Critical Appraisal of Research Evidence

Department of Evaluation and Research Services

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http://research.fraserhealth.ca/
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FHA Research Study Database

Department of Evaluation and Research Services

The FHA Research Study Database contains all studies that have been conducted in FHA since 2005. Its purpose is to inform you about the type of research studies [e.g., cardiology] conducted in FHA, by for example, researcher, approval status, and funding source. In addition, you will be able to find selected published material for individual studies.

www.clinicaltrials.gov

Contact Us / Help

Fraser Health REB# (e.g. yyyy-###)
Keywords
Researcher Name
Researcher Degree
Program
Researcher Discipline
FHA Site Name
Area
Research Type
Research Status
Clinical Trial Registration#

Clear  Search
FH Methodology Unit - How can we help?

**Research & Grant Development Facilitator**
- Conducting a search for funding opportunities
- Targeted notification of new funding sources and deadlines
- Identifying a research team
- Preparing letters of intent
- Identifying resources required for conducting research
- Formulating the research budget
- Facilitating proposal development in collaboration with researchers
- Understanding FH and funding agency requirements regarding preparation of specific documents
- Administration of funding awards
Epidemiologist

- Specifying the research goal, objectives and hypothesis
- Identifying measurable outcomes
- Specifying the variables for analysis
- Identifying sources of data
- Developing data collection tools for quantitative or qualitative studies
- Developing the statistical analysis plan
- Understanding how to use statistical software, such as SPSS
Objectives

- Increase awareness of issues around quality and reporting of research evidence
- Increase awareness of common research designs in health care
- Use research tools that facilitate appraisal of research reports
- What is your experience with critical appraisal, comfort with reading articles?
Critical Appraisal

What it is:

- The assessment of evidence by systematically reviewing its relevance, validity and results to specific situations

- A balanced assessment of strengths of research against its weaknesses. It is a skill that needs to be practised
Critical Appraisal

- Is not:
  - Negative dismissal of a piece of research
  - Assessment of results alone
  - Based entirely on detailed statistical analysis
  - An exact science (not always a right or wrong answer)
  - Undertaken only by research experts
Critical Appraisal

Why do it?
- To be able to understand and assess the quality and applicability of research
- Published research may not be reliable/valid
- Published research may not be relevant
- To identify gaps in knowledge
Approaches to Critical Appraisal

- Common sense
- General appraisal tools
- Design specific appraisal tools
  - Appraisal tools help you focus on the important parts of the article
Common Sense

- Group activity 1:
  - Read the scenario described in the handout and answer the questions
  - Report back with your comments
Wakefield et al., 1998 Lancet 351 (9103): 637–41

Reported on observation of bowel symptoms in 12 children with ASD.

Suggested possible link with MMR vaccine.

Called for suspension of triple MMR vaccine.

Based on retrospective recall by parents on time of behavioural symptom onset and MMR administration.

Ileocolonoscopy and lumbar puncture conducted without ethical approval.

Decline in vaccines in UK, rise in measles and two child deaths.
Lessons Learned

Never rely on only one study
Temptation to pick and choose which evidence to use

Instead:
What is the trend in the literature?
Components of a Research Article

- Abstract
- Introduction
- Methods
- Analysis and Results
- Discussion
Assessing Bias is Key to Appraisal

Main concerns - Quality

- Validity: strength and accuracy of findings
  - Internal validity
    - "avoidance of systematic error/bias"
    - Example: baseline characteristics of groups are the same except for the intervention type/exposure
  - External validity
    - generalizability/applicability of findings
    - Example: baseline characteristics of the study sample are similar to the general population
- Reliability: reproducibility/repeatability of findings
General Appraisal

- **Bias**
  - Any *systematic* error in the study that leads to distortion of the results (validity)
  - Can occur at any stage of research
  - Can occur with all types of designs
  - Usually a matter of degree of bias (i.e. minimizing)
  - Different forms of bias/ specific to study design
Different forms of bias

- Most common types
  - Selection: groups compared are different, sample unrepresentative of population
  - Measurement: using a tool that is not valid, recalling past events, design and question not matched
  - Intervention: standardization of procedures, different settings used, groups treated same except for intervention
Judging the soundness of qualitative and quantitative research

<table>
<thead>
<tr>
<th>Traditional Criteria for Judging Quantitative Research</th>
<th>Alternative Criteria for Judging Qualitative Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal validity</td>
<td>Credibility</td>
</tr>
<tr>
<td>External validity</td>
<td>Transferability</td>
</tr>
<tr>
<td>Reliability</td>
<td>Dependability</td>
</tr>
<tr>
<td>Objectivity</td>
<td>Confirmability (Can findings be confirmed by others?)</td>
</tr>
</tbody>
</table>


