Research Certificate Program Summer Seminar 2023 Friday, July 28, 2023

Today's Agenda:

12:30 Introductions and Certificate Requirements
Lisa Hutchison, PharmD, MPH

12:40 Workshop: How to Identify Clinical Problems to Research
Lisa Hutchison, PharmD, MPH

1:00 How to Develop a Good Research/Project Question
Ben Teeter, PhD

2:00 Break

2:15 How to Write an Abstract
Megan Smith, Pharm.D.

3:15 Overview of Calculating Sample Size
Chenghui Li, PhD

4:15 Next Assignments: Worksheet(s), ASHP Module Certificates, September Research Forum
UAMS COP Residents: Video for IRB Overview
Lisa Hutchison, Pharm.D. MPH

4:30 Adjourn

UAMS COP Postgraduate/Residency Research Committee Members:

Megan Smith, Catherine O'Brien, Ben Teeter, Jacob Painter, Lisa Hutchison

Lisa Hutchison is inviting you to a scheduled Zoom meeting.

Topic: RCP Summer Seminar

Time: Jul 28, 2023 12:30 PM Central Time (US and Canada)

Join Zoom Meeting

https://uams.zoom.us/j/98926485923?pwd=R1pidmhiSnRMRisyRzhLeEhHbTh5Zz09

Meeting ID: 989 2648 5923

Passcode: 971940

Current Certificate Requirements

1. Complete ASHP Essentials of Practice-Based Research for Pharmacists per assigned schedule

https://elearning.ashp.org/products/5427/essentials-of-practice-based-research-for-pharmacists-not-for-ce

2. Participate in all Summer Seminar and Winter and Wrapping it up Seminar workshops

   and lectures

3. Participate in the Residency Research Forum (September)- Megan Smith will review the dates for the Residency Research Forum

4. Provide feedback on peer reviewed research (platform presentation, poster presentation, or similar) of a non-resident (i.e. faculty, preceptor, or student)

5. Present current research at either local, state, regional, or national conference.(platform presentation, poster presentation, or similar)

6. Submission of a manuscript suitable for publication describing the resident's research.

   Manuscript must follow author guidelines from a peer-reviewed journal.

   Manuscript must include a description of the background, project rationale and detailed description of methods, results including any relevant figures and/or tables, and conclusions.

   Residents will be asked to select whether or not they intend to seek publication and intended journal.

The due date for documentation of your presentation and your manuscript is **June 3, 2024**

"The idea of finishing my project within 1 year initially seemed overwhelming. While each individual step seemed manageable, the totality of the project made me cringe and even lose sleep occasionally (honestly, quite often). Despite the valuable guidance I received from my mentors, they didn't seem to share my level of anxiety about the project. After all, it was my residency certificate that was hanging in the balance! Overall, I'm grateful for the experience because it taught me so much and really prepared me for future projects."

—Former PGY2 Ambulatory Care Resident

Research Certificate Program Progress Report

Requirement	Due Date	Completion Date
ASHP Essentials • Components of a Resident Research Plan • Identifying Contemporary, Relevant and Practical Research Questions • Study Design and Sample Selection	July 14, 2023	
		Email certificates to: hutchisonlisac@uams.edu
Summer Seminar (Zoom)	July 28, 2023	
ASHP Essentials • Project Management for Residency Projects • Data Acquisition and Data Cleaning	September 1, 2023	
		Email certificates to: hutchisonlisac@uams.edu
September Research Forum	September 30, 2023	
ASHP Essentials • Data Management • Data Analysis • Presenting Residency Project Results	November 1, 2023	
		Email certificates to: hutchisonlisac@uams.edu
Winter Seminar (in person)	November 6, 2023	
ASHP Essentials • Publishing a Scientific Report of Residency Project Results • Putting it All Together – An Example of a Residency Research Project	January 1, 2024	
		Email certificates to: hutchisonlisac@uams.edu
Wrapping it Up Seminar (Zoom)	TBA-January/February	
Review of Non-resident Research (poster, platform) Suggested meetings: AAHP, ASHP MCM, APhA	March 31, 2024	
		Email review form to: hutchisonlisac@uams.edu
Presentation of Residency Project (poster, platform)	June 3, 2024	
Provide Title:		Provide Conference Name:
Manuscript suitable for publication	June 3, 2024	
Provide Manuscript Title:	Identify Journal used for author guidelines:	Request UAMS Faculty Review: Yes/No

Email Completed Progress Report to: hutchisonlisac@uams.edu

Resident Signature:_____Date:_____

Workshop: How to Identify Clinical Problems to Research

Lisa C Hutchison, PharmD, MPH, FCCP

Ideas for research from clinical practice:

- Problem encountered without a solution from your literature search
- How well has evidence-based care been implemented in your institution
- Patient-specific clinical question
- Institution's concerns related to Joint Commission or CMS quality measures
- Process improvements or resource justification
- Published study discussion gives recommendations for future research
- Poster/platform sessions at professional meetings

Kauffman YS, Billips SJ. Developing the Research Idea. IN: Kauffman YS, Witt DM, eds. The Essential Guide to Pharmacy Residency Research, Kindle edition. American Society of Health-system Pharmacists 2020.

Activity:

Overview: Working in groups, take the assigned example situation and come up with related questions or gaps in knowledge that come to mind. Identify 2 related questions to share.

Step 1: go to your Zoom group.

Step 2: Identify who has the next birthday in the group—he/she becomes the moderator who will make sure that everyone contributes, group voting occurs, and the group is done in 15 minutes.

Step 3: Identify who has the most recent birthday in the group—he/she becomes the spokesperson to track all the ideas and report to the full session. Have group vote on the top 2 questions if there isn't consensus.

Step 4: At 10 minutes, rejoin the main group. Share your top 2 questions in the Zoom chat. Each group's spokesperson will report on their scenario and their top 2 research questions.

