection approach

Questionnaire: examples

This published study from a PhD student used two different measuring instruments to assess health-related quality of life (HRQoL).

Element	Description
HRQOL measurement	a state of health perceived and reported by the patient as impacting on their functioning and reflects their patient's physical, social and emotional health
Instruments used	• Medical Outcomes Short Form (SF-12) • Seattle Angina Questionnaire (SAQ)
Measurement points	• at 4 weeks and • 6 months after PPCI
	• Both instruments well-established, valid and reliable • commonly used in cardiac populations • suitable for telephone administration

Measuring instruments performance characteristics

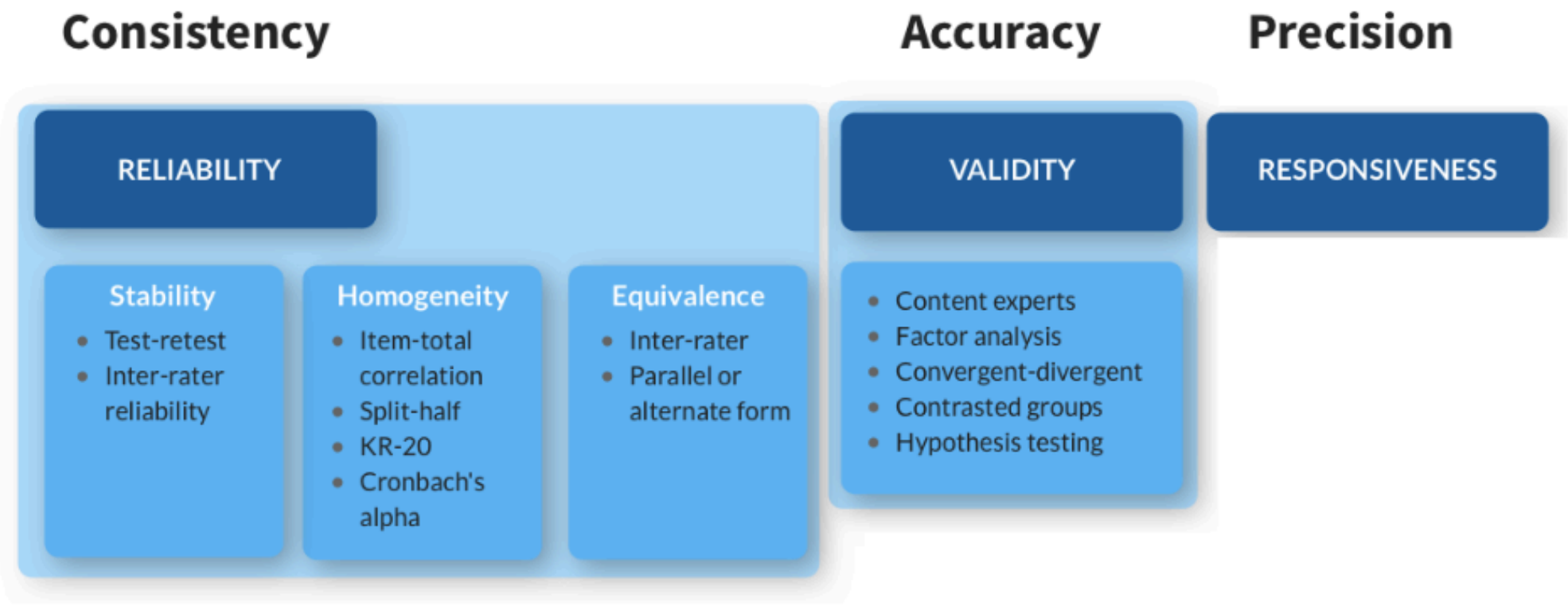
Weeks 4-6 | Data collection rapids: Data collection approach

Measuring the outcome of interest

To measure your outcome of interest, you will need to explore the following issues and characeteristics::

- Candidate (existing) measuring instruments? (identified from previous studies or other literature)
  - For potential instruments to use, examine their
    - Psychometrics – reliability, validity, precision
    - Utility – feasibility for your study
    - Access – public domain? Fees?
- Minimal (clinically) Important Difference (MID)

Psychometric propoerties



Reliability and validity

An instrument must consistently measure 'something' before determining whether it's ability to reflect the concept of interest ...

