Research Methods & Evaluation Strategy

Carol Ott, PharmD, MPH, BCPP
Clinical Professor of Pharmacy Practice, Purdue University
Clinical Pharmacy Specialist, Psychiatry & Gender Health, Eskenazi Health
Indianapolis, IN

Disclosures

- Dr. Ott does not have financial or other relationships to disclose in relation to this presentation
- This presentation will not include discussion of off-label, experimental, and /or investigational use of drugs or devices

Learning Objectives

1. Define retrospective vs prospective study design
2. Identify requirements for a quantitative, qualitative, and mixed methods study designs
3. Discuss the necessity of appropriate statistical measures
4. Know what is needed to complete study in a timely manner

Is Your Study Retrospective or Prospective?

- Retrospective studies look back in time and do not require recruiting study participants
  - Will generally evaluate existing data: prescription fill histories, diagnoses, laboratory monitoring, patient demographics
  - Are often considered to be IRB exempt studies as long as patient records are de-identified and how this is done is clearly provided to the IRB
  - As long as data reports are available in a timely manner, retrospective studies are easier to do but not as flexible in the research question
- Prospective studies look forward in time and require study participants or plans to look at future patient records after an intervention
  - Requires plan to recruit and compensate participants
  - Requires informed consent
  - More commonly expedited by the IRB due to potential risk to loss of privacy

Quantitative Studies

- Collects and quantifies numerical data
- Logical and objective
- The research question should allow for measurable data, not opinion
- Examples:
  - Survey research
  - Use of rating scales to assess change over time in symptoms
  - Descriptive – prevalence rates of a disease in a certain population

Qualitative Studies

- Gathers the experiences, beliefs, attitudes, and perceptions of the participants
- Interviews and focus groups are common means for qualitative studies
- Requires a mentor with expertise in qualitative research
- Participant responses are collated and “coded” to look for common themes
- Qualitative studies often include a behavioral theory to explain the results
- Posters and manuscripts include quotes from participants

Mixed Methods Studies

- Combining quantitative and qualitative research methods
- Surveys (quantitative) and interviews (qualitative)
- A variety of mixed methods study designs are available
- The two types of data are often used to support each other or use participant responses to build surveys
- Lower sample sizes needed to ensure that interviews can take place in a timely manner

Statistics

- An appropriate statistical method should be chosen to analyze data
- Descriptive statistics: summarize data using the mean or median
- Inferential statistics: uses statistical tests to draw conclusions
- The statistics that will be used in the study should be reported in the methods section
- This is a good reference article for choosing statistical methods that is easy to read and follow:
  - Kim N, Fischer AH, Dyring-Andersen B, Rosner B, Okoye GA. Research techniques made simple: choosing appropriate statistical methods for clinical research. *Journal of Investigative Dermatology.* 2017;137:e173-e178.

Evaluation Strategy

- Researchers are not always skilled in statistics
- Plan for who is going to do the statistical evaluation
- Statisticians are available in university settings; they may charge by the hour of per study
- For residency projects, some institutions have statisticians or preceptors who run stats for the residency projects
- Plan for the evaluation strategy when developing the research question and timeline

Questions? Please contact Dr. Ott at: caott@iu.edu

Thank you for attending!

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