

CHERP: Clinical Research 101



Kimberly “Max” Brown

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What are we going to discuss?

- ❖ Introduce concepts of research methods
- ❖ Describe basic methods
- ❖ Learn the general steps in the research process from research idea to project implementation



What is Research?

Basic Research

- ❖ Generating new knowledge

Applied Research

- ❖ Seeks solutions to immediate problems



What is the Goal of Research?

Promotion of ***evidence-based practice***

- ❖ Clinicians make decisions based on the best research evidence
- ❖ Their clinical expertise
- ❖ The healthcare preferences of their patients



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Clinical Trials

- ❖ Involve human volunteers
- ❖ Assess the safety and effectiveness of new ways to diagnose, prevent or treat disease
- ❖ Insight about a disease process and how it might be better treated



Types of Clinical Trials

Observational

- ❖ No drugs or treatments
- ❖ Researchers observe participants' health over a period of time

Interventional

- ❖ Test the safety and effectiveness of a drug, therapy or experimental treatment



Randomized Clinical Trial

- ❖ Randomization: research subjects are randomly assigned to various treatments as a way to minimize bias in results.
 - » Control Group
 - » Group that receives treatment



How are people protected?

- ❖ Procedures reviewed by Institutional Review Boards (IRBs)
- ❖ IRB panels composed of scientists, doctors and lay people.
- ❖ Ensure the rights and welfare of participants
- ❖ If the risk is too high, the IRB will not approve the project, or will specify changes that must be made before the research can begin



How are people protected?

- ❖ Consider the inclusion and exclusion criteria
- ❖ Ensure **informed consent** is adequate and understandable by participants
- ❖ Require patient data to be kept secure (e.g. HIPAA, HITECH, FOIA, regulations)



Quantitative Research

Major Research Methods

Quantitative Research has been the traditional scientific approach used by many disciplines

- ❖ Widely accepted techniques and measures
- ❖ Tight control over the research situation
- ❖ Generalizability



Qualitative Research

Major Research Methods

Some clinician researchers consider Qualitative Research to be inferior, but this is changing rapidly

- ❖ Subjective meaning
- ❖ Contextualized and Lived Experiences
- ❖ Individual opinions



Outcomes Research

- ❖ Focuses on measurable outcomes of interventions with certain patient populations
- ❖ Driven in part by the high cost of health care
 - » Want to know if care provided is cost effective
 - » Will purchased services improve health?
- ❖ Type of research CHERP does most



A good research question is...

❖ Feasible

- » Subjects
- » Resources
- » Manageable
- » Data available?

❖ Interesting

❖ Novel

- » In relation to previous findings
 - Confirm or refute?
- » New setting, new population

❖ Ethical

- » Social or scientific value
- » Safe

❖ Relevant

- » Advance scientific knowledge?
- » Influence clinical practice?
- » Impact health policy?
- » Guide future research?



A Research Question identifies:

1. The ***variables*** under study
2. The ***population*** being studied
3. The ***testability*** of the question



Variables

- ❖ Have 2 or more properties or qualities
 - » Age, sex, weight, height
- ❖ Is one variable related to another?
 - » “ Is X related to Y? What is the effect of X on Y?”
etc.



Variables

❖ Independent variable:

- » has a presumed effect on the dependent variable (outcome)
- » May or may not be manipulated

❖ Dependent variable:

- » Something that varies with a change in the independent variable
- » *Outcome* variable



Hypothesis

- ❖ Frames the relationship between 2 or more variables
- ❖ Converts the research question into a **statement** that predicts an expected outcome



How does a study work

❖ What happens day-to-day?



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Real world example:

❖ CHERP Pilot project

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