Step 5: Select a question (from your group or others). Use the form provided and evaluate the question as you listen to Dr. Teeter's and Dr. Smith's talks on Good Research Questions and Writing an Abstract. Send finished form to Lisa: hutchisonlisac@uams.edu

Groups

Institution	Last Name	First Name	Group
ARCare	Vinson	Haley	1
ARCare	Abdullah	Elma	2
ARCare	Lomboy	Ryback	3
ARCare	Jolliff	Bre	4
ACH	Galbreath	Ashley	5
BMH LR	Rozell	Savannah	1
BMH LR	Robertson	Ashley	2
BMH NLR	Hunt	Hannah	3
BMH NLR	Wilson	Brian	4
CAVHS	Campbell	Emily	5
CAVHS	Connor	Taylor	1
CAVHS	Glatter	Colby	2
CAVHS	Midkiff	Brendan	3
CAVHS	Petersen	Chase	4
CAVHS	Willard	Katie	5
CHI SVI	Smith	Erica	1
CHI SVI	Green	Sadie	2
St. Bernards	Thornburg	Lauren	3
St. Bernards	Tinker	Ashlee	4
Unity	Nuhung	Ariana	5
Unity	Cannefax	Victoria	1
Unity	Ameyaw	Philip	2
Unity	Gates	Marissa	3
UAMS	Dunn	Abigail	4
UAMS	Welch	Jasiha	5
UAMS	Wingfield	Jacob	1
UAMS	Fulton	Tia	2
Wadley	Dominguez	Shelby	3
Wadley	Smith	Terry	4
WRMC	Hartis	Kole	5
WRMC	Kocher	Austin	1

Group # and Situation to Spark a Research/Project Question

1. You are a pharmacist in a Pediatric Clinic that provides education to pediatric patients with newly diagnosed asthma. Your supervisor wants to justify the amount of time spent to her superiors.

2. Your clinical practice is in the adult HIV clinic and you observe a high frequency of statin use. You wonder if statins benefit patients with HIV and if drug-drug interactions are a concern, but find the literature is mixed.

3. You work in a community pharmacy that asked to establish a center for home blood pressure monitoring for the senior center participants. The site will be an office area at the center and will include opportunity to sell blood pressure monitoring equipment.

4. Several family members with diabetes talk with you about berberine and the success they've had in managing their blood glucose, but you are worried about side effects and potential drug-drug interactions.

5. A physician has tried mirtazapine for appetite stimulation at the nursing homes you both work at. You find no supporting studies and are curious if your patients are benefiting or not.

Good Research Questions

Benjamin S. Teeter, PhD
Investigator, Center for Implementation Research
Associate Professor, Department of Pharmacy Practice

Goals for today

- Review elements that make for a good research question
- Understand that some questions are better than others, and that's OK
- Understand that we all work within limitations to create the best research questions we can
  - Limitations = e.g., time, money, available expertise, time, available data, and time

2 Approaches

- The "scientist trying to make a living at science" approach
  - To flesh out the elements of good (and "fundable") research questions/projects
- The "clinician-scientist" approach
  - Blending of clinical work and research/QI
  - Opportunistic approach towards improving local clinical practice and making gains in knowledge

Exercise: What is wrong with these research questions?

1. How many steps does it take to get from my office to the elevator?

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1. How many steps does it take to get from my office to the elevator?
2. Is cigarette smoking related to lung cancer?

Exercise: What is wrong with these research questions?

1. How many steps does it take to get from my office to the elevator?
2. Is cigarette smoking related to lung cancer?
3. What is the most cost-effective method of implementing comprehensive medication management in rural primary care clinics?

Exercise: What might be wrong with these research questions?

1. How many steps does it take to get from my office to the elevator?
2. Is cigarette smoking related to lung cancer?
3. What is the most cost-effective method of implementing comprehensive medication management in rural primary care clinics?
4. Is the medication *Expensonil* (expected $10,000 per day out of pocket cost) more efficacious than placebo in the treatment of shopping addiction?

FINERMAPS

- Feasible
- Interesting
- Novel
- Ethical
- Relevant
- Manageable
- Appropriate
- Potential value and publishability
- Systematic

Choosing an Area/Topic…

- This element is pretty much taken care of already for you as Residents; but, in general:
- You should find your area/topic sufficiently interesting and important to you to spend your time on it!
- Is your institution able to mentor you and support your work in this area?

Find a gap to fill

- **You want to address an unknown**
  - Do we know the answer already? Keep looking…
  - If we already know something about the area/topic, is there room for improvement?
- **How do you know what is unknown??**
  - Your own assessment of the literature
  - Review paper recommendations
  - Published "priorities" and requests from NIH, professional organizations, etc.
  - Ask the local and national experts in the area

Fill a gap that people want filled <u>now</u> (*or soon…*), or is "timely"

- **Who is out there saying we need this question answered sooner rather than later?**
  - Healthcare systems, professional groups, NIH, etc.?
- **Is there a <u>natural experiment</u> about to happen that can be capitalized on?**
- **Is there a new policy or system mandate about to go into effect?**

Have a good answer to this question:

- **What will be the <u>impact</u> of answering your research question?**
  - Who will benefit?
  - What will be better or "fixed"?
  - Are there many benefits to many stakeholder groups? How many "wins" are you creating?

Make sure your question(s) can be feasibly answered

- **Can you answer the question…**
  - in the time frame you have?
  - with the money you have?
  - with the data you have or you can get?
    - Can you measure what you want to study?
  - with the mentoring/support you have?
- **But, lets not think too small…**
  - Balance feasibility with potential impact/importance

Be clear and focused in the language of the question

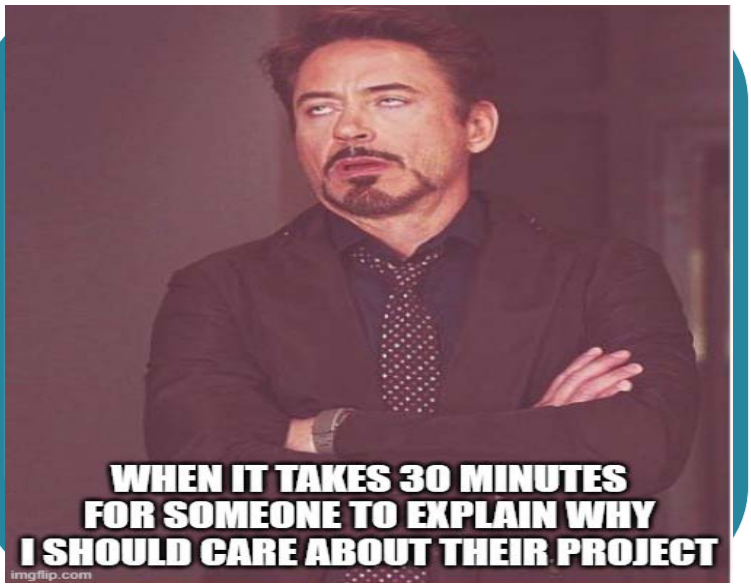
- **Focus on the relationship or issue being uncovered**
- **I like questions that start with "what" or "how"**
  - What impact does *intervention X* have on *outcome Y*?
  - How does a change in *behavior X* affect *outcome Y*?
  - What are the barriers to the *implementation of X*?
  - How did *new policy X* impact *clinician behavior Y*?
  - What is the relationship between *financial incentives to perform behavior X* and the *rate of behavior X*?

