



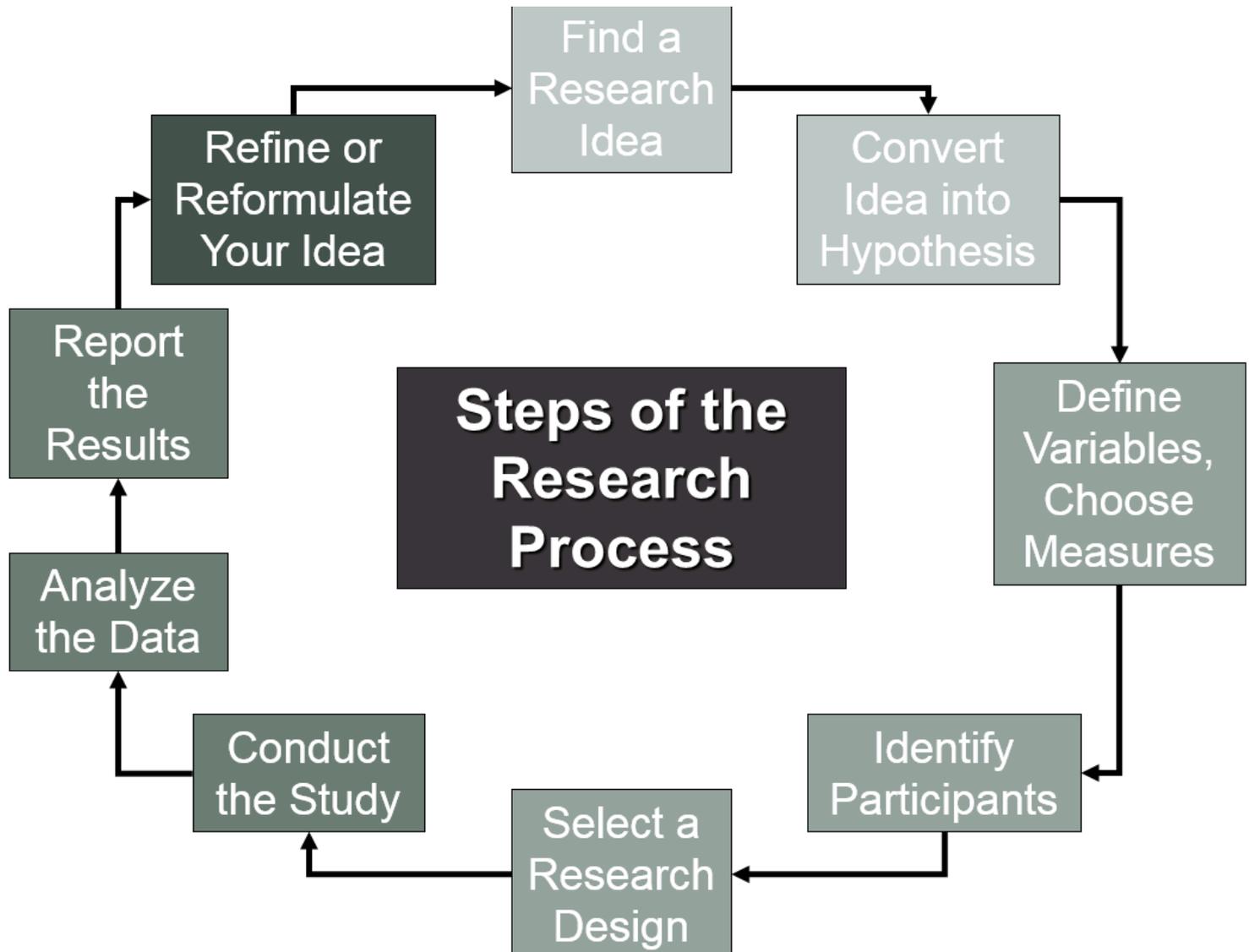
FLORIDA STATE UNIVERSITY COLLEGE OF MEDICINE

Research Workshop Series #3
Research Design I





The Research Process





Research Protocol

- A written plan of the study
- Documents the objectives, design, methodology, statistical considerations, and organization of the clinical study
- Addresses the protection of human subjects and integrity of the data collected



