

RESEARCH METHODS & STATISTICS MANUAL

1st Edition (2023)

A guide to statistical methodology and research
study design for practitioners of all levels



CFMS FEMC

Canadian Federation of Medical Students Fédération des étudiants et des étudiantes en médecine du Canada

Global Health Program
Programme de santé mondiale

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RESEARCH METHODOLOGY

OVERVIEW OF RESEARCH STUDY DESIGN

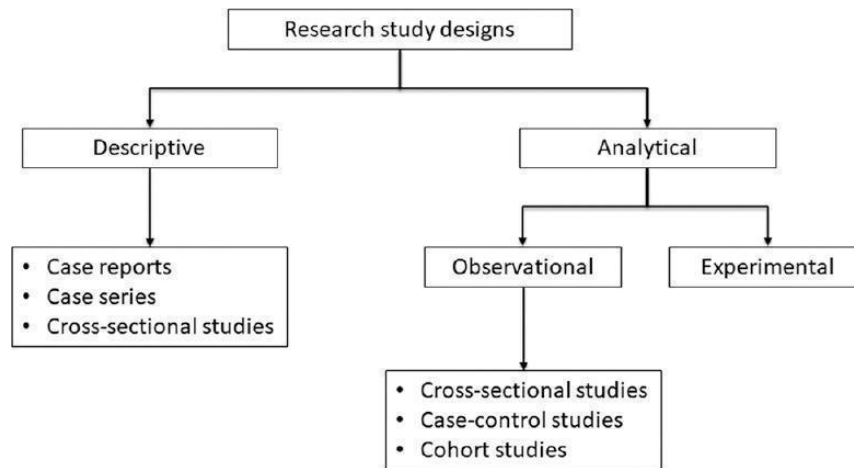
DESCRIPTION

OVERVIEW

- **Research study design** is a set of methods used to collect and analyze data on variables to answer a research question
- **Variable** is a measurable attribute
 - Categorical variable: finite number of categories or distinct groups (e.g. sex, disease status)
 - Continuous variable: infinite number of values (e.g. age, serum protein level)
- **Primary research**: generation of new data
- **Secondary research**: synthesis of data and literature that has already been published
- Several study designs are available, each with inherent advantages and limitations
- Choice of study design depends on nature of the research question, goal of the research, and availability of resources

CLASSIFICATION OF STUDY DESIGNS

- Observational vs. interventional
 - **Observational**: the researcher does not actively intervene; the exposure is naturally occurring (e.g. smoking/alcohol use)
 - **Interventional**: research actively performs an intervention; the exposure is artificially occurring (e.g. drug/vaccine administration)
- Observational studies can be further classified
 - *Descriptive vs. analytical*
 - **Descriptive**: describes data on one or more characteristics; do not establish relationships between variables
 - **Analytical**: test a hypothesis involving variables; establishes relationships between variables
 - *Prospective vs. retrospective*
 - **Prospective**: outcome of interest has not yet occurred yet at time of enrolment; data is collected over a period of follow-up
 - **Retrospective**: outcome of interest has already occurred at time of enrolment; data collected from records or participant recall (memory), no follow-up is involved
- By definition, interventional studies are always analytical and prospective



BASIC ALGORITHM FOR DETERMINING STUDY DESIGN OF AN ARTICLE

1. Did the study question aim to draw inferences about relationships between variables?
 - a. Yes, the aim is to determine relationships between relationships ☑ **analytical study**
 - b. No, the aim is to describe the characteristics of a sample ☑ **descriptive study**
2. From 1a. Did the investigator determine the exposure?
 - a. Yes, the exposure will be artificially determined ☑ **experimental study**
 - b. No, the exposure will be naturally occurring ☑ **observational study**
3. From 2b. When was the outcome determined?
 - a. Start of study ☑ **case-control study**
 - b. End of period of follow-up ☑ **cohort study**
 - c. Simultaneously with exposure ☑ **cross sectional**

RESOURCES

- <https://www.youtube.com/watch?v=SaP1O0i1bdc>
 - Degree of difficulty: beginner
 - Type: video
 - Content and depth of coverage: brief introduction to classification of study designs
 - Recommendations about how to use: beginning point for individuals with little knowledge background on research methodology
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6176693/>
- <https://www.statisticshowto.com/experimental-design/#RandomC>
 - Degree of difficulty: beginner-intermediate
 - Type: review article and website
 - Content and depth of coverage: introduction to classification of study designs and how to determine the study design of a research article
 - Recommendations about how to use: read after having a basic understanding of research methodology classification (e.g. after watching video)
- **Martin Bland. (4th ed). An introduction to medical statistics.**

- o Degree of difficulty: intermediate
- o Type: textbook
- o Content and depth of coverage: in-depth information on types of study designs and how to tailor study design to the research question. Great resource for medical students
- o Recommendations about how to use: read or reference after solidifying a basic foundation in terms of research methodology

CASE REPORTS AND CASE SERIES

DESCRIPTION

What is the method?

- Case report: description of patient with a rare disease, a disease that has rarely reported on in the literature, or an unusual presentation of a disease
- Case series: collection of multiple case reports, usually with same or similar disease entities

How is the method performed?

- Retrospectively collect and report on data (e.g. demographic, presentation, prognosis, etc.) of patients after obtaining consent

What information can it give you/what conclusions can be drawn?

- Anecdotal information with very limited applicability to other patients but can be important in:
 - Highlighting a clinical pearl
 - Introducing a new disease/manifestation
 - Opening a new avenue of research

In what situations is the method appropriate?

- Illustrating a clinical message or manifestation that is new, uncommon, or interesting
- Highlighting potential for medical and research advancement
- Simple, quick, inexpensive

In what situations is the method inappropriate?

- Cannot provide robust information on prevalence nor relationships between exposure/disease/intervention and outcomes
- High confidence in results needed to change clinical practice

Example of how it is used in medical research:

- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4593263/>

RESOURCES

- <https://www.youtube.com/watch?v=Jd3gFT0-C4s>
 - Degree of difficulty: beginner
 - Type: video
 - Content and depth of coverage: brief introduction to different types of study designs, situations in which each is used, and advantages/limitations of each
 - Recommendations about how to use: beginning point for individuals with little knowledge background on research methodology
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6371702/>
- <https://www.statisticshowto.com/experimental-design/#RandomC>
 - Degree of difficulty: beginner-intermediate
 - Type: review article and website

- o Content and depth of coverage: introduction to types of descriptive studies, situations in which each is used, and advantages/limitations of each
- o Recommendations about how to use: read after having a basic understanding of different types of study designs
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6306179/>
 - o Degree of difficulty: intermediate
 - o Type: review article
 - o Content and depth of coverage: in-depth information on the importance of case reports and their role in advancing medical literature and clinical practice
 - o Recommendations about how to use: read or reference after solidifying a basic foundation in terms of research methodology

CROSS SECTIONAL STUDIES

DESCRIPTION

What is the method?