Watch out for too narrow or too broad

- **Try to avoid yes/no questions ("Does")**
- **Try to avoid over-specific questions**
- **Most people err on the side of too broad…**
  - **Maybe key in on populations/samples**
    - "*Among older patients with diabetes*, what impact does intervention X have on…"
  - **Maybe key in on types of settings/contexts**
    - "What are the barriers to implementing X *in rural primary care clinics?*"

"Elevator Test"

- **You enter the elevator in ED2 on the ground floor. Dean Stowe enters right after you. You are both going to the 6th floor. As the door closes, the Dean asks, "What are you doing for your residency project?"**
  - Can you present the research question/project in a clear and focused manner by the end of the ride? Does she have time to make a comment on how cool (and manageable) it is?
  - When you are coming up with your research question/project, keep this in mind-- "Can I tell someone the gist of this quickly and they'll get it?"



Will your question/project produce generalizable results?

- **How do the findings relate to:**
  - Other patent populations?
  - Other clinical settings?
  - Other educational settings?
- **The more your results generalize, the more they are publishable**
  - There are notable exceptions– e.g., case studies, some qualitative work, etc.

How implementable are your findings ?

- **Can your findings be easily acted upon?**
- **If you tested the effectiveness of a clinical intervention, how hard might it be to be adopted and used in clinical practice?**
  - Will patients be OK with it?
  - Will clinicians be onboard?
- **Does your new QI tool easily fit into the clinic flow?**

OK… Reality check

- **No question/project is "great" on all of these elements**
- **Where you compromise depends on your situation**
  - How much time you have
  - What data you have access to or can collect
  - How much mentoring/support you have

Approach of a clinician-scientist (or a resident scientist)

- **Research is not #1 priority**
- **But, you can approach your work with a "research attitude" (Durbin, 2004)**
  - "Why do we do the things we do?"
  - "Is there a better way"
  - "Can I inform others about the things we are doing/trying?"

Approach of a clinician-scientist (continued)

- **With the "research attitude" you could…**
  - Encounter potential research questions all the time (daily??)
  - Be on the look out for opportunities to create a "researchable" question from what needs to be solved anyway
  - Be on the lookout for natural experiments and capitalize on them
  - Attract and/or seek collaboration from "R"esearchers who are looking for and NEEDING good ideas from the real world!

So, lets re-look at those key elements again…

- **Gap?**
  - From literature, sure; but also from your own clinical/educational work
  - Fix a local gap, yes; but with a mind towards "testing" a solution if you can and sharing what you find
  - Not too big of a gap

So, lets re-look at those key elements again…

- **Timing?**
  - What really needs to be fixed *right now* in your location?
  - Do others agree that this is a good thing to tackle now?
- **Important?**
  - If you fixed the problem, would the impact be substantial?
  - Do others agree that it would be substantial?

So, lets re-look at those key elements again…

- **Feasible?**
  - REALLY have to pay attention to this element!
  - Your other duties cannot suffer
  - Observe others who have already made a project work in that setting
  - Work with your mentor to make sure the project is not too big, and make adjustments if you need to
  - For Residents, you have less than a year to get through the whole thing, including sharing the results…

So, lets re-look at those key elements again…

- **Generalizable?**
  - Take a more "relaxed" view on this
  - Would other local environments potentially benefit?
  - Even if your "findings" might not generalize well, would your "process"?
  - Even in generalizability is low, bring the research attitude to QI

So, lets re-look at those key elements again…

- **Implementable?**
  - This one is easier for clinician/resident scientist as the project is probably local
  - It is probably one of the research questions!
    - "How feasible is the innovation in this setting?"

Goals for today

- Understand elements that make for a good research question
- Understand that some questions are better than others, and that's OK
- Understand that we all work within limitations to create the best research questions we can
  - Limitations = e.g., time, money, available expertise, time, available data, and time

Exercise revisited : What's wrong with these questions?

1. How many steps does it take to get from my office to the elevator?
   So what? Not a gap that needs filling.
2. Is cigarette smoking related to lung cancer?
   We know this already.
3. What is the most cost-effective method of implementing comprehensive medication management in rural primary care clinics?
   Not feasible for you as a resident scholar. Too big.
4. Is the medication *Expensonil* (expected $10,000 per day out of pocket cost) more efficacious than placebo in the treatment of shopping addiction?
   The intervention itself is not implementable. If nobody can afford the treatment, why study it in the first place?

Questions?

HOW TO WRITE YOUR ABSTRACT

--AND A COUPLE OTHER THINGS

Megan Smith, PharmD, BCACP
Postgraduate Research Certificate Program
July 28, 2023

Expectations for this Hour

- Use Reactions
- Use Comment Box
- Use annotations – let's try!
- Camera On – we will pause for camera off at least once
- Other ideas you like?

FINER Criteria for Research Questions

Feasible	Adequate number of subjects (Sample Size) Adequate technical expertise (Personnel) Affordable in time and money (Funding) Manageable in scope (Time)
Interesting	Answer is interesting to investigator, peers, and community
Novel	Confirms, refutes, or extends previous findings
Ethical	IRB approvable and ethically conducted and designed
Relevant	To scientific knowledge To clinical or health policy To future research