Therefore,

- An instrument can be reliable without being valid
- An unreliable instrument cannot be valid

Reliability: Measurement attributes

The performance of an instrument to measure the variable of interest can be tested in a number of ways, with related statistical test and desired levels of performance. See the table below. (Note there is a lot of information here, which can be overwhelming - we will work through these issues here, and if needed in discussion posts or ***R&D Camp***).

Property	Test	Purpose	Performance Characteristic
Stability	Test-retest	Similar scores on repeated testing of stable trait	Correlation coefficient ≥ 0.70
	Intra-rater	Consistency of one rater on two different occasions	Correlation coefficient ≥ 0.70
Homogeneity		All instrument elements measure the same characteristic: item-total; subscales; split-half	Cronbach's a ≥ 0.80 for developed instruments KR-20 / 21 for dichotomous variables
Equivalence	Inter-rater	Consistency between 2 observers	Pearson *r* ≥ 0.80 % agreement 70-90% Kappa (k)

Reliability

Weeks 4-6 | Data collection rapids: Data collection approach

Considering an instrument's reliability is commonly the first characteristic to:

- review (if assessing whether to use in a proposed study)
- test (if assessing with collected data in a study being conducted)

Reliability: Measurement attributes

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Equivalence	Inter-rater	Consistency between 2 observers	Pearson *r* ≥ 0.80 % agreement 70-90% Kappa (k) • moderate: 0.41-0.60 • substantial: 0.61-0.80
	Parallel (alternate form)	2 different tests measuring the same trait	Pearson *r* • Developing ≥ 0.70 • More established ≥ 0.80

Construct validity of a measuring instrument

Weeks 4-6 | Data collection rapids: Data collection approach

Instrument validity

Precision of the instrument measuring the variable of interest.

A continuum of evidence, not dichotomous

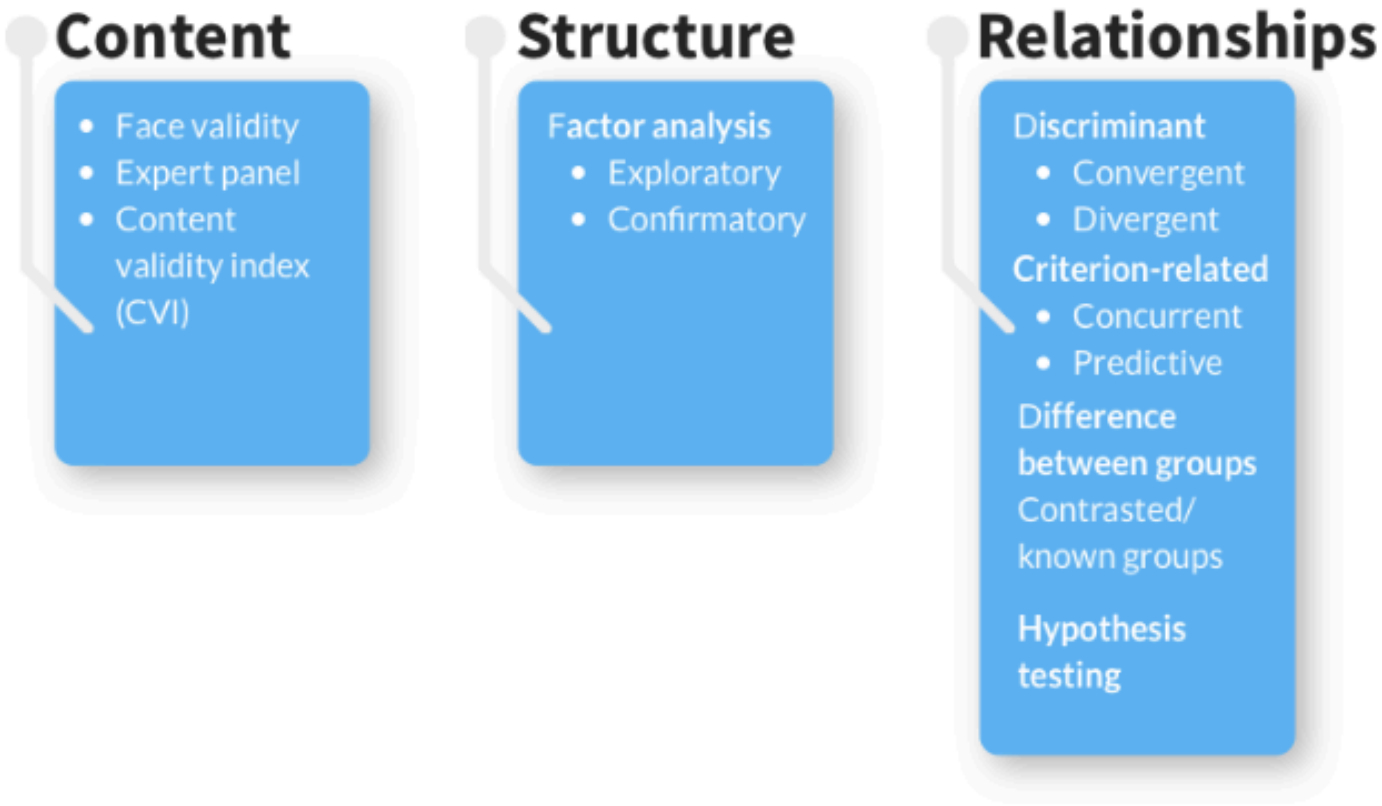
Established over time...