- Descriptive analysis of variables of interest collected at one point in time

How is the method performed?

- Collect data on the presence or level of one or more variables of interest at individual level at one point in time

What information can it give you/what conclusions can be drawn?

- “Snapshot” of multiple variables of interest (e.g. exposure, outcome) in a population at one point in time
 - Prevalence of risk factor or disease
 - Characteristics of a disease in a population

In what situations is the method appropriate?

- Provides information on disease burden and health care needs of a population, including geographic distribution, which informs resource planning
- Can be repeated at a future date to identify temporal trends in variables of interest
- Helps generate hypotheses regarding causes and prognosis of disease which can be explored with more complex study designs
- Simple, quick, inexpensive

In what situations is the method inappropriate?

- Study sample is not representative of population
- Cannot provide robust information on relationships between exposure/disease/intervention and outcomes
 - Association may be confounded by variables that are related to both the exposure and outcome (e.g. smoking confounds the association between yellow fingernails and lung cancer. Yellow fingernails do not increase risk of cancer, smoking does)
- High confidence in results needed to change clinical practice

Example of how it is used in medical research:

- <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0117349>

RESOURCES

- <https://www.youtube.com/watch?v=Jd3gFT0-C4s>
 - Degree of difficulty: beginner
 - Type: video
 - Content and depth of coverage: brief introduction to different types of study designs, situations in which each is used, and advantages/limitations of each
 - Recommendations about how to use: beginning point for individuals with little knowledge background on research methodology
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6371702/>

- <https://www.statisticshowto.com/experimental-design/#RandomC>
 - Degree of difficulty: beginner-intermediate
 - Type: review article and website
 - Content and depth of coverage: introduction to types of descriptive studies, situations in which each is used, and advantages/limitations of each
 - Recommendations about how to use: read after having a basic understanding of different types of study designs

- **Martin Bland. (4th ed). An introduction to medical statistics.**
 - Degree of difficulty: intermediate
 - Type: textbook
 - Content and depth of coverage: in-depth information on types of study designs and how to tailor study design to the research question. Great resource for medical students
 - Recommendations about how to use: read or reference after solidifying a basic foundation in terms of research methodology

ECOLOGICAL STUDY

DESCRIPTION

What is the method?

- Correlational study design that looks for association between exposure and outcome across populations, rather than individuals

How is the method performed?

- Correlate pre-collected data on exposure vs. outcome variables of interest at group level (e.g. province, country)

What information can it give you/what conclusions can be drawn?

- Relationships between exposure and outcome variables on a population level
 - What exposures are risk factors for a disease or disease outcome

In what situations is the method appropriate?

- Data already collected and available from reliable source
- Differences in variables between individuals smaller than differences in variables between groups
- Helps generate hypotheses regarding causes of prognosis of disease which can be explored with more complex study designs
- Simple, quick, inexpensive

In what situations is the method inappropriate?

- Cannot provide strong evidence of causality between exposure/disease/intervention and outcomes
 - Association at group level may not be true at individual level
 - Temporality (i.e. exposure came before outcome) cannot be ascertained
 - Association may be confounded by variables that are related to both the exposure and outcome (e.g. smoking confounds the association between yellow fingernails and lung cancer. Yellow fingernails do not increase risk of cancer, smoking does)
- High confidence in results needed to change clinical practice

Example of how it is used in medical research:

- <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1661390>

RESOURCES

- <https://www.youtube.com/watch?v=Jd3gFT0-C4s>
 - Degree of difficulty: beginner
 - Type: video
 - Content and depth of coverage: brief introduction to different types of study designs, situations in which each is used, and advantages/limitations of each
 - Recommendations about how to use: beginning point for individuals with little knowledge background on research methodology
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6371702/>

- <https://www.statisticshowto.com/experimental-design/#RandomC>
 - Degree of difficulty: beginner-intermediate
 - Type: review article and website
 - Content and depth of coverage: introduction to types of descriptive studies, situations in which each is used, and advantages/limitations of each
 - Recommendations about how to use: read after having a basic understanding of different types of study designs

- **Martin Bland. (4th ed). An introduction to medical statistics.**
 - Degree of difficulty: intermediate
 - Type: textbook
 - Content and depth of coverage: in-depth information on types of study designs and how to tailor study design to the research question. Great resource for medical students
 - Recommendations about how to use: read or reference after solidifying a basic foundation in terms of research methodology

CASE-CONTROL STUDY

DESCRIPTION

What is the method?

- Retrospective study design that enrolls participants with and without a disease/outcome, elicits history of exposure in each group, then compares to identify associations between exposure and outcome variables of interest

How is the method performed?

- Enrol cases (participants with outcome) and controls (participants without outcome that are representative of population from which cases were drawn) from hospital records, disease registries, etc. → identify history of exposure in each group → describe associations between exposure and outcome variables of interest with odds ratio
 - **Odds ratio:** ($\frac{\text{\# cases with exposure}}{\text{\# cases without exposure}}$) / ($\frac{\text{\# controls with exposure}}{\text{\# controls without exposure}}$)
- Matching (ensuring same characteristic, such as smoking status or age, in each case-control grouping) may be used to reduce risk of confounding

What information can it give you/what conclusions can be drawn?

- Relationships between exposure and outcome variables on an individual level
 - To what extent do certain exposures increase the risk of developing a disease or outcome
- Due to lack of 'at-risk' group, cannot calculate incidence (e.g. how many of exposed individuals develop disease) nor relative risk (incidence among exposed divided by incidence among non-exposed individuals)

In what situations is the method appropriate?

- Rare diseases, where identifying cases is easier than following up large numbers of exposed persons (such as in cohort studies)
- Initial study design to assess relationships between exposure and outcome variables of interest due to simplicity and resource efficiency
- Examine relationship between an outcome and multiple exposures
- Evidence can justify a more complex study design (e.g. cohort, interventional)

In what situations is the method inappropriate?

