

Using Research Methods in Community & Patient Engaged Research

Group Technical Assistance Webinar | February 22, 2017

Colorado Foundation for Public Health and the Environment

Learning Objectives

- After this technical assistance session, awardees will be able to answer the following questions:
 - What do we mean by research methods?
 - Why are research methods important?

Why Focus on Research Methods?

What do we mean by research methods?

Methods explain the approach investigators will take to collect data, administer the study, and analyze the results.

Why are research methods important?

Better methods lead to better research. More valid and trustworthy information will lead to better healthcare decision and, ultimately, to improved patient outcomes.



Anatomy of Research

The tangible elements that make up your study plan:

1. Research Question
2. Significance and Background
3. Design
4. Subjects
5. Variables
6. Statistical Issues

The Research Question

Should answer the “so what?” in research and should be F.I.N.E.R.

1. Feasible

Do you have enough technical expertise? Is this doable with the funding?

2. Interesting

Are decision makers, funders, your population interested?

3. Novel

Does this confirm or refute previous findings?

4. Ethical

Are research ethics followed? Does it truly engage patients, researchers and stakeholder equitably?

5. Relevant

Is the question relevant to your population? To scientific knowledge?

Significance and Background

Should answer “why is the research question important?”

- This is where defining and understanding the comparators (condition to which an intervention is compared) are captured.
Ask yourself:
 - *What do people already know?*
 - *Why do you hypothesize that one comparator will have better outcomes than the other?*
- Needs to be compelling!
 - Think outreach planning; how can you make sure that the right information gets to the right people at the right time.

Design

Should answer “How Can we Do this Research?”

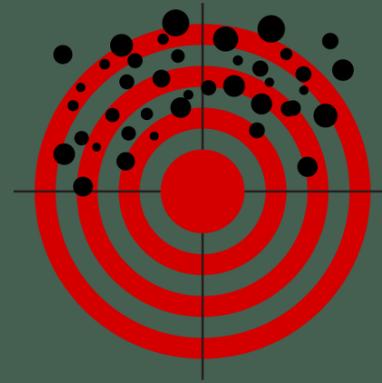
There are many types of study designs (ways to answer your research question).

1. **Observational**
2. **Experimental**
3. **Quasi-experimental**

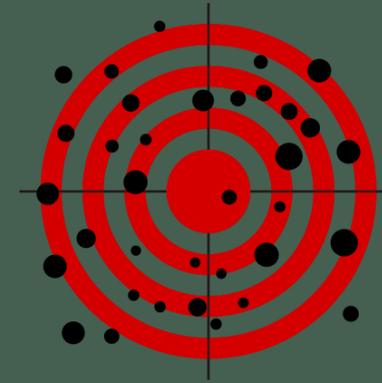


Reliability and Validity

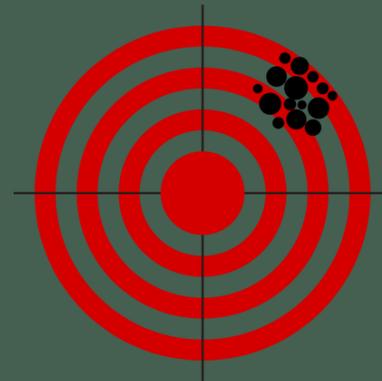
- Reliability – the degree to which your work produces stable and consistent results
- Validity – How well does your work measure what it says it measures



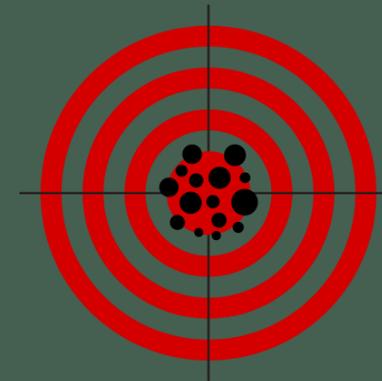
Unreliable & Unvalid



Unreliable, But Valid



Reliable, Not Valid



Both Reliable & Valid

Design (Type 1 of 3)

Observational Designs – Passive investigator role. *Less reliable but more valid.*

- a) Cohort
 - Group followed over time
- b) Cross Sectional
 - Group examined at one point in time
- c) Case-Control
 - Two groups, based on the outcome
- d) Case Study
 - Specific outcome (one instance)
- e) Descriptive
 - Describes characteristics of a population/phenomenon
- f) For all of the above, timeframe is important – *retrospective* or *prospective*



Design (Type 2 of 3)

Experimental Design – Active role with randomization and control in intervention.

