Resident Research:
Get it Started Right

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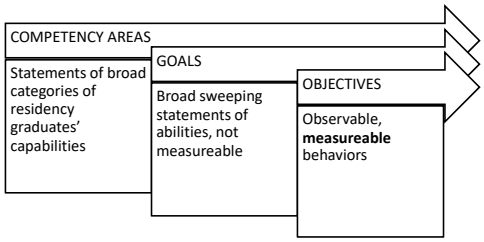
Objectives

1. Review the ASHP residency goal and objectives related to residency projects
2. Describe the importance of a well-devised research question
3. List criteria of a good research question
4. Identify metrics and outcomes suitable for pharmacy resident research
5. Outline strategies for the successful assembly and management of a research committee

PART 1: ASHP GOALS AND OBJECTIVES RELATED TO RESEARCH

PGY1 Competency Areas, Goals, and Objectives



PGY1 Goals Related to Research

- **Required Goal R2.2**: Demonstrate ability to evaluate and investigate practice, review data, and assimilate scientific evidence to improve patient care and/or the medication-use system.

OR

- **Elective Goal E1.1**: Conduct and analyze results of pharmacy research

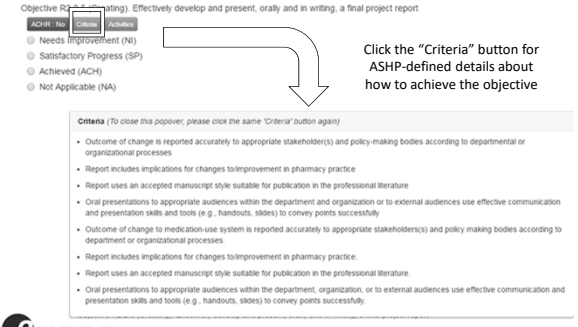
R2.2 Objectives

- **R2.2.1**: Identify changes needed to improve patient care and/or the medication-use system.
  - Action: Find a problem, identify a research question
- **R2.2.2**: Develop a plan to improve patient care and/or the medication-use system.
  - Action: Design your project
- **R2.2.3**: Implement changes to improve patient care and/or the medication-use system.
  - Action: Implement your change

R2.2 Objectives continued

- **R2.2.4**: Assess changes made to improve patient care or the medication-use system.
  - Action: Collect and analyze data
- **R2.2.5**: Effectively develop and present, orally and in writing, a final project report.
  - Action: Present at ASHP Midyear and Great Lakes Pharmacy Resident Conference

PharmAcademic Tip



Click the "Criteria" button for ASHP-defined details about how to achieve the objective

PART 2: DEVELOPING A RESEARCH QUESTION

Take time to plan your project carefully

What is a research question?

A research question is the fundamental core of a research project, study, or review of literature. It focuses the study, determines the methodology, and guides all stages of inquiry, analysis, and reporting.

Reference: https://researchrundowns.com/intro/writing-research-questions/

Criteria for a good research question

Think FINER

- **F**easible
- **I**nteresting
- **N**ovel
- **E**thical
- **R**elevant

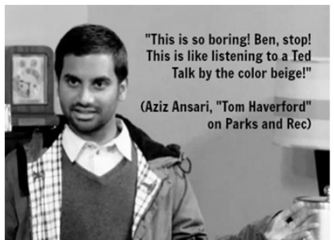
Hulley S, Cummings S, Browner W, et al. *Designing clinical research*. 3rd ed. Philadelphia (PA): Lippincott Williams and Wilkins; 2007.

Feasible

- Adequate number of subjects?
  - Consider targeting 50-100 subjects depending on the complexity of data collection
- Ability to measure/collect desired data?
  - Is your health system already collecting what you want to measure/analyze?
- Adequate time and resources?
  - Does your research require staff training, EMR changes, workflow modifications, etc.?
- Manageable scope?
  - Don't bite off more than you can chew – remember, you already have a full time job ☺

Interesting

- You have to enjoy and have a sincere interest in your research – you're going to spend a lot of time with it



Novel

Does the research question

- Confirm or refute previous findings
- Extend previous findings
- Provide new findings

Ethical

May we join your research committee?
We'll get the job done, no problem.