- Cannot provide strong evidence on causality between exposure/disease/intervention and outcomes
 - Temporality cannot be ascertained
 - Association may be confounded by variables that are related to both the exposure and outcome
- Incidence or relative risk is needed
- High confidence in results needed to change clinical practice

Example of how it is used in medical research:

- <https://academic.oup.com/aje/article/185/12/1255/3778245>

RESOURCES

- <https://www.youtube.com/watch?v=Jd3gFT0-C4s>
 - Degree of difficulty: beginner
 - Type: video
 - Content and depth of coverage: brief introduction to different types of study designs, situations in which each is used, and advantages/limitations of each
 - Recommendations about how to use: beginning point for individuals with little knowledge background on research methodology

- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6463505/>
- <https://www.statisticshowto.com/experimental-design/#RandomC>
 - Degree of difficulty: beginner-intermediate
 - Type: review article and website
 - Content and depth of coverage: introduction to types of analytical observational studies, situations in which each is used, and advantages/limitations of each
 - Recommendations about how to use: read after having a basic understanding of different types of study designs

- **Martin Bland. (4th ed). An introduction to medical statistics.**
 - Degree of difficulty: intermediate
 - Type: textbook
 - Content and depth of coverage: in-depth information on types of study designs and how to tailor study design to the research question. Great resource for medical students
 - Recommendations about how to use: read or reference after solidifying a basic foundation in terms of research methodology

COHORT STUDIES

DESCRIPTION

What is the method?

- A cohort is a group of people with shared exposure
- Cohort studies follow groups of individuals with similar levels of exposure to determine differences in occurrence of the outcome

How is the method performed?

- Enrol participants who are free of outcome at baseline ☐ determine presence or absence of exposure in each subject ☐ follow up over time (either retrospectively or prospectively) to determine occurrence of outcome ☐ describe associations between exposure and outcome variables of interest with relative risk ratio
 - **Relative risk ratio:** ($\frac{\text{\# of exposed who developed outcome}}{\text{\# of all exposed}}$) / ($\frac{\text{\# of non-exposed who developed outcome}}{\text{\# of all non-exposed}}$)

What information can it give you/what conclusions can be drawn?

- Relationships between exposure and outcome variables on an individual level
 - To what extent do certain exposures increase the risk of developing a disease or outcome
- Can calculate incidence and relative risk, unlike case-control studies
- Best alternative to when experimental studies are not feasible (e.g. unethical to assign participants to smoking, or impractical to diabetes as an exposure)

In what situations is the method appropriate?

- Provides stronger evidence than case-control studies on relationships between exposure and outcome variables of interest due to ascertainment of temporality
- Examine relationship between multiple outcomes and multiple exposures
- Calculate incidence and relative risk
- Evidence can justify a more complex study design (e.g. cohort, experimental)

In what situations is the method inappropriate?

- Very rare diseases
- Limited resources and time (cohort studies often require long duration of follow up)
- Does not provide the strongest evidence on causality between exposure/disease/intervention and outcomes
 - Association may be confounded by variables that are related to both the exposure and outcome

Example of how it is used in medical research:

- <https://link.springer.com/article/10.1007%2Fs00198-010-1499-4>

RESOURCES

- <https://www.youtube.com/watch?v=Jd3gFT0-C4s>
 - Degree of difficulty: beginner
 - Type: video

- o Content and depth of coverage: brief introduction to different types of study designs, situations in which each is used, and advantages/limitations of each
- o Recommendations about how to use: beginning point for individuals with little knowledge background on research methodology
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6463505/>
- <https://www.statisticshowto.com/experimental-design/#RandomC>
 - o Degree of difficulty: beginner-intermediate
 - o Type: review article and website
 - o Content and depth of coverage: introduction to types of analytical observational studies, situations in which each is used, and advantages/limitations of each
 - o Recommendations about how to use: read after having a basic understanding of different types of study designs
- **Martin Bland. (4th ed). An introduction to medical statistics.**
 - o Degree of difficulty: intermediate
 - o Type: textbook
 - o Content and depth of coverage: in-depth information on types of study designs and how to tailor study design to the research question. Great resource for medical students
 - o Recommendations about how to use: read or reference after solidifying a basic foundation in terms of research methodology

RANDOMIZED CONTROLLED TRIALS

DESCRIPTION

What is the method?

- Experimental comparison study in which participants are randomly allocated to different exposures (including lack of exposure) and outcomes are compared between groups

How is the method performed?

- Group of participants free of both exposure and outcome of interest → randomly assigned to one or more experimental (receive exposure, most often intervention/drug) and control (no exposure) groups → describe associations between exposure and outcome variables of interest with relative risk ratio
- Advantage over cohort studies is that randomization theoretically minimizes the risk of confounding (i.e. all variables and characteristics are balanced between groups except for the exposure of interest; thus any difference in outcomes will be due to exposure of interest)
- **Variants**
 - Factorial design: participants are assigned to both single and combined intervention groups - to assess the efficacy of each intervention and each combination of interventions
 - Crossover design: after a fixed period of time, participants initially assigned to exposure ‘crosses over’ to the non-exposure group, and vice versa – advantages that each participant can serve as their own control and fewer participants needed than traditional RCT
 - Cluster design: groups (e.g. schools, communities) rather than individuals are assigned to groups – when interventions cannot be easily administered to groups

What information can it give you/what conclusions can be drawn?

- Provides highest level of evidence among primary research designs on causal relationships between exposures and outcomes
 - To what extent do certain exposures increase the risk of developing a disease or outcome
- By extension, provides the most robust evidence on the safety and efficacy of a medical intervention/drug

In what situations is the method appropriate?

- Provides strongest evidence among primary research designs on causal relationships between exposure and outcome variables of interest (ascertained temporality, eliminated confounding)
- Examine relationship between multiple outcomes and a few exposures
- High confidence needed to change clinical practice

In what situations is the method inappropriate?

- Rare diseases
- Exposure of interest cannot be assigned to individuals, either due to ethical or practical reasons

- Limited resources and time
- Very rare diseases
- Anticipated sample is small in size and/or not representative of the population of interest

Example of how it is used in medical research:

- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4362615/>

RESOURCES

- <https://www.youtube.com/watch?v=Jd3gFT0-C4s>
 - Degree of difficulty: beginner
 - Type: video
 - Content and depth of coverage: brief introduction to different types of study designs, situations in which each is used, and advantages/limitations of each
 - Recommendations about how to use: beginning point for individuals with little knowledge background on research methodology
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6647894/>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6801992/>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7034134/>
- <https://www.statisticshowto.com/experimental-design/#RandomC>
 - Degree of difficulty: beginner-intermediate
 - Type: review articles and website
 - Content and depth of coverage: introduction to types of experimental studies, situations in which each is used, advantages/limitations of each, and methodological considerations unique to experimental studies (e.g. allocation concealment, blinding, calculation of sample size, accounting for missing data)
 - Recommendations about how to use: read after having a basic understanding of different types of study designs
- **Martin Bland. (4th ed). An introduction to medical statistics.**
 - Degree of difficulty: intermediate
 - Type: textbook
 - Content and depth of coverage: in-depth information on methodological considerations and statistical analyses used in experimental studies. Great resource for medical students
 - Recommendations about how to use: read or reference after solidifying a basic foundation in terms of research methodology

SYSTEMATIC REVIEWS AND META-ANALYSES

DESCRIPTION

What is the method?

