Designing a Research Study

How do I get started?

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First...why do this?

- Curious, critical thinker
- Beneficial to career
- Advance science
- Program mandate
What are some of the career benefits?

- Professional meeting presentations
- Journal publications
- Fellowship applications

Overview of Steps

- Identify study area
- Form study team
- Review literature
- Formulate study question
- Select an approach
- Submit plan
- Go...
Importance of the Research Question

- **Question** informs the design.
- Design drives the analysis.
- Design & analysis determines the methodology.

1. Each Design has a Specific Purpose

- **Testing efficacy**
  - Randomized Controlled Trial
- **Determine safety/quality**
  - Prospective Registry – all comers
- **Calculate incidence**
  - Prospective Cohort
- **Test risk factors (1 or more)**
  - Retrospective (case/control)

- **Calculate prevalence**
  - Cross Sectional
- **Generate new hypotheses**
  - Descriptive
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Each Purpose has Specific Analysis

- Efficacy for mortality outcome
  - Chi square analysis and Relative Risk
- Efficacy for laboratory outcome
  - Student’s t-Test for Independent Group Means
- Risk Factor Assessment
  - Chi square analysis and Odds Ratio
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When is the Best Time to Start a Research Project?

<table>
<thead>
<tr>
<th>Idea</th>
<th>Proposal</th>
<th>IRB</th>
<th>Implementation</th>
<th>Analysis</th>
<th>Abstract</th>
</tr>
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- Paper/poster/slides
- Conference Presentation

MAR - APRIL 2022

May 2022
1st Step: Identify Area of Interest

- **Topic**
  - Select what is most interesting to you

- **Consult with faculty**
  - Bounce topic off of faculty/colleagues

- **Consult with Research**
  - Discuss topic with Director of Research

- **Consult the literature**
  - Look for scientific trends in your topic genre

Where do ideas come from?

- **Observation**
  - Keep a small journal/notebook for ideas.

- **Consultation**
  - Identify faculty and attending physicians.

- **Collaboration**
  - Organize informal meeting to share ideas.

- **Reading**
  - Discussion section of published manuscripts
    (future directions/challenges to reader).
REVIEW LITERATURE

Why is this done?

- Theoretical basis
- New direction
- Add to body of knowledge

What is a “good” question? FINER

- Feasible
- Interesting to the investigator
- Novel
- Ethical
- Relevant
Where the Best Questions Come From: Clinical Observation

- A clinical problem / issue:
  - Iatrogenic blood loss in ICU
  - Intra operative dexamethasone

- A hospital policy / standard practice:
  - Pre procedure bleeding risk score

- Patient experiences:
  - Tetanus sero positivity and perceived protection

Transforming the Question, cont.

- Topic Question: Does early trauma cause fibromyalgia?

- Research Question: Is there an association between early trauma & fibromyalgia?

- Testable Hypothesis: There is no association between early trauma & fibromyalgia.
Transform Question into a Testable Hypothesis

- **Topic question:**
  - Is CABG Better?

- **Research question:**
  - Is CABG superior to PCI for outcomes?
  - There is no difference in mortality rates between CABG and PCI for multi-vessel disease.

- **Testable Hypothesis:**
  - The Null ($H_0$)

Transforming the Question, cont.

- **Topic Question:**
  - Is lead exposure linked to illness severity in Covid19 patients?

- **Research Question:**
  - Is severity in lead exposed greater than non exposed Covid19 patients?
  - No difference in Covid Severity between lead exposed and non exposed hospitalized patients?

- **Testable Hypothesis:**
  - $H_0$
**What Type of Question is Best?**

- **Simple!**
  - Does not need to be ground breaking
  - Does not need to be completely original

- **Important!**
  - A topic you care about
  - A clinical issue/problem you encounter
  - Novel enough to add something new to the scientific literature.

**Example Simple Topics**

- Screening rates of Hepatitis C among high risk patients at a community clinic.

- Accuracy of weight estimations by health care professionals.

- Association between patient perceived medical severity and clinical acuity.
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Research elements to consider:

- Study Design
  - Retrospective vs. prospective design?

- Sample size
  - Power calculation

- Measures
  - Define how variables measured

- Plan of Analysis
  - Select statistical tests
SUBMIT PLAN
Do I need approval?

- Residency Approval
  - program director or designee

- IRB Approval:
  - Local or central

YES