CHERP: Clinical Research 101

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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
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

- Widely accepted techniques and measures
- Tight control over the research situation
- Generalizability
Major Research Methods

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

Qualitative Research

- 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?
Real world example:

- CHERP Pilot project