- Systematic review: summary of literature that uses reproducible methods to systematically search, critically appraise, and synthesize all available information on a specific issue
- Meta-analyses: statistical synthesis of data from multiple independent primary studies to produce a single estimate of an association between an exposure and outcome

How is the method performed?

- Complex process that is beyond the scope of this manual, but in general:
 - 1. Define the research question
 - A common method for defining the research method in systematic reviews is the PICO method. for example:

Population	Who would your conclusions apply to?	In undergraduate medical students enrolled at medical schools in Canada
Intervention	Your experimental treatment of-interest	are warm cookies
Comparison	Placebo/standard of care	compared to cold cookies
Outcome	How you determine whether you treatment 'works'	effective at reducing self-reported stress levels?

- 2. Search scientific resources such as electronic databases with a search strategy
- 3. Screen the retrieved papers by title/abstract and then full text to identify eligible papers
- 4. Assess the quality of studies using validated tools
- 5. Synthesize the outcome measures of individual studies
- 6. Subgroup (limiting analyses to subgroups of participants, e.g. adults vs. children) and sensitivity (repeating analysis with substitutions of alternative decisions or ranges of values for decisions that were arbitrary or unclear, e.g. excluding studies with dubious eligibility) analyses

What information can it give you/what conclusions can be drawn?

- Provides highest level of evidence among secondary research designs on relationships between exposures and outcomes
 - Quality of evidence depends on quality of studies synthesized in the systematic review

- By extension, provides the most robust evidence on the safety and efficacy of a medical intervention/drug

In what situations is the method appropriate?

- Provides the strongest evidence among secondary research designs on relationships between exposure and outcome variables of interest (higher generalizability and consistency than individual primary research studies)
- Examines relationship between multiple outcomes and a few exposures
- Summarizes available data and identify gaps in research evidence
- High confidence needed to change clinical practice

In what situations is the method inappropriate?

- Research question is broad or general (e.g. no specific outcome of interest)
- Limited amount of evidence on the subject of interest
- Limited amount of numerical data on the subject of interest (specific to meta-analysis)

Example of how it is used in medical research:

- [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30531-6/fulltext?rss=yes](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30531-6/fulltext?rss=yes)

RESOURCES

- <https://www.youtube.com/watch?v=WB9pbHqUs5c>
 - Degree of difficulty: beginner
 - Type: video
 - Content and depth of coverage: brief introduction to systematic reviews and meta-analyses, situations in which each is used, and advantages/limitations of each
 - Recommendations about how to use: beginning point for individuals with little knowledge background on research methodology
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3894019/>
 - Degree of difficulty: beginner
 - Type: review article
 - Content and depth of coverage: introduction to systematic reviews and meta-analyses, how they are conducted, and how they are used by clinicians
 - Recommendations about how to use: read after having a basic understanding of different types of study designs
- **Martin Bland. (4th ed). An introduction to medical statistics.**
 - Degree of difficulty: intermediate
 - Type: textbook
 - Content and depth of coverage: in-depth information on methodological considerations and statistical analyses used in systematic reviews and meta-analyses. Great resource for medical students
 - Recommendations about how to use: read or reference after solidifying a basic foundation in terms of research methodology

HIERARCHY OF EVIDENCE

DESCRIPTION

- Levels of evidence are assigned to studies based on methodological quality of design, internal validity, generalizability, and applicability to clinical practice
 - Lower level = higher quality of evidence, with level I being the highest
- Hierarchy of evidence are different depending on the type of research question (e.g. effectiveness, diagnosis, prognosis, economic evaluations) because some research designs, especially RCTs, are not suitable to certain question types
 - Systematic reviews and meta-analyses are the highest level of evidence for every type of clinical question
 - Afterward, evidence is generally organized according to below:

Level of evidence	Description
Level I	<ul style="list-style-type: none"> ● Systematic review of meta-analysis of all relevant randomized controlled trials (RCTs) ● Evidence-based clinical practice guidelines based on systematic reviews of RCTs or three or more high quality RCTs with similar results
Level II	<ul style="list-style-type: none"> ● At least one well-designed, large RCT
Level III	<ul style="list-style-type: none"> ● Well-designed controlled trials without randomization (i.e., quasi-experimental)
Level IV	<ul style="list-style-type: none"> ● Well-designed cohort or case-control studies
Level V	<ul style="list-style-type: none"> ● Systematic reviews of descriptive and qualitative studies
Level VI	<ul style="list-style-type: none"> ● Single descriptive or qualitative study
Level VII	<ul style="list-style-type: none"> ● Opinion of authorities and/or reports of expert committees

RESOURCES

- https://www.youtube.com/watch?v=u_-lxyFtlN8
 - Degree of difficulty: beginner
 - Type: video
 - Content and depth of coverage: brief introduction to levels of evidence and how they influence clinical practice
 - Recommendations about how to use: watch after developing a basic understanding of research methodology
- https://jbi.global/sites/default/files/2019-05/JBI-Levels-of-evidence_2014_0.pdf
 - Degree of difficulty: beginner-intermediate
 - Type: article
 - Content and depth of coverage: introduction to hierarchy of evidence classified by type of clinical question
 - Recommendations about how to use: read after developing a basic understanding of research methodology

- **Gordon Guyatt, Drummond Rennie, Maureen O. Meade, Deborah J. Cook. (3rd edition). Users' guides to the medical literature.**
 - Degree of difficulty: intermediate
 - Type: textbook
 - Content and depth of coverage: in-depth information on levels of evidence, how to critically appraise medical literature, and how to inform clinical practice with medical literature
 - Recommendations about how to use: read or reference after solidifying a basic foundation in terms of types of study design and levels of evidence

- <https://recruit.ucsf.edu/events/recruitment-underrepresented-study-populations#>
 - Degree of difficulty: beginner
 - Type: webcast
 - Content and depth of coverage: brief introduction to levels of evidence and how they influence clinical practice
 - Recommendations about how to use: watch after developing a basic understanding of research methodology

- <https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-016-1384-3>
 - Degree of difficulty: beginner-intermediate
 - Type: article
 - Content and depth of coverage: introduction to hierarchy of evidence classified by type of clinical question
 - Recommendations about how to use: read after developing a basic understanding of research methodology

DESCRIPTIVE STATISTICS

DESCRIPTION

These are summary statistics utilized to describe basic characteristics of a data set.

Descriptive statistics are used to:

- Summarize and organize information.
- Describe variables collected for a sample.
- Draw conclusions about aggregates of respondents.

How is it performed?

Using three types of measures:

- Measures of central tendency
- Measures of variability
- Sample proportions and frequencies

What information does the method give you?

Measures of central tendency provide information about how data “clusters” or about “typically” occurring values.

