Formulating a Research Question

Pathways to Careers in Clinical and Translational Research (PACCTR)

Curriculum Core
What is a Research Question?

• The uncertainty that you want to resolve
• Defines the area of interest to be addressed in your study
• Forms the foundation of your study
• Must be specified **before** you begin your analysis
What is a Research Question?

• Often begins with a general concern:
  – Should women take hormones to prevent bone loss?
  – Can a vegetarian diet reverse cardiovascular disease?
  – Can diabetic patients be taught to control their blood glucose levels?
What is a Research Question?

• Must be narrowed to something measurable and researchable
  – Is taking estrogen associated with a lower risk of osteoporosis in women 60+?
  – Does a plant-based diet reduce serum cholesterol levels in patients with cardiovascular disease?
  – Can a structured intensive diabetes education program help patients with type 2 diabetes control their blood glucose levels?
How to generate a research question

- Literature
- Your previous research
- Mentor
- Conferences
- Patients
Searching the Literature

• Good scholarship is key -- no need to re-invent the wheel

• Conduct a meta-analysis or systematic review to evaluate the existing literature

• Consult The Cochrane Library and other sources for systematic reviews
[Protocol]

Hormone replacement therapy for osteoporosis in postmenopausal women

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Abstract

This is the protocol for a review and there is no abstract. The objectives are as follows:

The objective of this systematic review is to develop estimates on the benefits of preventive treatment with hormone replacement therapy (HRT) for osteoporosis, taken for long term in postmenopausal women.

We will test the following hypothesis: the use of HRT slows bone loss and has a beneficial effect on the axial and appendicular bone density, thus preventing fractures of women in menopause.
Previous Research

• If you’ve been working in a particular area, your own work may generate new research questions
  – In a study you published in the Journal of Managed Care Pharmacy, you reported that a pharmacist-led education program increased medication compliance 2-months post-hospitalization in transplant patients.
  
  – Now you wonder if a similar program might help diabetic patients control their blood glucose levels.
    • Can a structured intensive diabetes education program help patients with type 2 diabetes control their blood glucose levels?
Mentor

• Your mentor is a good source for possible research questions
• In addition to the ideas generated through conversations and collaboration, your mentor may be able to help with grant-writing, office space, lab facilities, etc.
Conferences

- Conferences are a great source of new ideas
- Attend sessions, read through abstracts, contact researchers
Patients

• Jerry Smith, a 64-year-old patient with serum cholesterol levels of … comes to you with an article from Vegetarian Times magazine touting the health benefits of a vegetarian diet. He asks you if a vegetarian diet might help him reduce his need for daily statins. You search the literature and find little research in this area.

• You decide to design a study to answer the question:
  – Does a plant-based diet reduce serum cholesterol levels in patients with cardiovascular disease?
Criteria for Research Questions

• FINER:
  – Feasibility
    • Sample size (link: how to calculate; BREAD)
    • Technical expertise
    • Affordability (link to budget description/worksheet)
    • Manageability
  – Interesting
  – Novel
  – Ethical
  – Relevant
Another way of looking at it

• Importance:
  – Effects on patients, caregivers, society
  – Severity - mortality, morbidity, QOL
  – Duration
  – Financial costs - to the individual and society
  – Ability to change practice
  – Feasibility of the assessment
  – Other - innovative, timely, social/political concerns
What goes in the research question?

- Disease or condition of interest
- Population and setting
- Intervention to be tested
- Comparison group(s) -- placebo? Existing treatment?
- Outcome measures
Sample research question

• Interest: Should women take hormones to prevent bone loss?

• Research question: Does taking estrogen after menopause reduce the likelihood of bone density loss in women over 60 years of age, compared to women not taking estrogen?
Sample research question

• Interest: Can a vegetarian diet reduce cardiovascular disease?
• Research question: Does an entirely plant-based (vegan) diet reduce blood serum cholesterol levels in men over 50 years old with lipid levels > … compared to a meat-based diet?
Sample research question

- Interest: Can diabetic patients be taught to control their blood glucose levels?
- Research question: Can a structured intensive diabetes education program help adult patients with Type 2 diabetes control their blood glucose levels, compared to patients receiving standard instructions?
Common problems/obstacles

• Question too broad
  • Reduce variables of interest; narrow focus

• Not enough subjects available
  • Expand inclusion criteria; lengthen time frame; modify exclusion criteria

• Too expensive
  • Consider less costly study designs -- fewer subjects; shorter duration; fewer follow-ups
Common problems/obstacles

- Methods beyond your skills
  - Collaborate with experts in those areas

- Not interesting, relevant, novel
  - Consult with mentors; review literature

- Unethical
  - Consult with IRB; revise research question
What next? Designing a protocol

- After you have a well-conceived, well-written research question, the human subjects protocol is next
References


PACCTR* Curriculum Core

- Jennifer Cocohoba, PharmD, School of Pharmacy
- Roberta Oka RN, ANP, DNSc, School of Nursing
- George Sawaya MD, School of Medicine
- Rebecca Jackson MD, School of Medicine
- Susan Hyde DDS, MPH, PhD, School of Dentistry
- Joel Palefsky MD School of Medicine

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