Relevant

- To scientific knowledge
- To clinical and health policy
- To future research directions

So how do I identify a research question?

- Work backwards!
  - What is your end goal (new service, demonstrate cost savings, evaluate new clinical tool) – can you design a question related to that?
- Narrow the question
  - Make sure you're scope is manageable
- Test it out
  - Review a patient chart, department workflow, and see if you can efficiently collect the information you want to answer your question

Research Outcomes

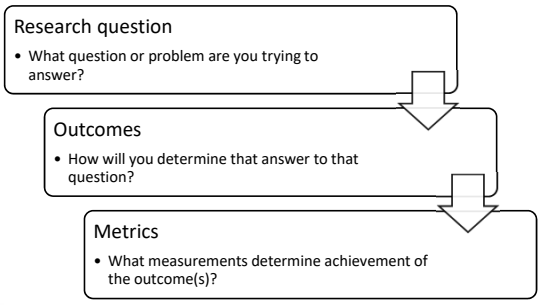
- Once you have a research question identified you will need to choose a primary, and possibly secondary, outcome(s).
  - A statement or status that will serve as an answer to the research question
  - Metrics will be used to support or refute the outcome
  - You MUST define outcome(s) that are not objectively measurable
    - Everything in research needs to be defined unless it is obvious
    - Watch out for words like, better, improved, appropriate, satisfied

Research Metrics

- To determine if an outcome has been achieved you will need to select, and possibly define, metrics.
  - What will you measure?
    - Direct measurement or surrogate?
  - How will you collect it?
    - Report, chart review, drug utilization, survey
  - How will you analyze it?
    - Statistics, power calculation?

TIP: Review examples of research in the same area and see what those researchers used for outcomes and metrics!

Research Design Summary



PART 3: RESIDENT RESEARCH EXAMPLES

Clinical Scenario

- **Observation**: ED providers are commonly ordering 1gm of valproic acid (VPA) and fosphenytoin (FOS) for patients with status epilepticus (SE)
  - Guidelines state patients should receive 20-40 mg/kg VPA or 15-20 mg PE/kg of FOS if they are refractory to benzodiazepines
- **Goal**: "Pharmacy to dose" service in the ED for IV VPA and FOS

Can you identify a research question?

Research Question Options

Which research question is most suitable for a resident research project?

- Does weight-based dosing of FOS and VPA reduce the rate of seizure recurrence?
- Does weight-based dosing of FOS and VPA increase the number of post-load therapeutic drug levels?
- Does a "pharmacy to dose" service for FOS and VPA improve dosing compliance with national treatment guidelines for SE?
- Will patients be more satisfied with dosages of FOS and VPA selected by a pharmacist compared to a physician?

How do we define "compliance?"

A total dose of 10–20 mg/kg for fosphenytoin should be given OR 10-40mg/kg for valproate (based on indication).

Partial loading doses should only be given if the patient had a serum phenytoin concentration or valproate level below the target level.

If a second loading dose is required for the above reasons, it must be administered within four hours of the first loading dose.

The loading dose based on pharmacokinetic equations does not vary by more than 20% of the calculated dose.

Doses of <10 mg/kg should not be used

- Past medical history
- Subtherapeutic level

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Research Design Example 1

Research question

- Does a "pharmacy to dose" service for FOS and VPA improve dosing compliance with national treatment guidelines for SE in the ED?

Outcomes

- Primary: Percentage of patients with an appropriate loading or partial loading dose of FOS and VPA for SE in the ED
- Secondary: ADE and seizure recurrence within 24 hours

Metrics

- Pt demographics, dose of medication, pt weight, drug level prior to loading dose, hypotension, recurrence of seizure

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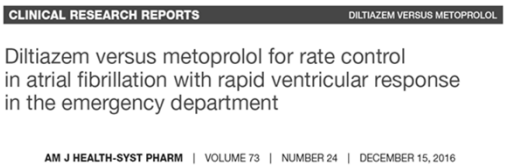
Research Design Example 2


CLINICAL RESEARCH REPORTS DILTIAZEM VERSUS METOPROLOL

Diltiazem versus metoprolol for rate control in atrial fibrillation with rapid ventricular response in the emergency department

AM J HEALTH-SYST PHARM | VOLUME 73 | NUMBER 24 | DECEMBER 15, 2016

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Why are we talking about a fib?!?!

