Creating Preliminary Data: Observational Studies

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No Disclosures
Outline

• What is prelim data?
• How to get prelim data? (our experience)
• Take home messages
What is Prelim Data

• Data generated **prior to conducting full scale studies**

• Why do we need it?
  • Evaluate **feasibility**
  • Test overall approach
  • Provide **proof of concept**
Generating a Research Question

• Daily clinical experience
  • Encounter many *uncertainties*
  • *Insufficient* evidence
  • *Controversial* management approach
  • *Poor* outcomes
  • *Challenge* dogmas
The Right Research Question

• Ask the right research question
• The right form of the question
  • **P**: Patient population
  • **I**: Intervention/exposure
  • **C**: Comparator
  • **O**: Outcomes
Literature Review

• Conduct a **thorough literature review**

• Evaluate **quality of available evidence**

• Does the literature answer your question?

• Identify a **knowledge gap (if any)**
How To Get Started

• Have a clear idea of the **overarching research question**

• Consult **senior researchers**

• Search for **collaborative opportunities**

• **Network**: Find other scientists working on the same topic
Conducting an Observational Study
What is an **observational study**?

- Passive observation
- **No intervention** by investigator
- Establish **association**
- **Support** overarching research goal
Why Observational?

- Inexpensive
- Faster data collection
- Large sample size
- Asses multiple outcomes
- Expedited board review
• **Lower standard** of evidence
• More prone to **bias and confounding**
• Can demonstrate **association** but not **causality**
• May **overpredict results**
Decide on a Study Design

- Prospective/Retrospective cohort study → Rare exposure
- Cross sectional study → Asses prevalence
- Case-control study → Rare outcomes
- Case series → Rare conditions
Decide on a Data Source

- Chart review → Granular data
- Biobank → Molecular data
- Multicenter data → Generalizable data
- Nationwide databases → Large sample size
- Quality improvement projects → Local experience
Getting IRB Approval

• Use deidentified data

• Protect patient confidentiality/welfare

• Ethical conduct of research
Data Management

1. Selection of variables
   - Data entry
   - Validation of entries

2. Data Collection
   - Incorrect entries
   - Data validation

3. Data Management
   - Missing data
   - Data reorganization
   - Recoding

Clean Dataset
Data Analysis

- Statistical support
- Univariate/multivariate analysis
- Appropriate statistical methods
  - Regression
  - Propensity scores matching
  - Subanalysis
Using Prelim Data

• Incorporate findings in **grant application**

• Use data to:
  
  • Calculate **sample size**
  
  • Adjust **design**
  
  • Estimate **cost**
  
  • Determine **timeframe** for patient recruitment
The Brain Injury Guidelines

Frailty

The University of Arizona
Putting It All Together

Do We Need a Neurosurgery Consult for Every TBI Patient

Insufficient Data → Retrospective Cohort Studies

BIG MIT

Interventional Studies Long Term Outcomes

What is the Impact of Frailty on Geriatric Trauma Patients

Insufficient Data → Retrospective Cohort Studies

Frailty MIT

Basic Science Inflammatory Markers
Take Home Message

Generate The Right Question

Choose Appropriate Study Design

Use The Right Database

Spend Time On Data Management & Methodology

Prelim Data Integral To Successful Grant Application
Thank You!

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