Abstract Rubric Criteria

- Varies for each meeting
- Find in the Call for Abstracts

APhA 2020 Evaluation Criteria

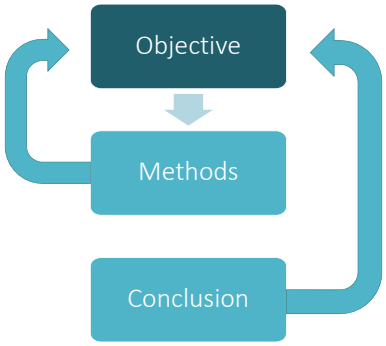
1. **Relevance/Originality**
   a. Rationale for the study clearly defined
   b. Topic makes important contribution to pharmacy practice (patient care, pharmacy operations, pharmacy profession) or theoretical basis of pharmaceutical sciences because it is original or of vital importance to the profession.
2. **Research Questions/Objectives**
   a. Question(s) to be answered or objectives to be met by research are clearly stated
3. **Methods**
   a. Evaluation of the methods considering all the following which are applicable for the type of research being presented:
   b. Measurement
   c. Study design
   d. Data collection process, sampling strategy or sources of data
   e. Data analysis clearly specified
4. **Results**
   a. Findings are reported for each study objective or research question
5. **Implications/Conclusions**
   a. Implications of findings to pharmacy practice, policy theory, or further research are discussed.
   b. Conclusions are appropriately stated based on the results

"Anatomy" of the Abstract

Big Picture Topic	Title
Problem/Gap in the Literature	Background or objective
Solution to Problem	Objective
Specific Method to be Examined or Used • How you will know if that solution was right or wrong	Methods - who, what, when, how
How to evaluate your original argument/thesis	Last part of Methods – what you will do with all the data you gathered. (data analysis)
What Happened	Results
Summary	Conclusion

Which part is most critical??

[type annotation on this screen or use chat feature]



The objective is to…

- to identify and characterize barriers of community pharmacies providing CMRs in the care management program
- evaluate the baseline impact of primary care clinical pharmacist interventions on health registry metrics for patients receiving clinical pharmacy services.
- evaluate patient baseline knowledge of newly prescribed antidepressant medications
- assess the clinical and economic outcomes of implementing a pharmacist-led asthma medication intervention for pediatric Medicaid beneficiaries in a Washington DC based managed care organization.

Research Objective

- Use action verbs that are specific enough to be evaluated or measured
  - assess, determine, compare, verify, calculate, describe
- Be specific
- Verb, target audience (pharmacist, patient), and outcome

Do something on someone/something in this context measuring this outcome

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Let's Examine One

Effectiveness of Community Pharmacist Integration into a Patient-Centered Medical Home on CMS Outcome Measure: Hemoglobin A1c

Objectives: In 2016, a feasibility and acceptability study of integrating a community pharmacist was conducted at a patient-centered medical home (PCMH). Upon completion of the study, a community pharmacist was integrated into this PCMH and began managing patients with diabetes with a Hemoglobin A1c(HbA1c) >9%. "Diabetes: Hemoglobin A1c Poor Control" is one of many outcome measures that the PCMH is evaluated annually from the Centers for Medicare and Medicaid Services (CMS). The objective of this follow-up study is to determine the effectiveness of the pharmacist at improving clinical outcomes for diabetic patients with a HbA1c >9%.

Methods: A quasi experimental study with a pre-post and non-equivalent control group will be conducted to compare and contrast the calculated clinic scores for patients with HbA1c >9%. The clinic score is calculated from the number of patients with Type 1 or Type 2 diabetes with a HbA1c >9% divided by the total number of patients in the clinic with Type 1 or Type 2 diabetes. The clinic score will be measured prior to pharmacist intervention, May-November 2016, and after pharmacist integration, May-November 2017. The clinic score at this PCMH will also be compared to the clinic score at another PCMH in the same city that does not have an integrated pharmacist during the study period (May-November 2017).

Results: Research in progress.

Objectives: Comprehensive Primary Care Plus (CPC+) is an advanced patient-centered medical homes (PCMH) payment model introduced by Centers for Medicare and Medicaid Services (CMS). This model aims to improve patient care by incentivizing primary care clinics to improve value and quality. "Diabetes: Hemoglobin A1c Poor Control" is one of many CPC+ quality measures; therefore, this measure is the focus of this follow-up study. The objective is to determine the impact of a community pharmacist on HbA1c (%) for patients that had interactions with the community pharmacist and determine the impact of a community pharmacist on the quality measure for patients with HbA1c >9%.

Methods: In May 2017, a Kroger pharmacist integrated into a primary care clinic for 20 hours per week. Pharmacists' interventions included patient education, medication adherence counseling and insulin titrations to patients with HbA1c >9%. A quasi experimental study with a matched pre-post design and non-equivalent control group will be conducted. Retrospective chart reviews will be used to gather the last HbA1c value drawn in 2016 and 2017 for all current patients in the clinic with a diagnosis of Type 1 or Type 2 diabetes, as defined by the CMS clinical quality measure definition, "Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)." This data will be used to calculate the clinic score for 2016 and 2017, at the intervention clinic and the control clinic. Statistical testing will be conducted using chi square analysis. Patients that directly interacted with the pharmacist will be evaluated further to directly evaluate the pharmacists' effectiveness. To do so, the HbA1c value obtained directly prior to the pharmacists intervention will be used as the pre-HbA1c. The post-HbA1c will be the next HbA1c value obtained and will evaluate using a paired t-test.

Results: Research in progress. The project has received IRB approval and results will be presented at APhA Annual Convention.

Common Pitfalls of Abstracts

- Making project too big
- Defending or concluding instead of **describing**
  - Example: Explore how technician protocols increase influenza vaccinations
  - Better: Determine the impact of technician protocols on influenza vaccinations in an independent pharmacy
- Can't follow or repeat the methods
- Objective doesn't match methods and conclusions

A couple other things…

Statistician Support

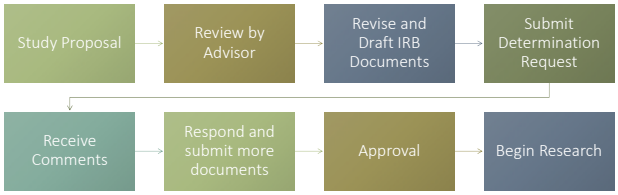
Assists with methodology and data can be analyzed appropriately to answer your question

Oh…we didn't collect that

We can't analyze that type of data?

I didn't think about confounders

Navigating the IRB – START EARLY!