- Interval- and ratio-level data measured using:
 - Mean
 - Median
 - Percentiles
- Nominal- and ordinal-level data measured using:
 - Mode
- Measures of variability provide information about how “spread out” observations in data are.
- Interval- and ratio-level data measured using:
 - Range
 - Variance
 - Standard deviation
- Nominal- and ordinal-level data measured using:
 - Range

Sample proportion and frequencies provides information about the sample size and any grouping within the sample. Typically represented in an easily interpreted visual format:

- Bar charts
- Histograms
- Pie charts

Situations Where Appropriate

When you want to:

- Describe an entire target population.
- Organize, analyze, and present known data.
- Make conclusions only about a particular group of observed individuals.
- Conduct “fact-finding”.

Situations Where Inappropriate

When you want to:

- Compare, test, or predict things about data that is beyond availability.
- Make conclusions about a larger group of individuals based on the smaller group that is sampled.
- Conduct “hypothesis testing”.

Example in Medical Research

- [Vascular Adhesion Protein-1 Is Associated With Acute Kidney Injury in High-Risk Patients After Cardiac Surgery](#) - Meersch et al. 2019
- [Link to article by Patrick et al. 2019](#) analyzing the descriptive statistics used in the Meersch et al. 2019 paper
- [A descriptive analysis of medical health services utilization of Veterans living in Ontario: a retrospective cohort study using administrative healthcare data](#)

Other Special Considerations

Descriptive statistics:

1. Do NOT describe cause-and-effect relationships.
2. Can be either qualitative OR quantitative (or both!)
 - a. E.g. case studies, census, policy research, etc.
3. Are often expressed with charts
 - a. Histograms → for continuous variables with MANY responses within a range of values.
 - i. E.g. interval- and ratio-level data
 - b. Bar charts → for categorical variables where you want to account for every possible distinct answer.
 - i. E.g. nominal- and ordinal-level data

RESOURCES

- [5 Minute Statistics in Clinical Research - Descriptive Statistics](#)
 - Degree of difficulty: low
 - Type: video
 - Content & depth of coverage: superficial overview of descriptive statistics
 - Recommendations for use: intro to descriptive statistics for those who have never used them before
- [Descriptive Statistics Playlist - Khan Academy](#)
 - Degree of difficulty: low
 - Type: video
 - Content & depth of coverage: in-depth explanations of basic concepts in descriptive statistics
 - Recommendations for use: prior to embarking on descriptive research project or used in tandem with university intro statistics coursework
- [An introduction to descriptive statistics: a review and practical guide \(using clinical practice in Radiology as an example\)](#)
 - Degree of difficulty: low
 - Type: article

- o Content & depth of coverage: overview of descriptive statistics grounded in clinical practice
- o Recommendations for use: gain insight into how descriptive statistics are relevant to the day-to-day practice of clinicians
- **How to run descriptive statistics in: [SPSS](#), [R](#), [Excel](#), [STATA](#), [SAS](#)**
 - o Degree of difficulty: intermediate
 - o Type: video
 - o Content & depth of coverage: how to run descriptive statistics in different analysis programs
 - o Recommendations for use: when running your own statistics for the first time

QUALITATIVE METHODS

ETHNOGRAPHY

DESCRIPTION

- What is the method?
 - Ethnography is a type of qualitative research that originated in the field of anthropology. It is the practice of recording and analyzing cultural and societal practices through participant-observation.
- How is the method performed?
 - Participant-observation involves using open-ended inductive long-term living with people to understand the local culture, values and practices. The ethnographer understands and records a written report of these practices from the point of view of locals.
- What information does the method give you/what conclusions can be drawn from the results of the method?
 - Ethnographic studies provide an insight into the local values and practices within wider local significations. It also showcases alternatives to ways of life such as different cultural ways of living. By investigating the ‘gate-post’ issues from a certain geographical location and culture, ethnographic studies contribute to our understanding of social institutions and social life.
- Application of the method:
 - In what situations/for what research questions is the method **appropriate**?
 - Situations where research would be appropriate is where the anthropologist believes a certain location/culture would be of interest to study, be it a place that is of personal interest to study or a place that helps address theoretical issues that rouse intellectual curiosity.
 - Ethnographic methods are used for very complex problems or research questions to answer. It is a useful approach for learning first-hand about behavior and interactions of people within a particular context.
 - In what situations/for what research questions is the method **inappropriate**?
 - Some situations where using ethnography might present limitations to the research is when avoiding observer bias is impossible or when researcher subjective interpretation is compromised. These ethnographic methods require well-trained researchers and a lack of one could compromise the quality of the research information generated.
 - Example: *Developing patient-centered care: an ethnographic study of patient perceptions and influence on quality improvement* is a study that utilized an ethnographic approach to investigate quality improvement from the perspective of patients.

- <https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-015-0770-y>
- Special considerations for ethnography
 - It is important to be aware of the fact that conclusions drawn depend on researcher's observations and interpretations and might be difficult to validate.
 - Observer bias is impossible to eliminate.
 - Ethnography studies are time-intensive and should be allocated enough time to allow for complete information gathering.

RESOURCES

- This website (<https://www.anthroencyclopedia.com/entry/ethnography>) is an intermediate level Cambridge Encyclopedia of Anthropology resource that explains in detail what ethnography is, how it came to become a research methodology and its precise uses in society.
- This article (<https://www.scribbr.com/methodology/ethnography/>) is a beginner level resource that explains in simple and easy-to-understand format what ethnography is and when and how it should be used.
- This book chapter (<https://study.sagepub.com/sites/default/files/Eriksson%20and%20Kovalainen.pdf>) is an advanced level resources that provides in-depth information about ethnography, detailed description its different types and uses and an analysis of how it is conducted and evaluated.
- This video (<https://www.youtube.com/watch?v=aOBh8haj4E0>) is a simple and easy way to understand what ethnography is.

GROUNDED THEORY

DESCRIPTION

- What is the method?
 - Grounded theory is a research method that aims to generate theories.
- How is the method performed?
 - The researcher collects relevant information about a particular area of interest systematically. Key to performing grounded theory is that data collection and analysis occur simultaneously, from which abstract categories are inductively constructed.
- What information does the method give you/what conclusions can be drawn from the results of the method?
 - Information gathered from grounded theory are used to make categories of commonalities and dissimilarities from which a theory is inductively generated.
- Application of the method:

- In what situations/for what research questions is the method **appropriate**?
 - This method is appropriately applied in situations where theories about a topic of interest have not been previously explored and require some modification. Grounded theory allows for generation of information inductively and the formation of theories to be applied and used in the future to understand a certain topic.
- In what situations/for what research questions is the method **inappropriate**?
 - As grounded theory allows for generation of core concepts which all other concepts relate to, a research topic investigated that does not allow for such a process might be an inappropriate fit for this type of research.
- Example: *Use of Grounded Theory in Cardiovascular Research* is a scholarly article that explains how grounded theory can be used in CVD through interviewing patients with CVD and DM as well as healthcare professionals in order to develop health literacy skills and instructional materials.
 - <https://nsuworks.nova.edu/cgi/viewcontent.cgi?article=2472&context=tqr>
- Special considerations for grounded theory analysis
 - It is important to be aware that information gathering and data analysis occur simultaneously. The researcher often does not know the result of their study until a significant amount of analysis has been completed.