- **Several studies**
- **Multi-method apporaches**

Not viewed as a unitary construct...

Construct validity

Is an over-arching term that includes establishing evidence on three domains...



Review the selected papers from your background review and / or resource papers that report development of an instrument you are considering for inclusion in your research proposals.

How did developers establish validity?

Construct validity | Establishing evidence

Weeks 4-6 | Data collection rapids: Data collection approach

Establishing evidence about the ***content*** of the measure

This is commonly the first step for an instrument developer to establish; to see whether the instrument ***appears*** to measure the concept of interest. For example, an ***expert panel*** may review a development version of the instrument to determine whether, on face value, the instrument items reflect the construct of interest; that is, ***face validity***.

Further evidence then needs to be established, by...

Establishing evidence about the ***structure*** of the measure

The aim of an instrument developer is to have the smallest number of items while maintaining accuracy. The structure of the measure is examined to:

- Reduce the set of items (variables) to smaller clusters (factors) of correlated items.
- Explores unidimensionality / multidimensionality.

Factor analysis is a statistical approach using various methods (e.g. principal components method); multi-step approach to examine the number of 'domains' or themes' that may exist in the instrument. Testing is by:

- Exploratory
- Confirmatory

See the example on the following page.

Establishing evidence of ***relationships*** between the measure & other variables

As noted in the table below, there are numerous approaches to exploring relationships, depending on the study context and the purpose of the testing.

Type	Approach	Purpose
Discriminant	Convergent[a]	Different measures of the same trait correlate.
	Divergent[a]	Measures of different constructs have low correlations.
Criterion-related (compared to gold standard)	Concurrent [a]	Groups known to differ in a way relevant to the concept.
	Predictive[a]	Test predicts who will develop condition on f/u
Differences between groups	Contrasted / known groups [b]	Test two groups known to be high and low on the measured concept
Hypothesis- testing	Predictive Relationships Experimental	Tests predictions based on theory Between variables / concepts Manipulation

Tested by, [a] correlation coefficient, [b] t-test / ANOVA

Responsiveness

Weeks 4-6 | Data collection rapids: Data collection approach

Responsiveness

Of the three psychometric properties, ***responsiveness*** is the least tested and reported in studies

- the ability to detect clinically important changes in the variable of interest
- relates to the measurement precision of an instrument, and floor / ceiling effects
- opposite to “stability”
- not commonly assessed