Guidelines for Reporting Research

Research Method	Recommendations
Qualitative: interviews and focus groups	COREQ Checklist
Observational Research	STROBE Checklist
Survey	Kelley K, Clark B, Brown V, Sitzia J. Good practice in the conduct and reporting of survey research. Int J Qual Health Care. 2003;15(3):261-266.
Systematic Review (Quant and meta analysis)	PRISMA Checklist
Systematic Review (Qualitative)	ENTREQ Checklist
Economic Evaluations	CHEERS guidelines
Randomized controlled trial	CONSORT Checklist

Adapted from J Am Pharm Assoc Author Guidelines: https://www.japha.org/article/S1544-3191(15)00044-8/pdf

Resident Research Forum

Who: Pharmacy residents

What: Venue for presenting background and methods of research

When: September 11, 12, 15

Where: Virtual (Zoom)

How: Diverse panel along with other residents and preceptors provide feedback and ask questions about your topic

Sign up: https://www.signupgenius.com/go/4090E48A4A62AA4F58-resident3

Google Folder to upload presentations, 2 days in advance

Please Sign Up by August 7th

Questions

1

Overview of Sample Size Calculation

CHENGHUI LI, PH.D.
POSTGRADUATE (RESIDENTS) RESEARCH CERTIFICATE PROGRAM
SUMMER SEMINAR

2

Outline

- Definition
- Review of hypothesis testing (leave for your own reading)
- Factors affecting power
- Case studies: Cases 1 and 2

3

What is sample size calculation?

- It is the statistical method to determine the **sample size** you will need, in order to achieve the **anticipated** **effect size**, at the desirable **significance level**, with sufficient **power**.

4

What is "Power"?

- Power, or statistical power, is the **probability** of a **test** to detect a significant effect when there is one.
- Power analysis is a way to test/justify whether the current **test** has sufficient statistical power to detect a **significant** result if exist.

5

Developing Hypotheses

- **Null hypothesis (H_0): presumed to be true unless sample data produce overwhelming evidence to prove the contrary**
- **Alternative hypothesis (H_a):** the opposite, or complement of H_0
- Null and alternative hypotheses are
  - Mutually exclusive and exhaustive
  - If H_0 is false then it implies H_a is true
- **Statistical hypothesis testing makes decisions about whether to reject the null hypothesis.**

6

Example: US Judicial System

- H_0 : defendant is not guilty
- H_a : defendant is guilty
- In another word, the null hypothesis (H_0 : defendant is not guilty) is presumed to be true unless there is overwhelming evidence to the contrary

One-sided vs. Two-sided Test

7

- One-sided test (directional test)
  - e.g. H_0 : mean ≥ 6; H_a: mean < 6.
- Two-sided test (non-directional test)
  - e.g. H_0 : mean = 6; H_a: mean ≠ 6
- In most cases, null hypotheses include the "=" (i.e. if there is an direction you want to test, it will be incorporated in the alternative hypothesis)
- How to set up the hypotheses depend on what researchers are interested to test.

Determine the Decision Rule

8

- Decision is either to **reject** or **fail to reject the null hypothesis**
- Can only make a **probability statement** about which is more likely to be true (no way to be absolutely certain of your decision)
  - That is, there is always a possibility that you are making a wrong conclusion.

Errors in Hypothesis Testing

9

		Truth	
		H_0 is true (No Difference)	H_0 is false (Difference)
Conclusion from Hypothesis Test	Reject H_0 (Difference)	**Type I (α) error**	**Correct conclusion**
	Fail to reject H_0 (No difference)	**Correct conclusion**	**Type II (β) error**

Errors in Hypothesis Testing

10

Source: To ERR is to HUMAN
Why Error Rate In STASTICAL TESTS Matter

- **Type I Error**

- **Type II Error**

Errors in Hypothesis Testing

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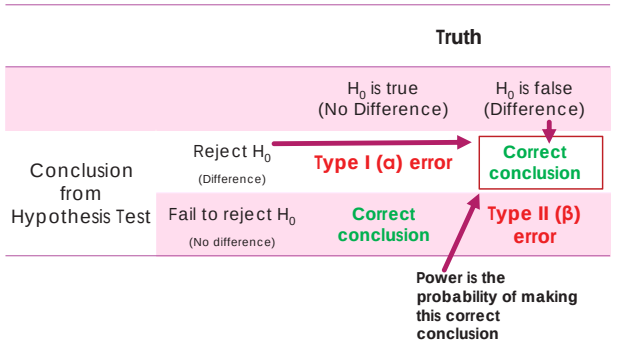
- **Type I error**: Rejecting H_0 when H_0 is true (or rejecting the true null hypothesis)
  - False positive
  - The maximum allowable probability of a Type I error is denoted as **α** and is referred to as the level of the test, or significance level. Often set at **α=0.05.**
  - **P-value** is the probability of observing the outcome from the study or more extreme values by chance, if null hypothesis is true. The "actual" probability of making a Type I error.

Errors in Hypothesis Testing

12

- **Type II error**: Fail to reject H_0 when H_0 is false (or accepting the false null hypothesis)
  - False negative
  - The maximum allowable probability of a Type II error is denoted as **β**
  - **1- β** is referred to as the **power** of the test.

13 Errors in Hypothesis Testing



14 Errors in Hypothesis Testing

- **Power** is the probability of rejecting the null hypothesis when it is false; i.e. how likely one can correctly conclude a significant treatment effect/difference when there is one.
- The generally acceptable level of power is at least **0.8**.

15 Errors in Hypothesis Testing

- Type I error and Type II error are **inversely** related
  - Reduce Type I errors will increase the probability of Type II errors.
  - The relationship is NOT 1 to 1: reducing the Type I error by 5% generally will not increase Type II error by exactly 5%
  - True ***IF*** **nothing else changes.**

16 Factors Affecting Power

- Effect size: ↑↑
- Population variations in the outcome (σ): ↑↓
- Type I error (α) or significance level (*what level?*) ↑↑
- Sample size (**n**)? ↑↑
- Study design* (depends)

17 Factors Affecting Power: Effect Size

- The effect size is the strength of the association **within the population** between the treatment and the outcome.
  - https://stats.idre.ucla.edu/other/mult-pkg/seminars/intro-power/
  - Cohen (1992) Power Primer

http://drsmorey.org/bibtex/upload/Cohen:1992.pdf

- The larger the effect size, the higher the power.
- Before starting the study, the actual effect size is unknown.
- **Minimum clinically significant** effect size: a medical and scientific judgment rather than statistical decision.
- Use published literature