RESOURCES

- This scholarly article (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6318722/>) is an excellent advanced level resource that provides extensive information about grounded theory and its creation.
- This website (<https://www.groundedtheoryonline.com/what-is-grounded-theory/>) is a beginner level resource that explains grounded theory and includes a video about it as well.
- This scholarly article (<https://ebn-bmj-com.uml.idm.oclc.org/content/19/2/34>) provides simple information about how to apply grounded theory and explains it in the context of health care system.

CASE STUDIES

DESCRIPTION

- What is the method?
 - Case study is a research format that generates in-depth understanding of a complex issue in real-life context. It uses a variety of disciplines, particularly social sciences.
- How is the method performed?

- The researcher clearly defines the research question asked and selects the case study of interest. Multiple sources of evidence are used for data collection (ex. Questionnaires, audits, interviews or focus groups) after which data is analyzed and interpreted accordingly.
- What information does the method give you/what conclusions can be drawn from the results of the method?
 - Information gathered from case studies help explain causal links and pathways between concepts studied.
- Application of the method:
 - In what situations/for what research questions is the method **appropriate**?
 - This method is appropriately applied in situations where in-depth understanding of a particular entity is desired. It provides insights into aspects of the clinical case as it explores and describes events in their everyday contexts.
 - It can be used to describe patient's episode of care, explore professional attitudes or experiences of a new policy/
 - Example: A case control study of the quality of patient care at Nurse Practitioner-Led Clinics
 - <https://pubmed.ncbi.nlm.nih.gov/28032834/>
- Special considerations for case studies
 - It is important to be aware that the volume of data collected can be large and one should know how they plan on using available data.
 - It might be difficult in some situations to provide generalization from data gathered through case control studies.

RESOURCES

- This video (<https://www.youtube.com/watch?v=Sv7j4uuu-VY>) is a beginner level resources that explains what case studies are and how they are conducted.
- This resource is an intermediate level approach to explaining what case studies are and how to conduct them (<https://bmcmethmethodol.biomedcentral.com/articles/10.1186/1471-2288-11-100>)
- This resource is another beginner level for a simple understanding of case studies (<https://ebn-bmj-com.uml.idm.oclc.org/content/21/1/7>)
- This resource explains what the advantages and disadvantages of using case control studies are (https://edtechbooks.org/studentguide/case_studies)

PHENOMENOLOGY

DESCRIPTION

- What is the method?

- Phenomenology is the study of structures of consciousness as experienced from the first-person point of view. Research asks: ‘What is this experience like?’, ‘What does this experience mean?’, and ‘How does the lived world present itself to the participant or to me as the researcher?’
- How is the method performed?
 - The researcher gathers information and perceptions about topics of interest through inductive, qualitative methods such as interviews, discussions and participant observation.
- What information does the method give you/what conclusions can be drawn from the results of the method?
 - Phenomenology studies the appearance of things, or the way we experience things. It also provides information about structures of consciousness along with relevant conditions of experience. Through this, emphasis is given to the personal perspective and interpretation for the individual involved.
- Application of the method:
 - In what situations/for what research questions is the method **appropriate**?
 - Phenomenological studies can be applied to single cases or selected samples.
 - In what situations/for what research questions is the method **inappropriate**?
 - Even though it can be applied to single cases, it is difficult to make inferences based on a small sample.
 - Example: This paper explores a phenomenology study about the lived experience of parenting a child with a life-limiting condition.
 - <https://ebn-bmj-com.uml.idm.oclc.org/content/21/4/96>

RESOURCES

- This resource (<https://plato.stanford.edu/entries/phenomenology/>) is an advanced level one that provides detailed information about phenomenology, its types and its history.
- This resource (<https://www.rgs.org/CMSPages/GetFile.aspx?nodeguid=7ad9b8d4-6a93-4269-94d2-585983364b51&lang=en-GB>) is an very advanced level of phenomenology and its practices.
- This article from the Encyclopedia of Philosophy (<https://iep.utm.edu/phenom/>) explores phenomenology in-depth and provides answers to most questions about it.

NARRATIVE RESEARCH

DESCRIPTION

- What is the method?

- Narrative research is a form of qualitative research that aims to explore and conceptualize human experience in a textual form. It aims to define the meanings people assign to their experiences.
- How is the method performed?
 - Researchers work with small samples of participants to learn more about their stories and experiences. Researchers interview participants about the topic of interest and gather information that would later be analyzed for theme generation.
- Special considerations for narrative research
 - It is of paramount importance that the study focuses on individual stories.
 - Researchers and participants must work closely together to come to a shared understanding of the participants' stories.
 - Narrative research provides useful information about lived experiences, but may not stand alone for evidence and support for the conclusions of a report. narrative research places information in a chronological order.

RESOURCES

- This video (<https://course.oeru.org/research-methods/modules-1-3/module-3-research-design/narrative-research-design/>) is a beginner level resource that explains narrative research in a simple way.
- This resource is an intermediate level approach to explaining what narrative research is (<https://www.sciencedirect-com.uml.idm.oclc.org/topics/nursing-and-health-professions/narrative-research>)

QUALITATIVE DATA ANALYSIS

Overview

- Qualitative data analysis can be grouped into 2 categories:
 - Deductive approaches to data analysis
 - Inductive approaches to data analysis

DEDUCTIVE APPROACHES TO DATA ANALYSIS

DESCRIPTION

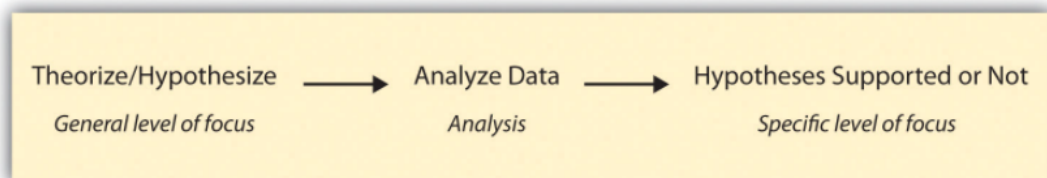
What is the method? (1-2 sentences)

- Simply put, deductive reasoning involves reasoning from the “general to the particular.” Researchers start with a theory and test its implications with data, ultimately moving from a more general level to a more specific one – a “top-down” direction.

