METHODS OF SIMULATION RESEARCH

Adam Dubrowski
Overview

• Workshop 1: Conceptualizing simulation research
• **Workshop 2: Methods used in simulation research**
• Workshop 3: Outcomes, evaluations and assessments
• Workshop 4: Data collection and analyses
• Workshop 5: Dissemination
• Workshop 6: Funding
• Workshop 7: Becoming familiar with BCHSP’s Research process
Today

• Review of your questions 20 mins
• Review domains of literature 20 mins
• Research continuum 20 mins
• Placing your question on the continuum 10 mins
• Presentations and critique 20 mins
• Break 10 mins
Today

• Applying designs to research questions:
  quantitative methods 20 mins
• Applying designs to research questions:
  qualitative methods 20 mins
• Independent work:
  Matching your question to design 20 mins
• Presentations and critique 40 mins
• Wrap up 10 mins
Review of your questions - 40 mins

• Research questions
• Theory and domains of literature
Research continuum
What questions are we asking?

- Results
- Behavior
- Learning
- Reaction
What questions are we asking?

**Level 1:** Were the trainees and the trainers/educators satisfied with the new simulation based program?

**Level 2:** Did the new simulation based program lead to improved performance as compared to the traditional teaching?

**Level 3:** Did the new simulation based program lead to reduced errors when the trainees engaged in clinical practice as compared to traditional teaching?
The Positive and the Negative

The positive results are encouraging but do not reveal the full story.

The negative results are problematic; we need to understand the “WHY?”
Some Reasons for Negative Results

**Theory/empirical evidence:** Lack of a theory/empirical evidence as the foundation

**Modeling:** Lack of refinement and assessment of buy in (feasibility and acceptability)

**Statistics:** Underpowered study

**Methods:** Uncontrolled variables/confounding

**Pedagogy:** Ineffective simulation, lack of instructional design
- trainees (level, motivation)
- trainers (untrained)
- simulators (too easy)
- conditions of practice (too long)
Some Reasons for Negative Results

The reasons are multi-dimensional and co-dependent
One framework that has been very successful in the development of complex clinical interventions has been proposed by Medical Research Council (2000, 2008).
Solution: MRC Phase I

The preclinical phase: Includes development of an intervention based on theoretical and empirical understanding of the targeted problem.
Solution: SIM Phase I

Identify research gaps in order to support need for intervention development.

Select a theory and/or empirical evidence to guide the simulation intervention design.
Identify the components of the intervention:

- Mode of delivery
- Dose (duration of delivery over hours, days, weeks)
- Ultimate goals

Develop a paper model, such as flowchart.
Solution: MRC Phase II

“Exploratory trials” characterize the version of the intervention that could be disseminated (including distinguishing constant and variable intervention elements) and demonstrate a feasible protocol for comparing the intervention with usual care or some alternative intervention.
Solution: SIM Phase II

Approaches

**Qualitative** research can be used to reveal how the intervention works and to find potential barriers and facilitators:

- focus groups
- Case studies
- open-ended questions

These can define relevant components of the intervention.
Solution: SIM Phase II

Approaches

**Quantitative research**
- surveys

This exercise can help to further refine the intervention based on stakeholder feedback.
Solution: SIM Phase II

Feasibility and Acceptability

Testing the **feasibility** of delivering the intervention and **acceptability** to educators and trainees (also decision-makers and other stakeholders).

Different versions of the intervention may need to be tested or the intervention may have to be refined to achieve optimal feasibility and acceptability ratings.
Solution: SIM Phase II

Designing the main trial

Basis for initial assessment for calculating sample sizes for the main trial. Other design variables can also be established.
Solution: SIM Phase II

Outcomes

Outcome need to be piloted during this phase.

Investigators should include outcomes that not only are relevant to trainees but also, if possible, encompass measures of wider relevance to the health system, including economic measures (keep Kirkpatrick in mind).