Protocol Components

- Research Topic & Question
- Background/ Literature Review
- Research Objectives
- Hypotheses
- Study Methods
- Independent & Dependent Variables
- Subject Selection/Inclusion & Exclusion Criteria
- Study Implementation Planning
- Data Management and Statistical Analysis
- References

**Additional components required for clinical drug trials*



“Hourglass” Notion of Research





Research Topic & Question



Selecting a Research Topic

- Building your research portfolio
- Insert your own passion and goals
- Assess your own knowledge, skills, & abilities
- Consider collaborators with additional expertise



Formulating your research question

- Research topic should be an **answerable** question
- Should not be too broad or too narrow
- Evidence-based frameworks to assist in mapping question
- Organize the topic into a concept and assign terms to each concept to combine in a search strategy
- Essential characteristics : “**FINER**”
Feasible, Interesting, Novel, Ethical, and Relevant



Formulating your research question

- | | | |
|--------------------------------|---|--------------------------------------|
| ✓ Problem | → | disease |
| ✓ Population | → | age |
| ✓ Intervention | → | education |
| ✓ Setting | → | school |
| ✓ Service provider | → | health educator |
| ✓ Methods/Theories of interest | → | study design
(e.g., cohort study) |
| ✓ Outcome(s) of interest | → | reduced risk |



Formulating your research question

- [Aslam, S., & Emmanuel, P. \(2010\). Formulating a researchable question: A critical step for facilitating good clinical research. *Indian Journal of Sexually Transmitted Diseases*, 31\(1\), 47–50](#)
- [Bragge, P. \(2010\). Asking good clinical research questions and choosing the right study design. *Injury*, 41, S3-S6](#)
- [Schardt, C., Adams, M. B., Owens, T., Keitz, S., & Fontelo, P. \(2007\). Utilization of the PICO framework to improve searching PubMed for clinical questions. *BMC Medical Informatics and Decision Making*, 7, 16](#)



PICO Method

- Popular framework in medical research
- Used for clearly defined clinical questions

P	Population, Patients
I	Intervention
C	Control
O	Outcome



PICO Exercise

- How would you frame this research question?
 - **Does hand washing among healthcare workers reduce hospital acquired infections?**

P	patients with a hospital acquired infection
I	hand washing
C	no hand washing
O	reduced rates of hospital acquired infection



Evaluating Research Questions

- What are the effects of childhood obesity in the U.S.?
 - *Too broad*
- How are schools addressing childhood obesity?
 - *Difficult to operationalize*
- What are the obesity rates among middle school students in Tallahassee, Florida?
 - *Too narrow*
- What are the effects of physical activity programs in middle schools on the rates of childhood obesity among 7th grade students?
 - *Best question – requires an investigation & evaluation*



Background & Literature Review



Background

- What is known about the topic at hand?
- Cites previous research that is relevant
- Indicates gaps with prior research & what uncertainties remain
- Specifies how study will help fill gaps & lead to new scientific knowledge



