Slide 1

ASPIRE SESSION 3:
Study Procedures and Data
Elements, Sources, Uses, and Issues

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DENVER
HEALTH
Level One Care For ALL

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Slide 2

Pre-Session Lecture

DENVER HEALTH

Study Procedures and Data Elements, Sources, Uses, and Issues

- Describe basics of a study procedure
- Illustrate data elements and sources
- Characterize methods for identifying study patients/subjects, exposures, and outcomes
- Appraise data limitations and means to overcome limitations
- Identify factors needed for and to calculate a sample size

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Slide 3

Example Study Review

DENVER HEALTH

- **Study Question**: Does a new protocol for "pharmacy to dose warfarin" increase percentage of patients with goal INR at day 5 of therapy?
- **Study Design**: Pre/Post

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Slide 4

Identification of Study Patients

- **Primary data**
  - Due to time constraints, not likely as would need to be actively enrolling throughout year
  - Better suited for a prospective interventional or observational design
- **Secondary data**
  - Random or targeted chart review
    - Time intensive
    - Possibility to miss patients or introduce bias
  - Data query

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Slide 5

Baseline Characteristics

- Demographics (age, sex, race, etc.)
- Patient identification (inclusion/exclusion criteria)
- Potential confounders
  - Think of your outcome (dependent variable); are there variables already known to affect/influence the outcome
  - Doing background research for your topic will help you figure this out!

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Slide 6

Outcome Data

- **Primary Outcome**
  - How will outcome be analyzed/presented
    - Proportions? Means?
    - Necessary to appropriately calculate sample size
- **Secondary Outcomes**:
  - Study protocol compliance?
  - Efficacy endpoints? Safety endpoints?
  - Think ahead! Are there any outcomes that would be difficult to meet power but that you still want to investigate?

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Slide 7

Calculating Sample Size

- Based only on the primary outcome
- Establish acceptable α (5%) and β (20%) error
  - Lower error = bigger sample size
- Determine expected difference
  - Sampling
  - Published data
  - Clinical significance

STOP! Is this study feasible?

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Example Sample Size Calculation

- **Primary outcome**: percentage of patients within goal INR at day 5
- Pre-implementation: 50%
  - Obtained from baseline data (previous project, random sampling, etc.)
- Post-implementation: 75%
  - Goal set by pharmacy department, clinically significant improvement
- α error = 5%, β error = 20%, power = 80%

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Example Sample Size Calculation

- **Primary outcome**: percentage of patients within goal INR at day 5
- Pre-implementation: 50%

55 patients per group

- Post-implementation: 75%
  - Goal set by pharmacy department, clinically significant improvement
- α error = 5%, β error = 20%, power = 80%

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Slide 10

Requesting Data

- Get input on your query prior to submitting
- Meet with analyst or whoever may be obtaining your data
  - Ask questions!
  - The more you both understand your data points, the more meaningful the data pull
  - Think about differences in how the same data point can be described (e.g. ICD-9 vs. ICD-10, broad categories vs specific diagnosis)
  - Where is the best place to obtain the data?

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Quality Assurance

- Output from data query is HIGHLY dependent on input criteria
- Spot check a few patients with chart review
  - Does the data point match what you are looking for?
    - Is the timestamp the order start? administration time?
    - Is glucose reading from a lab draw? POC?
    - Less patients identified than you thought or missing data? Is there actually no data or is there another way to request the data?

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Tip #1: Data Collection Tool

- Create and practice with your data collection tool early
- Especially important when a lot of data is coming from chart review (vs. database pulls)
- Helps identify challenges/limitations
  - Will these compromise the project?
  - Are there alternative data points that will give you the same information?
  - Useful to help budget time and set realistic goals

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Slide 13

Tip #2: Definitions are Key

- Develop definitions for any variables that require interpretation
- Ensures consistency
- Mitigates introducing bias into data collection
- Especially helpful if multiple people will be collecting data

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Tip #3: Missing/Incomplete Data

- Inherent limitation of retrospective studies
- Identify a strategy for how you will handle missing or incomplete data
  - Censor?
  - Carry forward previous data point?
  - Exclude patient completely?

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Tip #4: Perform Check-Ins

- Meet with preceptor to perform check-ins throughout the data collection process
  - Ask questions!
  - Earlier identification of missing data or need to add a variable
  - Minimize rework
  - Accountability

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QUESTIONS???

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