Levels of Evidence

I. Strong evidence from at least one systematic review of multiple well-designed randomised controlled trials

II. Strong evidence from at least one properly designed randomised controlled trial of appropriate size

III. Evidence from well-designed trials such as pseudo-randomised or non-randomised trials, cohort studies, time series or matched case-controlled studies

IV. Evidence from well-designed non-experimental studies from more than one centre or research group or from case reports

V. Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert committees

General Appraisal - Key Questions

- Was the study original?
- Whom is the study about?
- Was the design of the study sensible?
- Was systematic bias avoided or minimized?
- Was the study large enough, continued for long enough, to make results credible?

How to read a paper: assessing the methodology quality of published papers. BMJ. Trisha Greenhalgh. 1997
General Appraisal – Key Questions

- Original? – does the study add to the literature?
- Whom is the study about? – can I apply findings?

How to read a paper: assessing the methodology quality of published papers. BMJ. Trisha Greenhalgh. 1997
Appraising an Article - Introduction

- Is (are) the reason(s) for the study clearly stated?
- Is the review of the literature comprehensive?
- Was there reporting bias by the authors?

General Appraisal - Methods Section

- Appropriateness of study design
  - Linkage to study question
  - What has already been published
  - Is the primary outcome appropriate (incl. length of follow-up)
- Appropriate data collection tools (validated?)
- Ethical considerations
General Appraisal - Methods Section

- Is the sample appropriate?
  - Clear statement of sample size
  - Detailed description
  - Sample size justification
  - Ethical treatment
- Blinded assessment?
General Appraisal - Quantitative Research

Methods Section

- Are the measurements / data collection likely to be reliable and valid
- Is there a description of the statistical methods used
General Appraisal - Results Section

- Did the study proceed as planned
- Were findings described adequately
- Are calculations correct
- Was statistical significance tested (quantitative research)
General Appraisal - Conclusion/Discussion Section

- What do the main findings mean
- How are the hypotheses interpreted (quantitative research)
- Are the conclusions justified
- How do the findings compare with what others have found
- Application of findings
- Limitations
General Appraisal Tools

General appraisal tools can be used to assess the following:

- Is the study trustworthy?
  - Is the research question focused?
  - Was the method detailed?
- How was it conducted, e.g. randomisation, blinding, recruitment and follow up?
General Appraisal Tools

- General appraisal tools can be used to assess the following:
  - What are the results?
    - How was data collected and analysed?
    - Are they reported to be significant?
  - Will the results apply to my situation?
General Appraisal – Can I use this research?

Relevance

- Is it clear what the study is about?
  - Yes
  - Is the sample/context adequately described?
    - Yes
    - Are my patients/contexts sufficiently different that results won't apply?
      - Yes
      - Is it worth continuing?
      - No
      - Is the action/intervention/change indicated - available/possible in my setting?
        - Yes
        - Are the benefits and costs specified?
          - Yes
          - Are the patient's values/preferences satisfied by change? Are my colleagues and mine?
            - Yes
            - If they are not clear is it worth continuing?
              - No
            - If they are not then change is unlikely to be accepted / acceptable
              - No
          - If you cannot implement for these reasons is it worth continuing?
            - No
            - Can you use the results without this?
              - No
              - Consider whether you should read it

- No
  - Can I use this research in my-context?
    - Yes
    - Are the benefits and costs specified?
      - Yes
      - Are the patient's values/preferences satisfied by change? Are my colleagues and mine?
        - Yes
        - If they are not then change is unlikely to be accepted / acceptable
        - No
      - If they are not clear is it worth continuing?
        - No
      - If they are not clear is it worth continuing?
        - No
      - If they are clear is it worth continuing?
        - Yes
      - Can you use the results without this?
        - No
        - Consider whether you should read it

Craig & Smyth 2002 The evidence-based practice manual for nurses. 2002 p117
General Appraisal using tool

- Group activity 2
  - Use General Appraisal Checklist tool to critically appraise Chocolate study
  - Try to answer as many questions as possible
  - Report back
• Break
### Appraisal of specific study designs