18 Factors Affecting Power: Effect Size (example)

- E.g. Comparing a new drug vs. a standard drug for prevention of stroke
- Outcome is measured as a **binary variable** (e.g. indicator for whether a patient had a stroke or not)
- **Absolute Difference in Proportions** may be calculated as effect size
  - Proportion of the new drug patients had a stroke: P1
  - Proportion of the standard drug patients had a stroke : P2
  - Absolute Difference: P1-P2
- **Odds Ratios (OR)** may be calculated as effect size
  - Odds of events in Group 1: Odds1=P1/(1-P1)
  - Odds of events in Group 2: Odds2=P2/(1-P2)
  - OR=Odds1/Odds2

Factors Affecting Power: Effect Size (example)

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- E.g. comparing two weight-loss drugs and outcome is measured as a **continuous** variable (pounds of weight loss)
- **Mean difference in weight loss**
  - Sample Mean of drug 1: M1
  - Sample Mean of drug 2: M2
  - Mean difference: M1-M2
- **Standardized Difference** may be calculated (if variations differ between groups)
  - Pooled Standard Deviation (SD)
  - Standardized Difference
    - = (M1-M2)/SD_{pooled}

$$SD_{pooled} = \sqrt{\frac{(SD_1^2 + SD_2^2)}{2}}$$

Factors Affecting Power: Within population variation in the outcome (σ)

20

V.S.

COVID 19 Disease Severity: Why there is a difference?

21

Source: healthmatter.nyp.org

Factors Affecting Power: Within population variation in the outcome (σ)

22

- Population variation and power are **negatively** associated.
- The **larger the variability** of the outcome within a population, the more likely to observe a large effect by chance, the **less sure** we are whether there is a significant effect based on an observed sample.
- When σ is unknown, sample variation (S_n) from previous literature or pilot study may be used instead.
  - ***Caution*:** publication bias and findings from small samples in pilot study

Factor Affecting Power: Type I Error (α)

23

- Type I error and power are **positively** associated.
- Recall the trade off between Type I and Type II errors. Increasing Type I error will reduce the risk of Type II error and thus increase the power, if nothing else changes.
- Common practice: **α=0.05**.
- ***Caution***: adjustment of alpha for multiple hypothesis tests on the sample

Factors Affecting Power: Sample Size (n)

24

- Sample size and power are **positively** associated**.**
- **Increasing sample size increases power.**
- Researchers have more control over sample size than other factors, subject to financial and time constraints.
- Thus, **Power analysis and sample size determination/calculation are often used interchangeably.**

Factors Affecting Power: Study Design*

25

- Not directly entering the equation for power
- Will affect the variance **(σ)**
- Can also affect the observed effect size (may affect generalizability)
- Examples of Study Design Issues:
  - number of comparison groups and how they are selected; how frequently the outcomes are measured (e.g. repeated measure); balanced or unbalanced design; Instrument used to measure outcomes and its administration

https://stats.idre.ucla.edu/other/mult-pkg/seminars/intro-power/

When should power analysis be conducted?

26

- Should be conducted prospectively(sample size determination) before you start your study
- Retrospective (post-hoc when you could not find a significant result) – Not recommended
- Reading:
  - Hoenig, J. M. and Heisey, D. M. (2001). The Abuse of Power: The Pervasive Fallacy of Power Calculations for Data Analysis. *The American Statistician, 55(1)*, 19-24.
  - Levine, M., and Ensom M. H. H. (2001). Post Hoc Power Analysis: An Idea Whose Time Has Passed? *Pharmacotherapy, 21(4)*, 405-409.

Why is it important to conduct sample size calculation?

27

- If a null finding is due to insufficient sample size (lead to insufficient power), then wasted resources and conflicted literature.
- If sample size is too large, very small effect may be detected as statistically significant but not clinically significant. Also wasted resources and may lead to unnecessary harm to patients.

So, is there a formula for that?

28

- There is not a formula for ALL tests.
- Formula specific to how the treatment effect will be measured and the statistical test you will use to test that.
- Example of a website to calculate power: http://powerandsamplesize.com/

Case 1: Compare proportions Amy's Study

29

Incidence of Acute Kidney Injury Among Patients Receiving the Combination of Vancomycin with Piperacillin-Tazobactam or Meropenem

Amy D. Robertson,[1,2,*] Chenghui Li,[3] Drayton A. Hammond,[4] and Tiffany A. Dickey[1,2]
[1]Department of Pharmacy Practice, University of Arkansas for Medical Sciences Northwest Regional Campus, Fayetteville, Arkansas; [2]Mercy Hospital Northwest Arkansas, Rogers, Arkansas; [3]Division of Pharmaceutical Evaluation and Policy, Department of Pharmacy Practice, University of Arkansas for Medical Sciences College of Pharmacy, Little Rock, Arkansas; [4]Medical and Cardiac Intensive Care, Rush University Medical Center, Chicago, Illinois

What is the object of the study?

Amy's Study

30

- The primary objective of this study was to evaluate the comparative risk of AKI when VAN was combined with either PTZ or MER in hospitalized noncritically ill patients.
- If you are conducing this study, how to do power analysis/sample size determination?

Amy's Study

31

- Two-side test
- Ho: P(AKI) in VAN/PTZ = P(AKI) in VAN/MER
- Ha: P(AKI) in VAN/PTZ ≠ P(AKI) in VAN/MER

Amy's Study

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- "Sample size was determined based on detecting an **absolute difference in the risk of AKI of 18%**, **extracted from a 2016 meta-analysis** (AKI incidence rates of 32% in the PTZ and 14% in the MER group)."
- "A sample size of **82 subjects per group** was needed to achieve **80% power** using a **2-sided test** at **an α level of 0.05."**

Anticipated Effect Size

From published literature

What is missing factor?

What about σ?

Desired Power >=0.8

(minimum) Sample size n

Alpha or significance level

Simple formula for two-sided test for difference in proportions

33

Sample size in each group (assumes equal sized groups)

Represents the desired power (typically .84 for 80% power).

$$n = \frac{[P_I(1-p_I) + P_c(1-p_c)](Z_{\frac{\alpha}{2}} + Z_\beta)^2}{(P_c - P_I)^2}$$

A measure of variance or **σ**

Effect Size (the difference in proportions)

Represents the desired level of statistical significance (typically 1.96 for 2-sided test).