Validity and reliability of measures should be established as they relate to the specific content.
Solution: MRC Phase III

Phase III: A definitive randomized controlled trial often clustered and almost always multi-centered, evaluates the effectiveness of the intervention, providing an estimate of the expected effect magnitude across a range of representative settings.
The main trial will need to address the issues normally posed by randomized controlled trials:

- sample size
- inclusion and exclusion criteria
- methods of randomization
- dimensions of internal validity (selection, performance, detection and attrition bias)
- analysis
Solution MRC IV

Phase IV: Studies examine long-term consequences of the intervention, evaluating the sustainability of target effects and the emergence of unintended (adverse) effects.
Solution MRC IV

The purpose is to examine the implementation of the intervention into practice, paying particular attention to:

- the interaction with the context
- the economics
- the potential need for changing the learner groups
- the possible existence of adverse effects

This might be carried out by longitudinal studies, although currently there is no established mechanism.
Hands-on

• Placing your question on the continuum
  – 10 mins

• Presentations and critique
  – 20 mins
Break
Today

• Applying designs to research questions: quantitative methods 20 mins
• Applying designs to research questions: qualitative methods 20 mins
• Independent work:
  Matching your question to design 20 mins
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Experimental Design
You have performed a review of literature
You have generated an answerable question
What is the next step?
Decide on the design of a “clean” experiment.
is random assignment used?

yes

randomized or true experiment

no

is there a control group or multiple measures?

yes

quasi-experiment

no

non-experiment
is random assignment used?

yes

is there a control group or multiple measures?

yes

quasi-experiment

no

non-experiment
Experimental design is the process of eliminating other plausible alternative explanations. These are also known as threats to internal validity (Cook and Campbell 1979).
Minimizing Threats to Internal Validity:

**Argument.** This is the least effective ways to argue threats to internal validity.

– In a paper it is in the intro
Minimizing Threats to Internal Validity:

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**Design.** This is by far the most powerful method to rule out alternative explanations.

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Minimizing Threats to Internal Validity:

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**Design.** This is by far the most powerful method to rule out alternative explanations.

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**Analysis.** The researcher can use various statistical analysis performed on the collected data.

- In a paper it is in the methods and results
The three ways of **Minimizing Threats to Validity** are not mutually exclusive and a good research plan should make use of multiple methods for reducing threats.
Design construction

• Most research designs can be conceptualized and represented graphically from four basic elements
• Time, randomization, interventions, observations, etc.

XOXOXOXOXO
Time. In design notation time is represented horizontally.

Intervention(s). In design notation the intervention is depicted with the symbol "X".

Observation(s). Assessments and observations are depicted as the symbol "O".

XOXOXOXOXOX
Each group is indicated on a separate line.

The manner in which groups are assigned to the conditions can be indicated by a letter:

- "R" - random assignment,
- "N" - non-random assignment (i.e., a nonequivalent cohort)
- "C" - an assignment based on a cutoff score.

Group 1: R O X O
Group 2: N O X O
This is the most simple design in causal research and serves as a starting point for the development of better strategies.

What are the limitations of this design?
This is the most simple of all designs in causal research and serves as a starting point for the development of better strategies.

What are the limitations of this design?

No control for threats to internal validity:
  • Level before intervention?
  • Historical events?
O O X O O

• Provides a "baseline"
• No intervention vs. intervention
• Additional posttest assessments: decay, or a lag.

What are the limitations of this design?

• Still we do not know if X (or the intervention) caused change in O

• STATS: Repeated measures, one way ANOVA
Use a control group!

\[
\begin{array}{ccc}
N & O & X \\
N & O & O
\end{array}
\]

The interpretation:

- two groups, with non-random assignment of participants to each group initial assessment before the intervention implementation.
- participants in the first group receive the intervention (indicated by X), while participants in the second group do not.
- all participants are reassessed.

Why is the first “O” important?

To ensure no bias

*STATS: Mixed design, two factor ANOVA.*
• In education research the initial tests may be a contaminating factor.

• The posttest-only randomized experimental design allows the assumption the two groups are similar.

 STATS: Independent sample t-test or One-way ANOVA
• Intervention vs. a lack of alternative intervention.
• The much more challenging and more informative approach is to assess the effectiveness of an intervention when compared to a different intervention.

\[
\begin{array}{ccc}
O & X1 & O \\
O & X2 & O \\
R & X1 & O \\
R & X2 & O \\
\end{array}
\]
more complex designs
• Inclusion of additional groups in the design may be necessary in order to rule out specific threats to validity.

• For example, implementation of an intervention within a single institution can lead to unwanted communications between the participants which may pose threats to the validity of the causal inference.