Minimal clinical important difference

- Change in the instrument score that would be beneficial to a patient or require a change in clinical management
- Related to ‘effect size’ (changes in scores due to treatment effect)
- Need to consider ***clinical*** (practical) ***significance*** versus ***statistical significance***

Critiquing instrument performance

Weeks 4-6 | Data collection rapids: Data collection approach

Questions to shape your critique

In selecting a candidate measuring instrument for inclusion in your research proposal, consider:

- Purpose of the instrument defined and appropriate for study?
- Was reliability tested by an appropriate method?
- Is the reported reliability adequate?
- Is the reported validity adequate?
- How does this sample differ from previous reliability and validity testing?
- Appropriateness of reading level and socio-cultural appreciation?

Sourcing instruments for research use

- Literature databases
- Research articles
- Texts, e.g.:
  - Frank-Stromborg M, Olsen S. (2004). *Instruments for Clinical Health-Care Research* (3rd ed.). Boston: Jones & Bartlett.
  - Waltz CF. (2017). *Measurement in Nursing and Health Research* (5th ed.). New York: Springer.
- Websites

Measuring instruments | Application to your proposal

Weeks 4-6 | Data collection rapids: Data collection approach

Quantitative data collection | Application to your proposal

Weeks 4-6 | Data collection rapids: Data collection approach

Use reporting guidelines to develop your proposal sections, such as those defined by the Equator Network. You can also check methods from related studies.

Trustworthiness | Qualitative research

Weeks 4-6 | Data collection rapids: Data collection approach

Framework for trustworthiness

Aims to provide a new understanding of phenomenon

- Qualitative data is fluid and complex
- Less concerned about confounders / variables / cause and effect

Critique of approach

- Terms and techniques differ compared to quantitative research

Assessing rigor and study limitations

Relates to:

- The setting
- The role of the researcher in the process
- The impact of the study to other evidence within the field

Questions to consider

1. Does the research design align study aims and interpretation?
2. How systematic is the research design?
3. How systematic is the analysis?
4. How systematic is the interpretation?
5. How were the themes, categories and concepts derived?