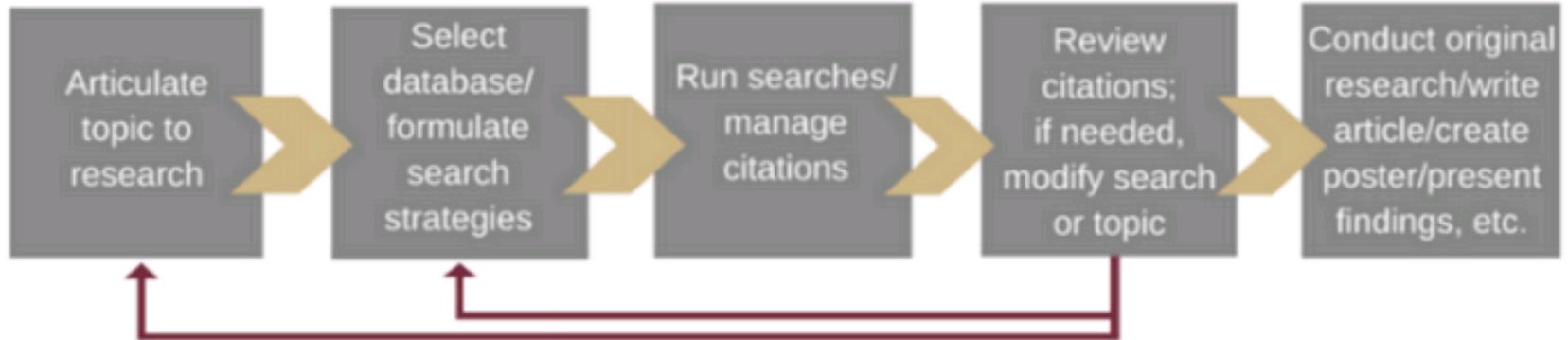
Why conduct a literature review?

- To evaluate existing research
- To describe other research
- To identify gaps in the literature
- To relate to your own research to existing research
- To identify ideas and information relevant to your own research



Literature Review Overview

THE LITERATURE SEARCH PROCESS





Health Sciences Databases

Subject-specific Databases

- [PubMed](#)
- [Cochrane Library](#)
- [PsycINFO](#)
- [CINAHL Plus with Full Text](#)

Interdisciplinary Databases on Multiple Subjects

- [Web of Science](#)
- [Google Scholar](#)



How to search effectively:

1. Determine your research question & main concepts
2. Choose databases (subject or type of information)
3. Search standard language in database (e.g., MeSH)
4. Identify keyword (synonyms) + MeSH terms
5. Create search strings of similar terms for each concept using **OR** combine search strings of each concept using **AND**



MeSH

What is MeSH?

- Medical subject headings
- Standard terminology/descriptors
- Defines term + hierarchy in relation to other terms
- Refines the search to relevant records

MeSH Database

- Search term
- Select subheading
- Restrict to major topic
- Review entry terms for other keywords
- Add MeSH term to search builder



Running the Search



PubMed

PubMed comprises more than 27 million citations for biomedical literature from MEDLINE, life science journals, and online books. Citations may include links to full-text content from PubMed Central and publisher web sites.

- ✓ look at # of results
- ✓ Display Settings → Abstract
- ✓ save citations to email, citation manager, Clipboard, My NCBI, etc.
- ✓ use limits (filters)
- ✓ review # of results as limiting search



Citation Management Tools

Advantages:

- Useful for managing & organizing several literature sources
- Allows you to build your own library for your research topic
- Simplifies creating a bibliography (auto-generate)
- Allows sharing references with peers
- Provides recommendations for sources
- Ability to change citation formats to fit journal submission requirements

Reference Managers:

- EndNote
- RefWorks
- Mendeley
- Zotero
- CiteULike
- JabRef



PubMed Exercise

How would you frame the research question we discussed earlier using MeSH terms in [PubMed](#) ?

Example Research Question:

What are the effects of physical activity programs on childhood obesity among 7th grade students?



Research Objectives & Hypotheses



Research Objectives

Objectives

- Should answer these questions:
 - Why does this research need to be done?
 - What will this study accomplish?
 - What will be its relevance?
- Simple, specific, and stated in advance

*Example:

- To evaluate the effects of physical activity programs on middle school students
- To examine the rates of childhood obesity among 7th grade students



Hypotheses Development

- A prediction about the relationship between two or more variables
 - An expected answer to a study question
 - Establishes the basis for tests of statistical significance
- A study may have one or more hypotheses
- Qualitative research is often used for hypotheses generation



Hypothesis Examples

- Increased frequency of hand washing among health care workers is related to a reduction in hospital acquired infections
- Middle school students that participate in at least 3 hours of physical activity per week have lower rates of obesity compared to students that are less active
- Drug A combined with Drug B will increase the incidence of psychosis in elderly patients



Thank you!

Questions & Discussion