• Add a nonequivalent group from a similar institution.

```
R O X O
R O O
R O O
N O O
```
Another possibility is to use pre-post cohort groups:

- The treatment group consists of current students,
- the first comparison group last year’s students assessed in the same year,
- and the second comparison group consists of the following year's students.
The Nature of Good Design

- Be innovative
- Be linked to theory
- Have practice implications
- Be realistic
- Be flexible
- Do not over-design

Word for today: parsimonious
• List all confounding variables that you can think of for your question.
Observational Designs
Ethnographic Research
Ethnography

“The task [of ethnographers] is to document the culture – the perspectives and practices – of the people in particular settings. The aim is to ‘get inside’ the way each group of people sees the world”

(Hammersley 1985:152)
Ethnography

• Research methodology for exploring and understanding everyday social settings and social processes

• Not a single research method or strategy of data collection or data analysis
Origins

- Social anthropology (Radcliffe-Brown)
- Sociology (Hughes, Park, Wirth)
- Organisational life (hospitals, schools), groups, gangs, professions
- Aims: discovery / understanding
Observation

• Observation is one of a number of methods within Ethnographic research tradition

• Never used alone without other forms of data collection
Principles

• Meaning emerges from interaction
• Interaction shapes social/cultural context
• Exploring phenomenon *in situ*
• Sampling: one (or a few) ‘cases’
Why observation?

- Quality of a particular activity rather than how many times it occurred
- Quality of relationships, activities, situations, or materials
- Describing in detail what goes on in a particular activity or situation
- Used in both qualitative and quantitative studies
Questions

• Begin by exploring genuinely open questions rather than testing theoretically derived (deductive) hypothesis
Major characteristics

• Real world situations - Non manipulative, unobtrusive, non-controlling
• Inductive analysis
• Focus is on complex interdependencies
• Context sensitivity
• Empathic neutrality - neutral non judgmental stance toward whatever content may emerge
• Design Flexibility- pursues new paths as they emerge
Steps

1. Identification of phenomenon to be studied
2. Identification of participants – sampling
3. Generation of Hypothesis – emergent
4. Data Collection - ongoing
5. Data Analysis – synthesizing and descriptive
6. Drawing Conclusions
Roles of an Observer

Occurs along a continuum:

- Complete participant – under cover
- Participant-as-observer
- Observer-as-participant
- Complete Observer
Advantages

• Can reveal nuances and subtleties of behaviour and interactions.

• Sensitive to dynamics within social situations – unspoken power differences, observable effects of...

• Deep understanding about complex and interrelated factors contributing to a phenomenon
Disadvantages

- **Observer Effect (Bias):** The presence of an observer can have a considerable effect on a subject and hence on the outcomes of a study.

- **Time commitment:** Observations are continual and sustained over period of time.
Observer Effect

Three main concerns:

1. Distraction by presence of researcher may produce less than normal behaviour

2. Behaviour might be influenced by researcher’s purpose

3. Bias - possibility that characteristics or ideas of observers may bias what they see and hear
Systematic Data collection

• **Field notes:** written account about what the researcher sees, hears, experiences and thinks
Systematic Data collection

Three other types of notes:

• **Field jottings**: quick notes - stimulus to help recall details they do not have time write down during an observation

• **Field diary**: a personal statement of the researcher’s feelings and perceptions

• **Reflective Field Notes**: keeping track of thoughts about analysis, methods, ethical dilemmas, points of clarification
Reflexivity

• Not possible to eliminate bias but can control for it

• Situating oneself within the work in order to understand how their own views and beliefs may influence the interactions and the participants

• Make this explicit in the research and the reporting
Thick Description

“ethnographers need to convince us [...] not merely that they themselves have truly ‘been there’ but [...] that had we been there we should have seen what they saw, felt what they felt, concluded what they concluded”

(Geertz 1988:16)
Triangulation

- Investigator triangulation
- Theory triangulation
- Data triangulation
- Methodological triangulation
Return of Findings

- Data
- Themes from analysis
- Research reports
Generalization

• The extent to which research findings and conclusions from a study conducted on a sample population can be applied to a population at large

• Observational studies are contextually specific and situated and are not considered generalizable in the way that quantitative studies are
Transferrable

• The degree to which the conclusions in your study would hold for other persons in other places and at other times.

• Data about ideas and skills emerging from an observational study may be transferrable from one context to another and be used as a prototype to repeat the study.
Summary

• Observation is one method within the ethnographic tradition
• Focuses on quality of interactions and processes
• Occurs in naturalistic settings over time
• Emergent in hypothesis generating, data collection, data analysis
• Role of observer occurs along a continuum
• Triangulation, reflexivity, thick description, return of findings – quality control
• Independent work: Matching your question to design
• Presentations and critique

• Homework May 9