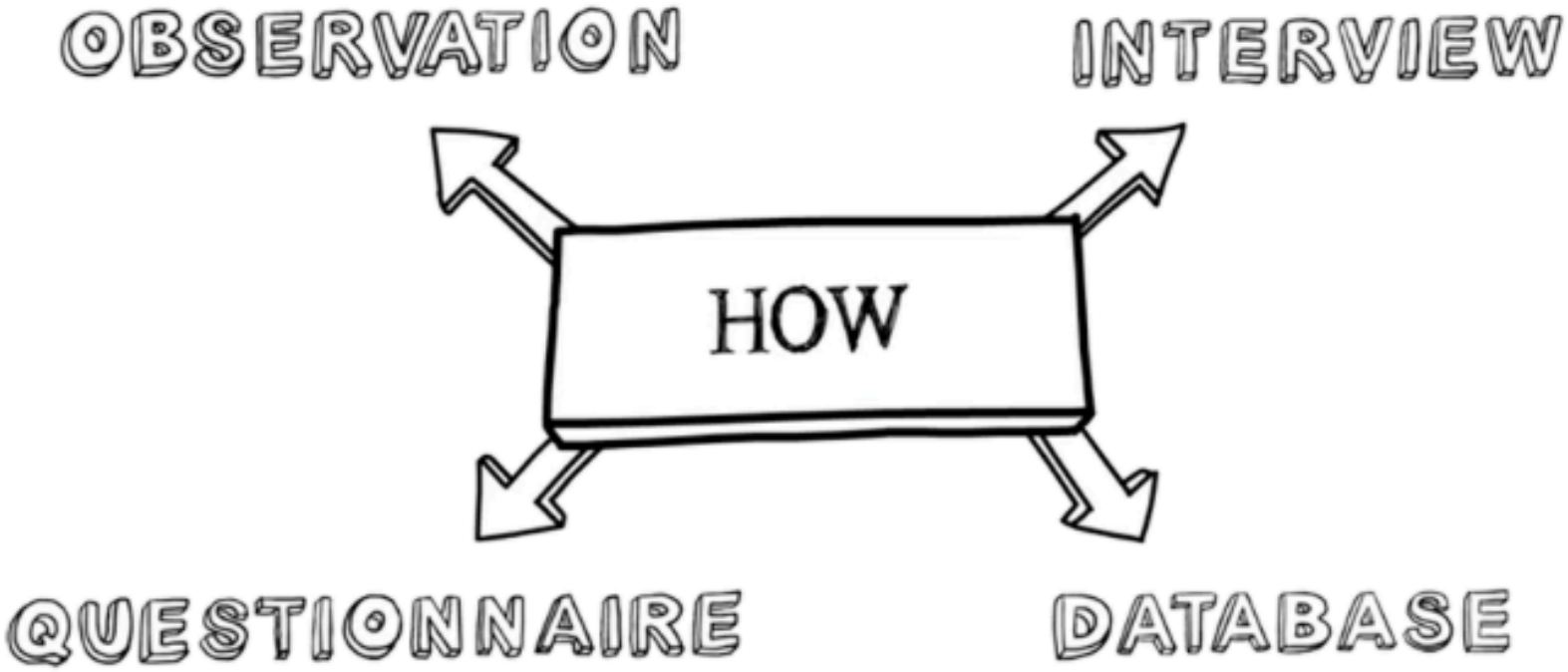
Rigour in qualitative research

Positivist Paradigm	Naturalistic inquiry
Internal validity	Credibility
Reliability	Auditability (dependability)
External validity	Fittingness (transferability)
Objectivity	Confirmability

Rigor is applied no less critically

Study validity | Quantitative research

Weeks 4-6 | Data collection rapids: Data collection approach



A goal as you develop your research proposal is to consider how to miminise any inherent bias in your methods.

From a quantitative perspective, bias is reflected as ***internal validity***. Consider:

- Rationale given for design / method selected
- Conceptual and operational definitions of all variables presented (explanatory, outcome)
- Sampling and data collection strategy consistent with chosen method
- Clearly identified and defined data collection method
- Measuring instruments clearly described

Internal validity (credibility of results) is established before considering external validity (generalisability)

Internal Validity

Methodological rigour and quality of the study

The degree to which the **intervention …**

…had a real and measurable effect on the **outcome …**

…without interference ('confounding') from other 'extraneous' variable that were not controlled in the study design

External Validity

Generalisability of study findings to wider population of interest or similar setting

Influenced by:

- Selection of participants and sampling
- Study conditions and reactive effects of testing
- Type of observation(s) made
- Effect of being studied (Hawthorne effect)

Threat	Description
Selection bias	Study participants need to be a representative sample of the population of interest; problematic where individuals self-reflect for participation in a study
Mortality (drop-out; loss to follow up)	Non-response of enrolled participants from the first data colelction point (pre-test) to the final data collection point (post-test)
Maturation	Developmental, biological or psychological processes of an individual that change over time and may influence the study variable.
Instrumentation	Changes in measurement or observational techniques of the variables that may influence measurement; includes consistency for multiple observers (inter-rater reliability)
Testing	The effect (experience) of taking a pre-test on the score of a post-test
History	A specific event that may affect the study variable, either within or external to the setting