This publication was a resident research project!!!!

Break Down the Study

Research question

- What, if any, associations exist between the patients who receive IV BB vs CCB in the ED for AF w/ RVR

Outcomes

- Primary: Effect of patient-specific factors on initial choice of IV BB or CCB
- Secondary: Efficacy, adverse effects, rate control therapy prescribed at discharge or used upon admission

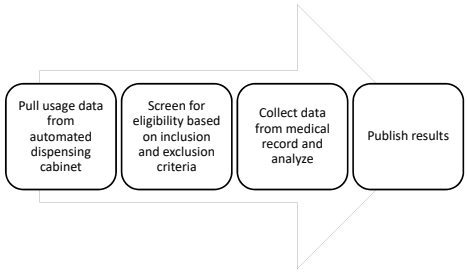
Metrics

- Patient demographics, rate control agent used, hemodynamic data, labs, signs and symptoms present on admission, PMH, home medications,

How were patients identified?

Do you have automated dispensing cabinets at your facility?

Project Design Overview



Results

- N=100 (45 IV metoprolol, 55 IV diltiazem)
- Similar baseline characteristics (see Table 1)
- Hx of AF, DM, and home beta blocker increased likelihood of IV beta blocker use
- Hx of home CCB use increased the likelihood of IV CCB use
- No significant difference in effectiveness
- No significant difference in adverse effects

Why was this resident's research successful?

- Identified patients using an internal department resource
- Used data already recorded in medical record
- Collected many data elements to bolster findings despite relatively small sample size
- It was published!!!

PART 4: RESEARCH COMMITTEES & TIME MANAGEMENT

Research Committee

- A group of professionals who help design, review, implement, analyze and report your research
- May be arranged by your program or up to you to assemble
- Include key stake holders – especially from other disciplines

Research Committee Benefits

- Subject matter experts
  - Familiarity with medical literature, pathophysiology, pharmacotherapy, previous facility research findings
- Workflow refinement
  - Ensure quick integration and targeted staff education
  - Especially important for new services
- Buy in
  - Ensure engagement and participation of staff
  - Especially important if research involves disciplines outside the pharmacy department

Research Committee Etiquette

- Identify expectations
  - Explain what you will need from each member and when you'll need it, however, you are the principle investigator
- Communicate concisely and regularly
  - No long-winded emails without clear requests for action
- Ask for help!
  - Work to resolve problems on your own, but don't forget to ask for help if you encounter a barrier
- Provide ample review time
  - Your committee members are busy and will need time to thoughtfully review your protocol, poster, presentation, and manuscript

Time Management

"Being busy is not the same as being productive"

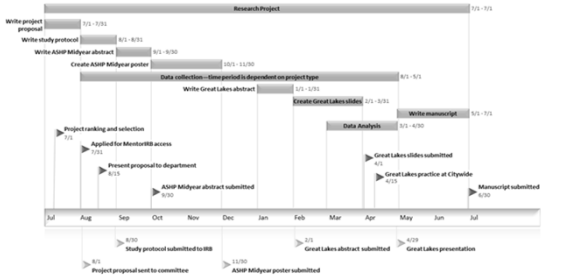
-Tim Ferriss

Time Management Tips

- Break your project down into components/phases and set personal deadlines for each one
- Set aside some dedicated time each week to work on your project
- Send a weekly or biweekly email that summarizes progress updates to your project advisor to keep yourself accountable

Sample Project Time Line

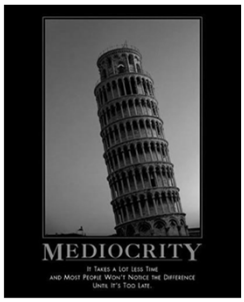
These dates are approximations and should serve as a general guideline. Adjust your personal timeline according to your project demands.



All submissions must be sent to your committee 10 business days before the due date

Why are these elements of research important?

Start off on the right path collecting the right data with the best people



In Summary

- Resident research is a required component of residency training
- Identify a **FINER** research question
- Design your project with outcomes and metrics that are achievable
- Assemble a group to help you design, implement, evaluate, and report your research
- Keep yourself accountable to a timeline

Have Fun!