How is the method performed? (1-2 sentences)

- The deductive approach follows the flowchart shown below: it involves beginning with a theory, developing hypotheses from that theory, and then collecting and analyzing data to test those hypotheses

Figure 2.6 *Deductive Research*



What information can it give you/what conclusions can be drawn? (2-4 sentences)

- The deductive approach will allow researchers to either reject or find support for their hypothesis.
- “Deductive approach offers the following advantages:
 - Possibility to explain causal relationships between concepts and variables
 - Possibility to measure concepts quantitatively
 - Possibility to generalize research findings to a certain extent.”

In what situations is the method appropriate?

- When there is a large wealth of literature available on the topic
- When there is only limited time available to complete the study
- When a researcher’s risk tolerance is low

In what situations is the method inappropriate?

- When there is a scarcity of literature available
- When there is no shortage of time to complete the study
- When general, unifying theories are desired

Example of how it is used in medical research:

- <https://pubmed.ncbi.nlm.nih.gov/29134826/>

RESOURCES

- https://saylordotorg.github.io/text_principles-of-sociological-inquiry-qualitative-and-quantitative-methods/s05-03-inductive-or-deductive-two-dif.html
 - o Degree of difficulty (beginner, intermediate, advanced): Beginner
 - o Type: Textbook
 - o Content and depth of coverage (2-3 sentences): Sociology textbook that describes the basics of inductive and deductive approaches to research and gives examples of studies where they were used.
 - o Recommendations about how to use: Read to gain a strong foundational understanding of both deductive and inductive approaches to data analysis. There are also exercises to test understanding at the bottom of the page.
- <https://www.ncbi.nlm.nih.gov/books/NBK470395/>
 - o Degree of difficulty (beginner, intermediate, advanced): Intermediate
 - o Type: Website
 - o Content and depth of coverage (2-3 sentences): Provides general overview of qualitative research and the methodology available.
 - o Recommendations about how to use: Although this resource does not focus on deductive approaches, it provides information about which qualitative research methodologies utilize this approach.

INDUCTIVE APPROACHES TO DATA ANALYSIS

DESCRIPTION

What is the method? (1-2 sentences)

- “The inductive approach involves beginning with a set of empirical observations, seeking patterns in those observations, and then theorizing about those patterns.” This involves moving from the specific to the general – a “bottom-up” direction.

How is the method performed? (1-2 sentences)

- The researcher begins with collecting relevant data. They then look for patterns in the data and use them to develop theories. In other words, the inductive approach involves starting with specific experiences and moving to a more general set of propositions.

Figure 2.5 *Inductive Research*



What information can it give you/what conclusions can be drawn? (2-4 sentences)

- Inductive approaches are used to generate general, unifying propositions based on a set of empirical observations. Thus, they are useful when one is aiming to find patterns in a data set and synthesize broader theories from them.

In what situations is the method appropriate?

- When there is a scarcity of literature available
- When there is no shortage of time to complete the study
- When risk tolerance is relatively high and the researcher accepts the possibility that no theory may emerge at all

In what situations is the method inappropriate?

- When there is an abundance of literature available
- When only a short time is available to complete the study
- When a researcher's risk tolerance is low

Example of how it is used in medical research:

- <https://pubmed.ncbi.nlm.nih.gov/32804989/>

RESOURCES

- https://saylordotorg.github.io/text_principles-of-sociological-inquiry-qualitative-and-quantitative-methods/s05-03-inductive-or-deductive-two-dif.html
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- Recommendations about how to use: Although this resource does not focus on inductive approaches, it provides information about which qualitative research methodologies utilize this approach.