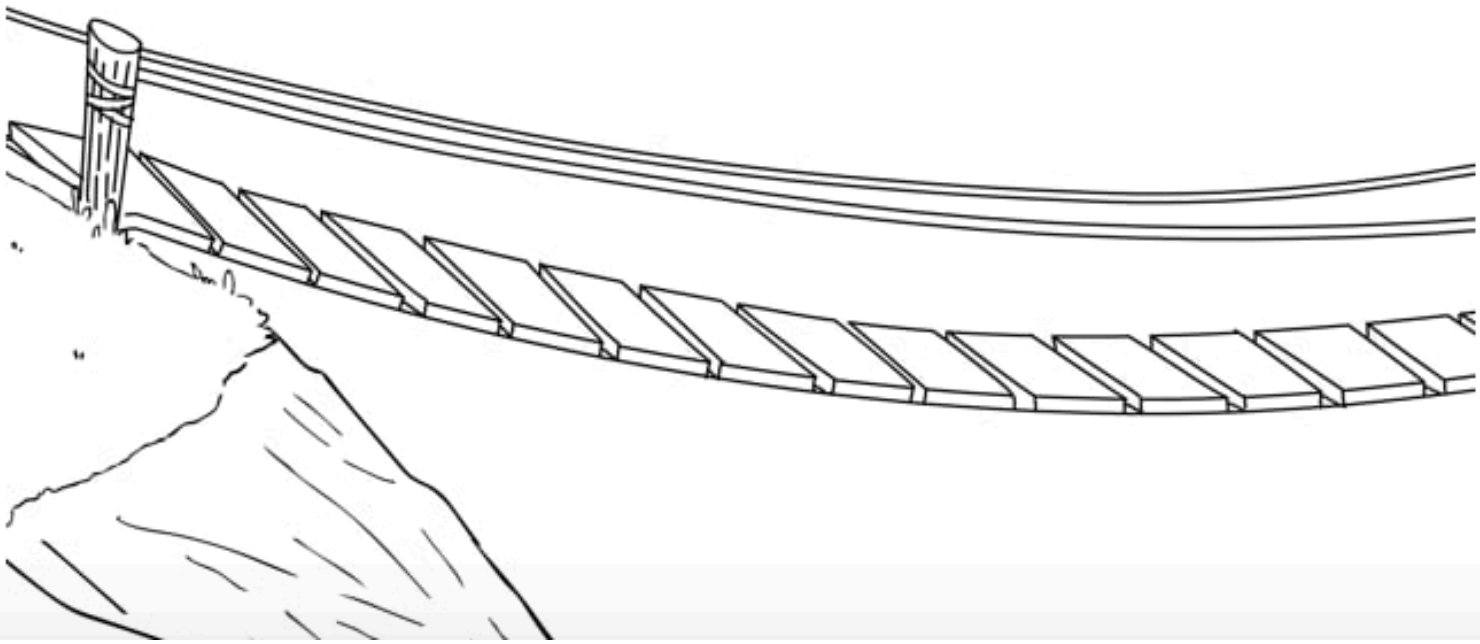
Draft narrative of 'data collection'

To-Do Date: Mar 22 at 16:00

Weeks 4-6 | Data collection rapids: Data collection approach

Data Management & Analysis Ravine | Data analysis approach

Weeks 8-11



How do you propose to analyse your data to answer your specific study aim / question?

For many of you, this may be your first exposure to data analysis. This learning material will provide you with some beginning understanding of ***qualitative*** and ***quantitative*** approaches, and apply this information to your research proposal, particularly in relation to how you plan to interrogate your data to answer your specific study aims /questions.

While more detailed exploration of data analyses is beyond the scope of this subject and course, the content will also serve as a base for those of you who may wish to implement your proposal in your work context, or pursue a research degree in the future.

Issues to consider

	Qualitative	Quantitative
Type of data collected	Level / depth of textual data	Primary and secondary outcome variables Level of measurement: • Nominal • Ordinal • Interval • Ratio
Type of analysis	• Qualitative descriptive • Content • Thematic	Descriptive / inferential? Test of differences in: • 'means' • 'proportions' • 'associations'
Quality of data	*'Trustworthiness'*	*'Internal Validity / Instrument Validity'?*

Note: For both ***qualitative*** and ***quantitative*** studies, some numerical data may be collected, particularly for participant demographic (and possibly clinical) data, to adequately describe your sample to readers.

QUALitative data analysis

Weeks 8 - 11 | Data Management and Analysis Ravine

Data collection and management

In your proposal, you will have decided that data will be collected using one (or more) of the following approaches:

- Field notes / observations
- Interviews / Focus groups
- Surveys
- Secondary Sources
- Artefacts / images
- Documentation policies, case studies
- Use of fieldwork journal or research diary to support data collection

As the data are text-based (words), analysis of key terms or phrases is the process, examining findings for similarities and differences.