Amy's Study

34

Study: Van/Ptz vs. Van/Mer on Acute Kidney Injury (AKI) in ICU patients

- From previous studies: the proportion with AKI
- Van/Mer: 14% (**p1**)
- Van/Ptz: 32% (**p2**)
- **Alpha**=0.05 (two-sided test);
- Za/2=1.96
- **Power**=0.8=> beta=1-power=0.2;
- Zb=0.84
- **n=(p1*(1-p1)+p2*(1-p2))*(Za/2+Zb)^2/(p1-p2)^2**~82

Amy's Study

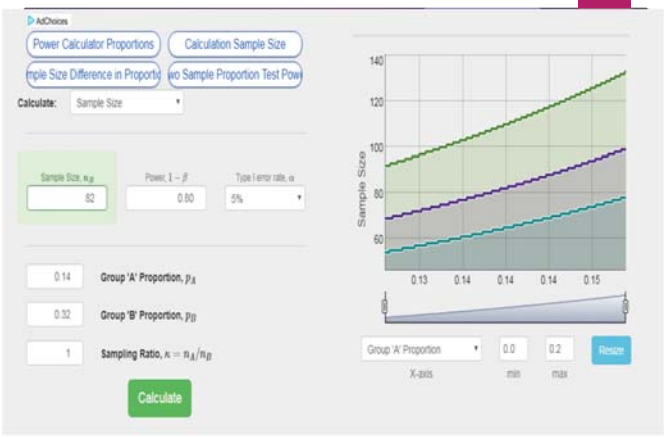
35

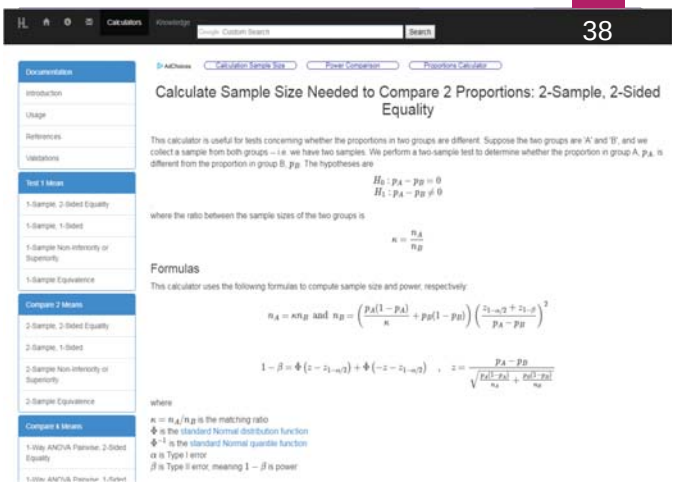
- Medical records for 576 patients were reviewed for inclusion and exclusion criteria. A total of 169 patients (85 in the PTZ group and 84 in the MER group) were included in the final analysis

Amy's Study

36

- Example of a website to calculate power:
- http://powerandsamplesize.com/
- Choose "Compare two proportions" on the left
- Choose: 2 samples, 2 sided equality





$$\kappa = \frac{n_A}{n_B}$$

Formulas

This calculator uses the following formulas to compute sample size and power, respectively:

$$n_A = \kappa n_B \text{ and } n_B = \left(\frac{p_A(1-p_A)}{\kappa} + p_B(1-p_B)\right)\left(\frac{z_{1-\alpha/2} + z_{1-\beta}}{p_A - p_B}\right)^2$$

Case 2: Compare two means

- Example: **Impact of AUC-Guided Versus Trough-Guided Vancomycin Dosing at a Community Hospital** by Stephens K, Howard Z, Fortner A, Briggs S, Propst C
- https://pharmacy.unc.edu/wp-content/uploads/sites/1043/2022/05/Stephens-Kasie.pdf

Case Study 2: Compare two means

- Background: In 2020, the Vancomycin Dosing and Monitoring Guidelines were updated to no longer recommend trough-guided monitoring. Guidelines now recommend an Area Under the Curve/Minimum Inhibitory Concentration (AUC/MIC) ratio of 400-600 mg·hr/L. Research has demonstrated that AUC/MIC targets can be obtained at troughs less than 15 mg/L, while decreasing rates of nephrotoxicity and acute kidney injury (AKI).
- Objective: To evaluate the safety and efficacy of the former practice of vancomycin trough-guided dosing and monitoring compared to implemented vancomycin AUC/MIC-guided dosing and monitoring.
- **Secondary outcomes** included total daily vancomycin dose (TDD)

Case Study 2: Compare two means

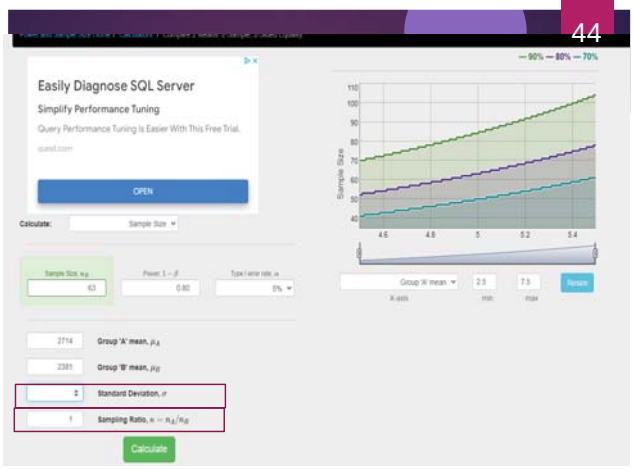
- Results: The average TDD for trough-guided and AUC-guided groups was (mean±SD) 2,714 ± 1064 mg/day and 2,381 ± 879 mg/day, p=0.008.
- What does the p-value tell us?
- Ho: Average/mean TDD trough-guided = Average/mean TDD AUC-guided
- Ha: Average/mean TDD trough-guided ≠ Average/mean TDD AUC-guided
- What is the effect size?
- Difference in average/mean: 2714-2381=333
- What are the variations? (**σ**)
- 1064 for through-guided and 879 for AUC-guided

Case 2: compare means

43

- Example of a website to calculate power:
- http://powerandsamplesize.com/
- Choose “Compare two means” on the left
- Choose: 2 samples, 2 sided equality