<table>
<thead>
<tr>
<th>Quantitative</th>
<th>Qualitative</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Analyzes numbers</td>
<td>▪ Analyzes words</td>
</tr>
<tr>
<td>▪ Explanation, prediction</td>
<td>▪ Explanation, description</td>
</tr>
<tr>
<td>▪ Test theories</td>
<td>▪ Build theories</td>
</tr>
<tr>
<td>▪ Known variables</td>
<td>▪ Unknown variables</td>
</tr>
<tr>
<td>▪ Larger sample</td>
<td>▪ Smaller sample</td>
</tr>
<tr>
<td>▪ Standardized instruments</td>
<td>▪ Observations, interviews</td>
</tr>
<tr>
<td>▪ Deductive</td>
<td>▪ Inductive</td>
</tr>
</tbody>
</table>
Crash Course in Qualitative Research Designs
Possible components of qualitative article

- Frameworks
  - Ethnography
  - Case studies
  - Phenomenology
  - Grounded Theory

- Sampling
  - Convenience
  - Purposeful
  - Theoretical
  - Snowball

- Methods
  - Observation
  - Interview
  - Focus Group
  - Written Text

- Analysis
  - Content analysis
  - Thematic analysis
Critical Appraisal of Qualitative Research

- Focus on
  - Purpose
  - Literature review
  - Study design
  - Sampling
  - Data collection
  - Procedural rigour
  - Analytical rigour
  - Auditability
  - Theoretical connections
  - Trustworthiness
  - Conclusions and Implications
Qualitative Appraisal

- Group activity 3
  - Read and appraise qualitative study using qualitative appraisal tool
  - Report back
Crash Course in Quantitative Research Designs
Quantitative Studies

- Randomized Controlled Trial
- Cohort
- Case-control
- Case Study
- Single Case Design
- Before and After
- Cross-Sectional
Experimental studies

- Random allocation
  - No: Non-randomised controlled trial
  - Yes: Randomised controlled trial

Observational studies

- Comparison group
  - Yes: Analytical study
    - Exposure ↓ Outcome
  - No: Descriptive study
    - Case series 1 or few
    - Cross-sectional study Many
  - Exposure ↑ Outcome
Randomized Controlled Trial

- Investigator assigns intervention
  - therapeutic or diagnostic interventions
- Treatment group and “control” group
- Random assignment to groups
  - Makes groups “comparable”
- Blinding of participants and/or researchers
Randomized Controlled Trial - Bias

Intervention biases

- Contamination: intervention and control in contact or control receive treatment accidentally
- Co-intervention: participant receiving other treatment at the same time
- Timing of intervention: interventions occurring over long versus short time periods (maturation in children)
- Site effects/characteristics: hospital size; homes versus hospital units
- Performance bias: Different therapist use different approaches; inadequate standardization of procedures
Randomized Controlled Trial

- Selection bias: use of probability sampling strategies
- Random allocation to treatment groups
- Concealment of group allocation from the clinicians, researchers, patients, data collectors and others
- Level & appropriateness of blinding used: double blind / single blind
- Detection bias: differences in the assessment of outcomes
- Exclusion bias: completeness of follow-up & systematic differences in withdrawals
Cohort Study Design

- Observational, analytic study
- A defined group of people (the cohort) is followed over time
- Typically begins with a sample of people who do not have the disease or outcome of interest
- Starting point is exposure
  - compare outcomes of those exposed or not exposed (e.g., to drug, intervention) to disease/study outcome
- Designed retrospectively or prospectively
- Prospective design provide higher quality data
Cohort Study

Follow cohort over time to see who develops disease / study outcome

- Exposed
- Not exposed

Start here
Cohort Study- biases

- Selection bias: groups differ in important ways other than intervention/exposure
  - Comparable in age, sex, SES, presence of co-existing illness
  - Transparency of procedures used to select the comparison group (e.g., matching)
- Loss to follow up: described and appropriately handled
  - All participants accounted for
  - Reasons for drop-out described
  - Drop-out over 20% affects validity
- Recall bias in retrospective studies
Case-Control Study

- Observational, analytic study
- Starting point is **outcome/disease**
  - compare people with a specific outcome of interest (**cases**) to people from the same population without that disease or outcome (**control**)
- Assesses relationship between the outcome and prior exposure to particular risk factors
Case-Control Study

look at exposure histories
to assess relationship

Cases

Controls

Start here
Case-Control Study - Bias

- The misidentification of when the individual becomes a “case”
- This leads to misclassification and affects study conclusions
- Selection bias: groups (cases & control) differ in important way other than intervention/exposure
- Validity of retrospective data
  - data collected for other purposes
  - standardized procedures used in data abstraction
Descriptive Studies: Cross-sectional

