Writing Research Hypotheses and Specific Aims

Cynthia Carnes, PharmD, PhD
Professor and Associate Dean
Carnes.4@osu.edu

July 19, 2011

Outline

• Define the research question
• From a question to a hypothesis
• Developing specific aims to test a hypothesis

Define the research question

Spend enough time to develop a good question

• READ, READ, READ
• A thorough literature review will help identify a high quality question
• Look for knowledge gaps or areas of controversy.
• Are you interested/excited/convinced about your idea?
Study hypothesis vs. Study Purpose

Every study has a purpose, not every study has a hypothesis

Every study does not require a hypothesis

Studies with a purpose

• May be observational, exploratory or descriptive

• Allow for a “first look”

• May be hypothesis generating

How does the question lead to a hypothesis?

• This is where you begin to really narrow your question.

• A solid hypothesis:
  – Makes predictions about relationships between variables (cause and effect)
  – Should address at least a part of the research question
  – Is well-grounded in existing literature and knowledge
Writing your Hypothesis

- A hypothesis is a tentative statement that proposes a possible explanation to some phenomenon or event.

- A good hypothesis will:
  - Have a strong rationale and address all or a portion of your research question
  - Have a measurable, reproducible outcome measure or measures

What makes a good quality hypothesis?

- It makes a prediction (you don’t have to agree with the prediction).

- It describes the relationship between an independent (controlled) variable and a dependent (measured outcome) variable.

- It is feasible for the scope of your project.

How do you get from a hypothesis to specific aims?
Hypothesis to Specific Aims

Once you have a good hypothesis, it should lead directly to your aims.

Brainstorm ways to test your hypothesis.

Most hypotheses can be addressed in different ways, so don’t limit your thinking too quickly (avoid love at first sight).

Hypothesis testing: Considerations for constructing aims

• Know your assumptions
• Know the limitations of your measurements
• CONTROLS, CONTROLS, CONTROLS
• Confounding variables can lead you astray

Specific Aims

Specific Aims are the roadmap for the project.

If you are going to measure it, it should be addressed in the aims.

If you measure it, have a plan to use it.

If you have an interesting idea that is not directly testing your hypothesis…save it for later.
How do you develop specific aims?

- Begin with the end in mind
- The specific aim or aims should be directly linked to the hypothesis.
- Each aim should be highly focused
- FEASIBILITY (time, resources, statistical power)

What should be measured?

- Optimal (True) endpoints
  - Longevity
  - Prevention of events (reduced morbidity)
  - Improvement in quality of life
  - Cost savings

References:

What if you don’t have the time or resources to get to a true endpoint?
**Surrogate Endpoints**

- Validation of surrogate endpoints
  - Changes in the surrogate must predict a relevant clinical outcome
  - Capture the effect of the intervention on the clinical outcome
  - **AND**

- Benefits
  - Shorter latency
  - Reduced size/cost/duration of trials
  - Avoidance of unethical practices
  - May be more feasible

- Limitations
  - Misclassification
  - Assumes causality or close linkage to disease process
  - May not be a complete picture (multi-factorial)

---

**Putting it all together**

- **Research question**
- **Purpose or Hypothesis**
- **Specific Aims**
  - What is measured?
  - How is it measured?
  - What are the controls?
  - How will you interpret your data?
Harinstein, et al. Use of an Abnormal Laboratory Value-Drug Combination Alert to Detect Drug-Induced Thrombocytopenia in Critically Ill Patients

Questions for Group Discussion

• What is the research question?
• What is the hypothesis?
• How could the hypothesis be tested?
• Are the objectives (aims) appropriate in scope?

Questions for Group Discussion

• What is the research question?

• What is the hypothesis?

• How could the hypothesis be tested?

• Are the objectives (aims) appropriate in scope?
Questions for Group Discussion

• What is the research question?
• What is the hypothesis?
• How could the hypothesis be tested?
• Are the objectives (aims) appropriate in scope?
Questions for Group Discussion

• What is the research question?
• What is the hypothesis?
• How could the hypothesis be tested?
• Are the objectives (aims) appropriate in scope?
Summary

• Start with a good question that you are interested in pursuing.
• Develop a testable hypothesis.
• Develop feasible, focused aims to test the hypothesis.

“Being busy does not always mean real work. The object of all work is production or accomplishment and to either of these ends there must be forethought, system, planning, intelligence, and honest purpose, as well as perspiration. Seeming to do is not doing.”

Thomas Edison

Questions and/or Comments?