44



Case 2: Compare means

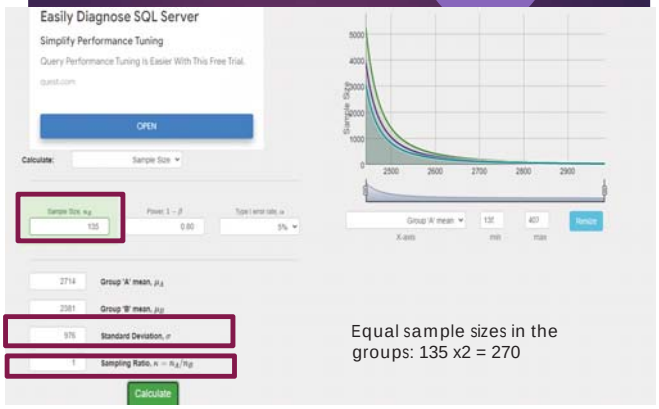
45

- Pooled Standard Deviation
- i.e. assume **σ(**through-guided)= **σ(**AUC-guided)
- Slide 47:
- Assume equal sample sizes:

$$SD_{pooled} = \sqrt{\frac{(SD_1^2 + SD_2^2)}{2}}$$

SD pooled =sqrt((1064^2+879^2)/2) ~ 976

46



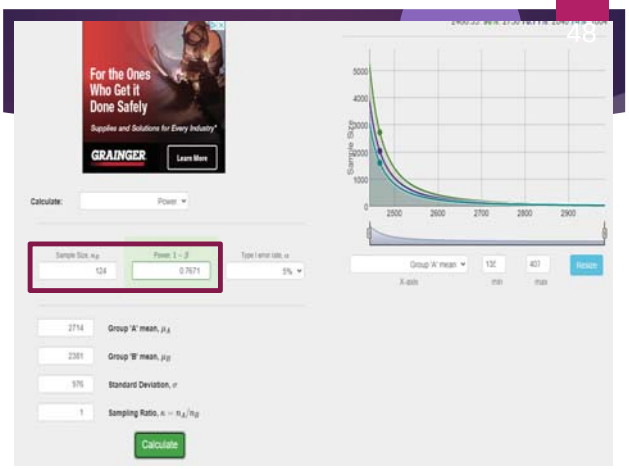
Equal sample sizes in the groups: 135 x2 = 270

Case Study 2: Compare means

47

- Results: “The study population (N=248) was comprised of equal trough-guided subjects and AUC-guided subjects.”
- How many in each group?
- 124

48



Case Study 2: Compare two means

- Results: "The average TDD for trough-guided and AUC-guided groups was (mean±SD) 2,714 ± 1064 mg/day and 2,381 ± 879 mg/day, p=0.008."

What is "Power"?

- Power, or statistical power, is the **probability** of a test to detect a significant effect when there is one.
- Power analysis is a way to test/justify whether the current **test** has sufficient statistical power to detect a **significant** result if exist.

Questions?

RESIDENCY RESEARCH CERTIFICATE PROGRAM: WHAT COMES NEXT?

You may still be feeling a little new at this!

What Comes Next?

At September Research Forum include a PICOT-D statement

Elias BL, Polancich S, Jones C, Convoy S. Evolving the PICOT Method for the Digital Age: The PICOT-D. J Nurs Educ. 2015 Oct;54(10):594-9. doi: 10.3928/01484834-20150916-09. Erratum in: J Nurs Educ. 2015 Nov;54(11):623. PMID: 26431521.

TABLE 1
PICOT-D Component Structure

PICOT-D Component	Component Wording	Evidence-Based Search Terms
Population/patient problem	In adult patients newly diagnosed with type 2 diabetes	
Intervention	How does transdermal monitoring of blood glucose	
Comparison intervention/ current state	Compared with finger-stick blood glucose testing	
Outcome/desired state	Affect compliance with blood glucose testing frequency and lowering HbaTC levels	
Time	Within a 6-month period	
Data	When looking at home blood glucose test frequency and HbaTC levels	

Note. PICOT-D = Population/patient problem, Intervention, Comparison intervention/current state, Outcome/desired state, Time, Data. HbaTC = glycated hemoglobin.

Elevator Speech or Ben Teeter's Elevator Test:

- You enter the elevator on the Ground floor of Ed II. Dean Cindy Stowe enters right after you. You are both going to the 6th floor. As the door closes, the Dean asks, "What are you doing for your residency project?"
  - Usually 30 seconds to 2-3 minutes
  - Purpose: Introduce yourself as a researcher, your project, and its significance so listener will want to know more!

Answer These Questions

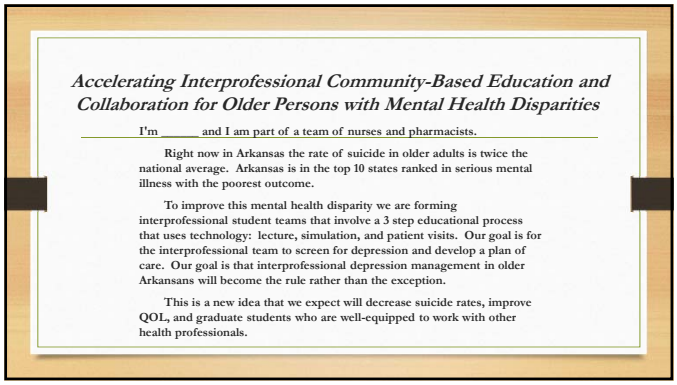
- Who are you/your team?
- What is the topic of your research?
- What is the problem, issue, or question that you are solving/asking?
- How are you addressing this problem/issue?
- Why is the problem interesting and important?

https://www.apa.org/science/about/psa/2014/06/elevator-pitch
https://www.bioquirin.com/article/scientists-here-s-the-best-elevator-pitch-to-sell-yourself-to-a-potential-employer-/

Main Sections

- The Problem and why it matters—The Hook
  - Capture their attention with a problem
  - Quick background to bring them in
  - Why should the listener care?
- What is your solution?
  - How does your work solve the problem?
  - Can summarize findings if you have any

https://academicpositions.be/career-advice/how-to-write-an-elevator-pitch


Accelerating Interprofessional Community-Based Education and Collaboration for Older Persons with Mental Health Disparities
I'm _____ and I am part of a team of nurses and pharmacists.
Right now in Arkansas the rate of suicide in older adults is twice the national average. Arkansas is in the top 10 states ranked in serious mental illness with the poorest outcome.
To improve this mental health disparity we are forming interprofessional student teams that involve a 3 step educational process that uses technology: lecture, simulation, and patient visits. Our goal is for the interprofessional team to screen for depression and develop a plan of care. Our goal is that interprofessional depression management in older Arkansans will become the rule rather than the exception.
This is a new idea that we expect will decrease suicide rates, improve QOL, and graduate students who are well-equipped to work with other health professionals.