Qualitative analyses

All analytic processes and steps share:

- Inductive reasoning (ideas generated from collected data; a 'bottom-up' approach)
- Text as the analytic unit (words, terms, phrases)
- Coding of text by assigning meaningful labels
- Analysis is circular and non-linear
- Collection and analysis of data is contemporaneous

Domain 3. Analysis and findings

Data Analysis	
24. Number of data coders	How many coders coded the data?
25. Description of coding tree	Did authors provide a description of the coding tree?
26. Derivation of themes	Were themes identified in advance or derived from the data?
27. Software	What software, if applicable, was used to manage the data?
28. Participant checking	Did participants provide feedback on the findings?

Reporting	
29. Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number
30. Data and findings consistent	Was there consistency between the data presented and the findings?
31. Clarity of major themes	Were major themes clearly presented in the findings?
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?

Context for qualitative data analysis

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Data analysis (units)

A researcher will pose questions of the data when examining the transcripts or documents, using the following process

- 'Read- re-read' approach; move between different transcripts
- Document anything interesting (in your research / reflective diary)
- If an interesting issue / finding is identified, ask yourself 'why?'
  - Open up interesting cases and compare
  - Ask why you as the researcher are interested?
- When reporting findings, elaborate / clarify topic / issue, using representative / exemplar quotes
  - Check examples in your literature review for how authors present this information and use direct quotes from participants

Describing data analyses

When reporting the ***data analysis*** section:

- Describe how data has been coded, how codes have led to themes, and how themes have been incorporated into your interpretative account
- Use of quotes gives participants a 'voice', offering the reader 'validity checks' of your interpretation against actual data
- Communicate how extensive your evidence is (e.g. is your theme unique to just one of your participants, is it common across an identifiable sub-group)
- It is plausible - don't take your interpretation too far away from the data

Interview data management and analysis

Description through to interpretation

- Coding of text - technical steps
- Intense scrutiny
- Case comparison
- Code hierarchy "associations/relationships"

Resource constraints may stop analysis...

Analysing text

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- Analyse: think about the data
- Construct: new meaning of the data
- Coding: dependable; should match with previous coding to ensure coherence when writing themes

Data saturation

- Account for in the research proposal
- Reached when new data does not add to the overall story, model, theory or framework
- Not every piece of data will be used

Types of qualitative analyses

Selection is based on the depth of interpretation available and researcher experience.

Type	Characteristics
Qualitative descriptive (Sandelowski 2010)	• Involves a level of interpretation (despite the label) • Can include some statistical analyses • Naturalism as the common theory
Content (Can be 'qualitative' or 'quantitative')	• Focuses on 'manifest' (what was actually written), not 'latent' (what was intended) meanings of narrative • Comparing and contrasting terms / phrases
Thematic	• Coding of terms / phrase • Iterative development of sub-themes • Revising, collapsing into themes and testing against data

Phases of thematic analysis

Here is a common step-wise process for engaging with qualitative data

Phase	Description of the process
1. Familiarising yourself with your data:	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas.
2. Generating initial codes:	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes:	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes:	Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. Defining and naming themes:	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.
6. Producing the report:	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of analysis.

Trustworthiness

Weeks 8 - 11 | Data Management and Analysis Ravine

Common techniques to demonstrate *trustworthiness* in qualitative research

Credibility + Auditability + Fittingness = Confirmability

Criteria	Evidence
Credibility	Member (participant) checking: Check analytic descriptions, categories, concepts, emerging themes with participants.
Auditability	Report audit trail: decisions on design, sampling, data collection, data analysis.
Fittingness	Peer checking: use of an independent coder or expert peers to evaluate emerging interpretations.
Confirmability	Findings reflected in above evidence.