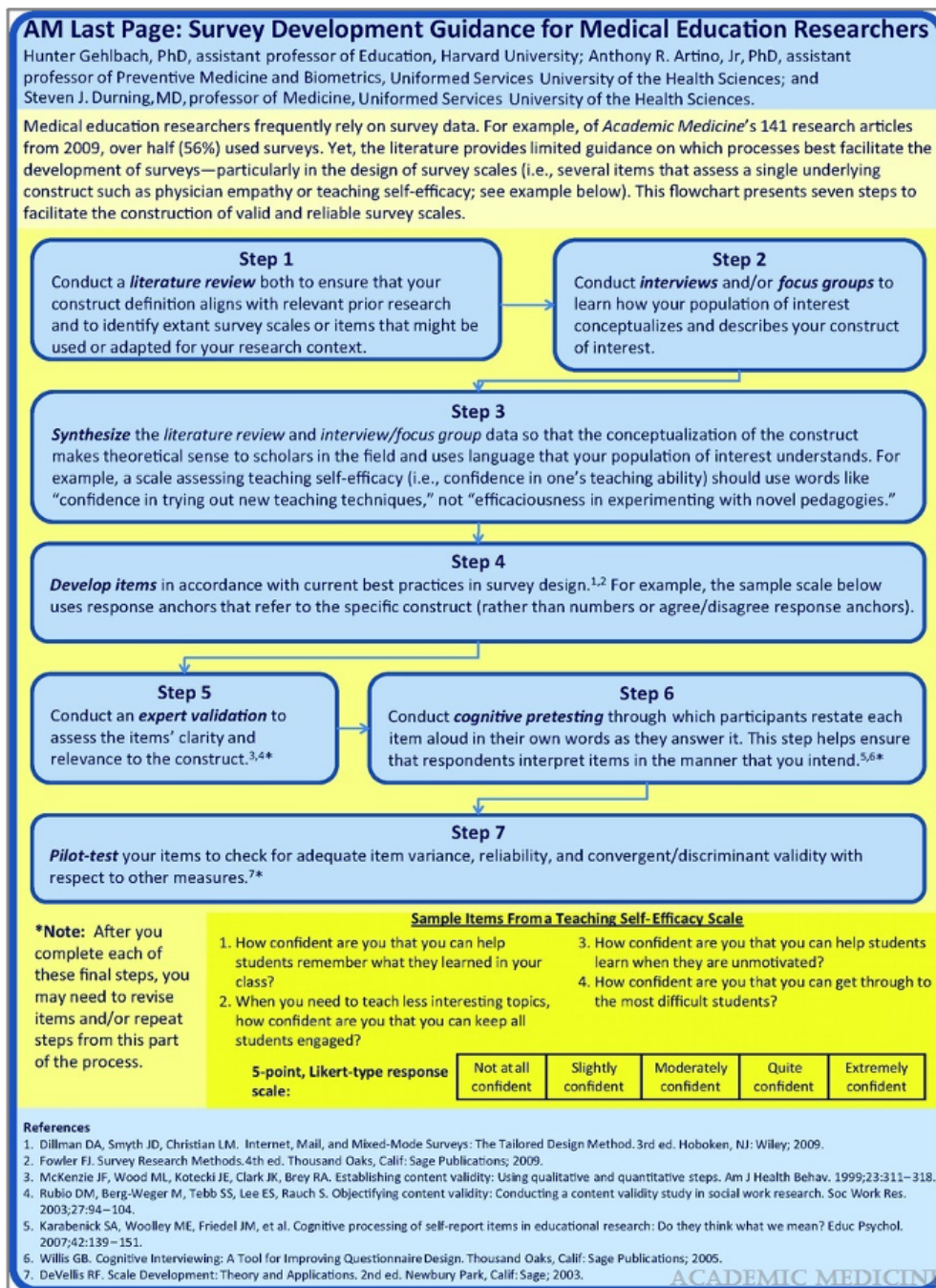
SURVEY

DESCRIPTION

- Surveys elicit and analyze information from research participants using a set of carefully constructed questions, known as questionnaires.
- Surveys are most commonly administered in a pen and paper format, or through online platforms such as Opinio or SurveyMonkey. Telephone and face-to-face surveys also take place.
- Survey results provide direct responses from participants that can be used for further analyses. It provides information on the thoughts, ideas, and feelings of your target demographic or sample population.
- Application of the method:
 - Surveys are effective research methods for exploring trends, themes, and outcomes in a large target population.
 - Medical education often relies on surveys to examine the viewpoints of the medical student population at large. An example of this is the [CFMS National Annual Survey](#), which aims to use the collected data to improve medical student experience across Canada.
- There are a range of ways to structure survey items, some of the most commonly used include:
 - Open-ended items
 - Ex: What do you think of household pets?
 - Closed-ended items
 - Ex: Which pet do you have? Dog? Cat? Fish? Other? None?
 - Dichotomous
 - Ex: Do you like dogs? Yes/No
 - Likert scales
 - Ex: On a scale of 1 to 5, where 1 is “strongly disagree” and 5 is “strongly agree”, please rate the following statement. Cats are interesting pets.
 - Rating or Ranking questions
 - Ex: Please rank the following pets in order of your preference: Dog, Cat, Fish, Turtle, Tarantula.

RESOURCES

- **Stepwise survey design guides:**
 - The following publications provide information on how to develop surveys in a step-by-step process.
 - Magee et al., 2013, J Grad Med Educ PMID: [24404217](#)
 - Artino Jr et al., 2014, Med Teach PMID: [24661014](#)
 - Hunter et al., 2010, Acad Med [Link](#), see below:



- **Encyclopedia of Survey Research Methods, Edited by Paul J Lavrekas (2008):** [link](#)
 - This is an intermediate-advanced level resource that provides comprehensive information on the various types of survey questions with examples.
 - Use this resource to learn about the different types of survey questions and which may be most suitable when constructing your own. This resource also has a “search” function should you wish to type in keywords of your topic of interest.
 - Note: link may require institutional access.

- **SurveyMonkey website:** [link](#)
 - This is a beginners-level resource that outlines the basics of how to analyze survey data.
 - This is best used as a big-picture reference on how to approach organizing and analyzing your data and what kind of conclusions to draw.

RESEARCH ETHICS

DESCRIPTION

- The World Health Organization states that “Research ethics govern the standards of conduct for scientific researchers.” These standards are essential to ensure that research participants' rights, safety, and privacy are protected.
- Research ethics is not a method you perform but rather guidelines that you must adhere to whenever undertaking research. These guidelines ensure the rights, welfare, and dignity of research participants are consistently protected. Therefore, it is crucial to understand the standards for conducting human or animal research set by both your institution and jurisdiction.
- Application of the method:
 - In Canada, research ethics boards (REB's) provide oversight for human and animal research to ensure the highest ethical conduct of researchers.
 - The principles and standards for ethics review will be similar across all Canadian REB's. However, the actual application and process will be dependent on the institution in which you are conducting the research.
 - For example, if you wish to enroll patients into a study evaluating if Vitamin D supplementation after a fracture improves healing, you would first have to obtain REB approval. This approval would require a detailed project proposal, including how you plan to obtain consent, maintain privacy, and any potential harms to participants. It would be the REB's role to assess the proposal and the risk vs benefit of conducting the study.
- It is essential to note that not all projects are considered research and therefore do not require a complete ethics review process. Some projects are considered quality improvement and can be exempt from ethics review. The best way to determine if your project falls into this category is to contact your local research ethics officer.

RESOURCES

- **A Brief Introduction To Research Ethics In Canada**
 - This is a beginner infographic introduction to research ethics in Canada.
 - This is a starting place for any student new to the topic of research ethics.
 - <https://cfms.org/what-we-do/education/research-101>
- **Research Ethics in Canada**
 - This video is an intermediate level explanation of research ethics in Canada and the considerations for conducting ethical research.
 - This is good to watch prior to conducting a project that requires ethics board approval.
 - <https://www.youtube.com/watch?v=Lir2gePgp2w>
- **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018)**
 - This is an advanced manual that outlines the ethical principles that all institutions in Canada are expected to comply with.
 - Would use this as a resource to answer any project specific questions around ethics.
 - https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

GRANTSMANSHIP

DESCRIPTION

- Grantsmanship is the technique of writing an application to secure funding from private, local, or federal agencies.
- Grantsmanship cannot replace the quality of the scientific method agencies scrutinize when reviewing funding applications. However, an inability to communicate your research ideas effectively and in a manner that is easily understood can get your proposal overlooked.
- Application of the method:
 - Good Grantsmanship is essential for a researcher that strives to become a principal investigator. There is limited funding available for research, thus making receiving funding a highly competitive process.
 - Successful grantsmanship should communicate your idea clearly to the review committee in a way that demonstrates the necessity of your project.
- An essential step to grant writing is following the application guidelines to the letter. The majority of funding agencies will screen out applications that do not meet their criteria, prior to forwarding applications to the selection committee. Therefore, failing to follow the procedure will result in your proposal being exempt from consideration.

RESOURCES

- **The Art of Grantsmanship, Dr. Jacob Kraicer (1997):**
 - This is an all-inclusive, intermediate level guide to writing a peer-reviewed grant application.
 - Would read while writing a research proposal for a grant competition.
 - https://cdn.dal.ca/content/dam/dalhousie/pdf/research-services/The_Art_of_Grantsmanship%20-Kraicer.pdf
- **The Ingredients of a Good Grant Proposal, Dr. Jocalyn Clark (2013):**
 - This is a beginners level video highlighting key concepts and tips to writing a grant application.
 - Would watch this prior to approaching a grant application.
 - <https://www.youtube.com/watch?v=3VLiDiTiQjA>
- **Grand Challenges Canada: Write Your Proposal**
 - This website contains top grants writing tips from experts and grant reviewers.
 - Visit this website to improve your grant application prior to submitting.
 - <https://www.grandchallenges.ca/funding-opportunities/innovator-toolbox/write-your-proposal/>