Designing Pharmacy Practice Research

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Objectives

• To outline the elements essential to good research design in pharmacy practice research studies
• To discuss your ideas for projects
The Research Question

- You need a well-articulated question
- Without this, it’s impossible to determine appropriate methods for your research
- Specify: “PICO”
  - Patient population: who are you studying?
  - Intervention: what is the intervention you are studying?
  - Control: what is the comparison group?
  - Outcome: what are you going to measure?
Study Design

• Randomized (highest level of “causal inference”)
  - By patient (each patient is assigned to intervention or control)
  - By “cluster” (each group of patients/clinicians/site is assigned to int or ctrl)

  *causal inference is the ability of a study to determine whether the intervention caused the outcome

• Issue for PPR: is the control group “usual care” and are clinicians willing to provide UC?

• “Before-after” design: compares baseline to end of follow-up
Population

- Inclusion criteria: defines who will be recruited
  - Choose those likely to be responsive to the intervention
  - Be specific
  - Be broad (but not too broad)
    - Narrow inclusion criteria are more difficult to recruit to, and are less generalizable to the wider world
    - Too broad inclusion criteria may include patients without the condition of interest or are unlikely to respond to the intervention
Population

- **Exclusion Criteria:** Defines those who will not be studied because they:
  - Don’t have the condition of interest
  - Don’t have a condition that is responsive to the intervention
  - Are unlikely to provide good data (e.g., due to poor adherence, unreliable or unavailable for follow-up, language barriers, etc.)
Recruitment

- Specify the setting your study will be conducted in
- You need a recruitment plan
  - Recruitment is the biggest problem once a study starts
- For PPR, investigators may not be familiar with looking for and recruiting patients
  - You need a plan... e.g., list of patients receiving metformin to find type 2 diabetes patients
Describe the intervention in detail:
- Reproducible
- Specify all components
- For PPR:
  - patient education, prescribing, recommendations, referrals, etc.
  - For investigators - so they know what they are supposed to do
  - What is the “dose”?
  - Is the intervention “strong enough”? 
Control

- Need to define what the control group “gets”
  - Define “co-intervention”: what other interventions can investigators provide to control group patients
- Contamination: components of the intervention given to the control group
- For PPR:
  - Often the control group is “usual care”
  - Problem with highly selected pharmacists – may not want to provide “usual care” (should at least discuss with pharms)
Follow-up

- Specify when follow-ups will occur
  - And when outcomes will be measured
  - Might be different between intervention and control groups
  - Decide on a “window” for f-ups
    - e.g., 8 +/- 2 weeks
  - Usually define a final follow-up visit for both groups
- For PPR:
  - Pharmacists are not used to scheduling follow-ups and patients are not used to returning to see their pharmacist
  - Loss of patients to follow-up is a major problem and a threat to validity
Outcomes

- How do you know your intervention “works”?
- Generally, specify a single primary outcome (you can have multiple secondary outcomes)
  - Primary outcome is the “most important” outcome
  - Pick something that is clinically relevant, convincing, important, and responsive to your intervention
  - By definition, you calculate your sample size on the primary outcome
Outcomes

• Generally, outcome measures are:
  – Continuous (measures on a known scale, like BP, weight, urinary output, etc)
  – Dichotomous (“yes or no”, like hospitalizations, proportion at HbA1c target, etc).

• Continuous outcomes provide more information and are more powerful

• Avoid unvalidated process outcomes like number of drug-related problems identified

• Specify how and when outcomes are measured
You must do a sample size calculation, without it:
- Study will be underpowered (no clear answer) or, less frequently, overpowered (uses excessive resources)

Calculate SS based upon your primary outcome

Justify your assumptions:
- For continuous measures: what is the baseline value (and standard deviation or variability), what is the expected effect size?
- For dichotomous: what proportion will reach the outcome in the control group, what is the effect size?

Many sample size Apps and online, but make sure your assumptions make sense (get help pm)
Confounding affects study outcomes and can “interfere” with evaluation of the intervention.

**Blinding**
- Of patients, often not possible for PPR
  - Can provide a “sham” intervention
- Of outcome assessors

**Loss to follow-up:** potential source of bias (esp in PPR)
- Need to have a plan to minimize
Conclusions

• PPR is vital to the profession, we need more to do it
• Rather than be intimidated, consider these general guidelines
• Ask for help!