- Observational, descriptive study
- Referred to prevalence studies
- Snapshot of the phenomena at a specified point in time
- **Exposures** and **outcomes** are measured at the same time
  - cannot establish temporal relation
- Surveys, questionnaires commonly used
Descriptive Studies: Case Study (n=1 or Case Series (n>1))

- Observational, descriptive study
- One or series of individuals usually all receiving the same intervention or experiencing same outcome
  - no comparison (control) group
- Starting point for future analytic studies
Descriptive Studies - Biases

- Selection bias: convenience sampling
- Measurement bias: use of surveys to collect data
  - Psychometric properties
    - Adopt standardised and validated methods/tools
    - Use objective measures
  - Social desirability/self reporting bias
  - Recall bias
Descriptive Studies - Biases

- Incidence-prevalence Bias
- Temporal Bias: consider when study is looking at causal relationships - not sure of sequence of exposure and outcome
- Confounding bias: consider when comparing groups
- Example: high incidence of autism in certain neighbourhoods
Other Design Considerations – Data Collection

- Before and after study, repeated measures
- Evaluates group of subjects before and after an intervention
- No control group
Appraising a Quantitative Article
- Key Questions

- Was the study original?
- Whom is the study about?
- Was the design of the study sensible?
- Was systematic bias avoided or minimized?
- Was the study large enough, continued for long enough, to make results credible?

How to read a paper: assessing the methodology quality of published papers. BMJ. Trisha Greenhalgh. 1997
Appraising a Quantitative Article
- Sample size

- Calculation described and justified
- Parameters used to calculate size are described
- Calculations compatible with design
- Adjustment for follow-up in repeated measures studies
- Underpowered studies may lead to Type II error: false negative
- Overpowered studies may lead to Type I error: false positive
Appraisal of Quantitative Research - Outcomes

- Relevant and useful
- Objective
- Frequency of measurement (spacing adequate? Carryover?)
- Reliability and validity
Appraisal of Quantitative Research - Intervention

- Detailed description
- Relevance to condition or situation
- Who delivered it?
- Where was it delivered?
- How often?
- Contamination or co-intervention?
Appraisal of Quantitative Research - Results

- **Statistical significance**
  - **p-value:**
    - probability that your result may have arisen by chance and not due to your intervention
    - <5% probability is acceptable, which = p-value of <0.05
  - **Odds Ratio (OR)**
    - odds that an outcome will occur given a particular exposure
    - used in case-control studies (sometimes in cross-sectional or cohort studies)
    - OR=1 exposure does not affect odds of outcome
    - OR>1 exposure associated with higher odds of outcome
    - OR<1 exposure associated with lower odds of outcome
Statistical significance

- **confidence interval (CI):**
  - estimates a population parameter based on observations
  - a range that is likely to include the parameter
  - wide range = less precision
  - can be used to estimate the OR

- **confidence level (C):**
  - probability that the CI includes the true value of the parameter
  - ≥95% C is best (= ≥0.95)
Appraisal of Quantitative Research - Results

- 95% CI means that there is 95% chance that the real difference between 2 groups would fall between the upper and lower limits measured or that the mean of the population falls between the 2 limits.
Appraisal of Quantitative Research - Results

- **Statistical significance**
  - the result is statistically significant

**VS**

- **Clinical significance**
  - the result is clinically meaningful

Eg. A change in a depression scale may be statistically significant but it may not result in improved or worse symptoms, may not lead to a change in treatment / practice.
Appraisal of Quantitative Research - Results

- Appropriateness of analysis: see statistical decision tree
Appraisal of Quantitative Research - Results

- Drop-outs
  - Reasons for drop-outs described?
  - How are drop-outs handled in the analysis?

- Intention to treat analysis
  - Based on the initial treatment assignment and not on actual treatment received
  - More ‘real-world’
Appraisal of Quantitative Research - Results

- **Effectiveness** – treatment positive under usual or routine care condition

VS

- **Efficacy** – treatment positive in a controlled experimental research trial
  (intention to treat analysis inappropriate)
Large Group Activity 4

- Examples of problematic descriptions of methods
Worth Investigating

- **Critical Appraisal Checklists**
  http://www.sign.ac.uk/methodology/checklists.html
  http://www.cebm.net/index.aspx?o=1157

- **Critical Appraisal Guidelines**
  GRADE http://www.gradeworkinggroup.org/index.htm