More reliable but less external validity.

- a) Randomized Control trial
- b) Time series

Adaptive Trial Design – Active role with randomization but allows for adaptation of some aspects throughout the trial to increase validity

1. Adaptation can take place in dosage, sample size, drug undergoing trial, patient selection criteria



*PCORI Standards for Adaptive Trial Designs:
[http://www.pcori.org/research-results/research-methodology/pcori-methodology-standards#Adaptive and Bayesian Trial Designs](http://www.pcori.org/research-results/research-methodology/pcori-methodology-standards#Adaptive%20and%20Bayesian%20Trial%20Designs)*

Design (Type 3 of 3)

Quasi-Experimental Design – Active investigator role but typically lacks randomization. The researcher cannot control every person who receives the intervention but perhaps can control where the intervention takes place.

- a) Pre-Post Testing
- b) Difference in differences
- c) Case-control



Design

- Comparative Effectiveness Research can use Observational, Experimental or Quasi-Experimental Design to be successful
 - Observational CER

Study Subjects

Should answer “who will this research affect” and “who are we researching”

Ask yourself:

- Are you measuring health outcomes of a population? If so, your subjects should be defined as that population and you should ask how they are engaged in the research.
- Are you measuring how a system is functioning (i.e. clinical procedures)? If so, your subjects might be both the patients and the clinical staff. How are you engaging both of them in the research?

Variables (data)

Should answer “what information am I seeking?”

- More than just the specific data that answers your question (dependent variables)
- should gather additional data that might affect the primary question (independent variables)



Statistical Issues

Should answer “how is the information I am seeking answering my question?”

- Starts with the hypothesis and how you analyze the data to get at that hypothesis
- Hypothesis is used by those analyzing the data
 - Consider sample size – how many observations must I make for this to be significant
 - Power – expected difference between groups to have a reasonable degree of probability

Physiology of Research

Keep in mind that all of this is to have the findings in the study help **to make inferences** (not conclusive) about a truth in the universe.

The truth in the universe that is supported by the data of the research will make for a more compelling story and a more clear reason action should be taken toward your subject of interest.



Now What? Formalize your Plans

- **Concept mapping** ([Get started here](#))
- **Outreach planning**
 - Where are the gaps (in both your knowledge and in steps)?
 - Structure your outreach plan to address those gaps.
- **Re-examine purpose and goals**
 - Is CER the best tool for your research question?
 - In the broader spectrum of research, is CER the best way for your research to move forward?
- **Add it to your Deliverables (Governance Document)**
 - Consider putting your research plan/hypothesis in your GD.
- **Significance**
 - Think about your audience in outreach planning, what info do you need to reach the right people at the right time?
- **Study Subjects**
 - Use your outreach plan to engage subjects.
- **Don't forget** - How are you engaging with each of the critical groups (patients, researchers, stakeholders) throughout all of this?

Resources

- FINER Criteria <http://www.scalelive.com/finer.html>
- Observational Research Designs <http://srmo.sagepub.com/view/the-sage-encyclopedia-of-social-science-research-methods/n648.xml>
- Quasi-Experimental Design
<http://www.socialresearchmethods.net/kb/quasiexp.php>
<http://study.com/academy/lesson/quasi-experimental-designs-definition-characteristics-types-examples.html>
- Glossary of terms published by the PCORI Methodology Committee/PCORI Staff
<http://www.pcori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-H.pdf>
- PCORI Methodology Report
<http://www.pcori.org/assets/2013/11/PCORI-Methodology-Report.pdf>
- PCORI Methodology Standards:
<http://www.pcori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf>

Questions? Comments?

Thank you for joining us!