Re-cap | Levels of measurement

Weeks 8 - 11 | Data Management and Analysis Ravine

Let's clarify the characteristics of the ***NOIR*** categories (Nominal, Ordinal, Interval, Ratio). Here's a quick reference below:

Levels of measurement

Measurement level	Description	Measurement of central tendency	Measures of variability
Nominal	Classification	Mode	Modal %, range, frequency distribution
Ordinal	Relative rankings	Mode, median	Range, percentile, inter-quartile range, frequency distribution
Interval	Rank ordering with equal intervals	Mode, median, mean	Range, percentile, inter-quartile range, standard deviation
Ratio	Rank ordering, equal intervals & absolute zero	Mode, median, mean	Range, percentile, inter-quartile range, standard deviation

Critiquing data analysis

Weeks 8 - 11 | Data Management and Analysis Ravine

Critiquing Statistical Findings

Given what you now understand about quantitative date analysis, please review your studies selected for your ***Background*** (literature review).

Conduct a focussed reading of the ***Data analysis*** and ***Results*** sections of each paper.

Reflection

In the comments box below note:

1. Are the statistical tests appropriate for the:
    - problem
    - method
    - level of measurement?
2. Are the results understandable?
3. Do results in tables and text agree?

Data analysis | Issues to consider

Weeks 8 - 11 | Data Management and Analysis Ravine

Let's return to considering your own research proposal now, in your role as a ***researcher***...

Issues to consider

Plan what you need to describe your study proposal:

- Descriptive statistics for demographic data and for observational designs
- Level/s of measurement for outcome variable/s
- If inferential testing possible, select tests based on study aim:
  - to compare means, proportions or associations
- Distribution of scores for outcome variable/s
  - non-parametric tests?
  - parametric tests?
- Measures of statistical significance, power

So, which statistical test will you propose for your study?

Statistical tests | descriptive and inferential statistics

Weeks 8 - 11 | Data Management and Analysis Ravine

These two types of statistics have different purposes when reporting data.

Descriptive statistics

This set of statistical tests enable a researcher to report the key characteristics of a study sample; commonly using frequency (count) or proportions (%) to ***describe*** participants.

Inferential statistics

As the name implies, for these group of statistical tests, a researcher aims to make ***inferences*** or predictions about a population of interest, based on a sample of participants or other data sources. Inferential statistics can be either ***parametric*** or ***non-parametric*** tests, based on the frequency distrubtion of values for a given variable.

Normal and non-normal distribution of variables

It's important to understand this distinction, and to appreciate the assumptions when sample data are distributed in a particular pattern. Note:

Variables that are **normally distributed**; that is all the values for a variable display a frequency distribution pattern shaped like a bell curve, **enable**:

- **Mean and standard deviation** to be used to describe the data; the average score, and the dispersion of score around the average
- **Parametric** tests to be used

Variables that are **not normally distributed**; that is, the shape of the frequency distribution is skewed / has a tail / is not a bell shape, **require**:

- **Median and IQR** values to describe the average score and score variations
- **Non-parametric** tests to be used

Tests of statistical significance

Weeks 8 - 11 | Data Management and Analysis Ravine

As you will by now appreciate, for ***inferential statistics*** there are a number of conditions to be met, and characteristics to understand. For example:

Statistical significance

The probability of rejecting a true hypothesis.

- α = 0.05 (minimum level of significance acceptable) - if the study were conducted 100 times, rejecting a true hypothesis would be wrong 5 times out of the 100 trials
- the likelihood of achieving statistical significance increases as the sample size increases (indicated by degrees of freedom - df)

95% Confidence Interval (95%CI)

- the range around the ***point estimate*** - **mean**
- from one study (sample), it can be estimated that there is a 95% chance that the "real" difference (population) lies between the two limits
- 95% = μ ± 1.96 sd / $\sqrt{}$ n

Tests of difference between outcome variables

- means
- proportions

Tests of relationships between variables

- associations
- predictive relationships

Review the following for the ***test purpose*** and the specific ***tests*** based on the distribution of data - ***normal*** or ***non-normal*** distribution curves:

Normal (bell curve) **distribution** = **parametric** tests

Non-normal (skewed **distribution**, or data variables are distribution free) = **non-parametric** tests