

# FORMULATING THE RESEARCH QUESTION

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## *Where do questions come from?*

- From patient-centered questions in routine clinical practice:
  - diagnosis “What do I have, doctor?”
  - etiology “Is it because I did X?”
  - prognosis “How long do I have?”
  - treatment or prevention “Will Y do me any good?”
- From new treatments or diagnostic tests “Are they better than what we have?”
- From physician and patient experiences “What causes quick consultations?”

## *The research process*

- Step 1 - Identify knowledge gap
- Step 2 - Formulate the research question
- Step 3 - Search for existing information
- Step 4 - Focus the research question
- Step 5 - Design the study
- Step 6 - Refine the specific aims and objectives of the study

## *Defining a good question*

- Importance
- Interest
- Answerability

## *Importance of research question* *The “so what?” test*

## *Interest of research question*

- Motivation
- Innovation
- Topicality
- Ethical considerations
- Political considerations
- Social considerations

## *Answerability of research question*

- Type III error: Asking the wrong question  
*“Far better an approximate answer to the right question, which is often vague, than an exact answer to the wrong question, which can always be made precise.” - John Tukey*
- Type IV error: Asking a question not worth answering

## *Types of questions*

### Variance questions

- Focuses on difference and correlation
- “Is (are) there” “Does” “How much” “To what extent”
- Quantitative/Clinical
- Starting point or primary determinant of the design

### Process questions

- Focuses on “how” and “why” things happen
- Qualitative

## *Components of the clinical question*

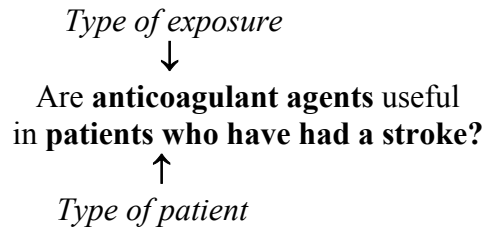
Population - type of person

Intervention (exposure) - type of exposure

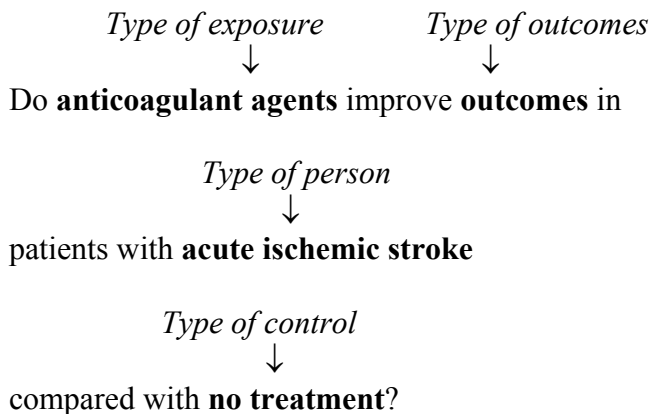
Comparisons - type of control

Outcomes - type of outcome

## *Refining the clinical question*



## *The well-formulated question*



## *Operationalizing the research question*

- Each component (variable) of the research question needs to be defined in terms of the operations required to measure them.
- These need to be specified in the Specific Aims section of a grant.

## *PICO - Population*

Example: Is amoxicillin effective for otitis media?

- Is “otitis media”
  - otitis media according to physician diagnosis?
  - otitis media based on tympanometry readings?
  - fever and ear pain?
- Do you consider infants and adults?

## ***PICO - Intervention***

Is amoxicillin effective for otitis media?

- Are antibiotics effective for otitis media?
- Are any drugs effective for otitis media? Decongestants?
- Are any treatments effective for otitis media? Myringotomy? Humidifier?

## ***PICO - Comparisons***

Example: Is amoxicillin effective for otitis media?

- Does this translate to:
  - Efficacy - vs. control or placebo
  - Comparative efficacy - vs. standard therapy

## ***PICO - Outcome***

Example: Is amoxicillin effective for otitis media?

- Does amoxicillin prevent long-term hearing loss?
  - Requires trials with long-term follow-up
  - Requires trials which assess hearing
- Does amoxicillin reduce pain?
  - Requires trials which assess pain

## ***The FINER criteria for a good research question***

- Feasible
  - Adequate number of subjects
  - Adequate technical expertise
  - Affordable in time and money
  - Manageable in scope
- Interesting
  - Interesting to the investigator

## *The FINER criteria for a good research question*

- Novel
  - Confirms or refutes previous findings
  - Extends previous findings
  - Provides new findings
- Ethical
- Relevant
  - To scientific knowledge
  - To clinical and health policy
  - To future research directions

## *Visualizing the research question*

- Visual refining of a research question can help in making a verbal commitment to it.
- Having a conceptual or theoretical framework also helps toward refining the research question.

## *Conceptualization theory construction Concept analysis*

### Principles

- Concepts should be clearly defined and well differentiated from other concepts (epistemological principle)
- Concepts should be coherently and systematically related to other concepts (logical principle)
- Concepts should be applicable to the world or operationalized (the pragmatic principle)
- Concepts should be appropriate to their use in context (linguistic principle) Morse, et al., 1996

## ***Relations of concepts Conceptualization types of research***

- Descriptive Research - Identify and fully describe the defining characteristics and particulars of concepts of interest
- Exploratory Research - Discover what other phenomena cause or coexist with the concept
- Explanatory Research - Shift from asking what factors are related to the concept to why they are related

## ***Interactive patient model Benefits of a well-formatted research question***

- Aids in reducing the work for a literature review
- Aids in the development of hypotheses
- Aids in the development of a conceptual or theoretical framework
- Aids in clarifying relationships among variables

## ***The qualitative research question***

- The research question is the result of an interactive design process rather than the starting point
- Initial questions are designed to focus and develop more specific questions during the research process

## ***Refining the qualitative research question***

- What you want to understand by doing the study vs. what you want to accomplish
- Example: “What is the best way to increase medical students’ knowledge of science?” vs. “How do exemplary teachers help medical students learn science?”
- In interview studies your research questions identify the things you want to understand; your interview questions generate the data that you need to understand these things.

## ***Approaches to the qualitative research question***

- Instrumentalist questions focus on what can be observed: “How are exemplary teachers observed to teach basic science?”
- Realist questions incorporate beliefs, feelings, and intentions as fallible evidence to be used critically to test ideas about what is going on: “How do exemplary teachers help medical students learn science?”

## ***Kinds of qualitative questions***

- Questions about the meaning of events and activities to the people involved in them
- Questions about the influence of the physical and social context on these events and activities

## ***Example of small grant concept paper***

Comments from the Chief of NIMH Health and Behavioral Science  
Research Branch:

- A detailed, empirically-supported conceptual/theoretical framework that guides specific aims, selection of measures, analysis, etc. is a critical foundation for any application.
- In addition to somatization disorder, would you be measuring depression and anxiety disorders/symptoms/related disability as part of the “stress-related symptoms?”
- Are there particular medical outcomes of interest based on prevalence estimates in this population from the existing literature? A more focused range of mental and medical outcomes would probably enhance the statistical power of your proposed study
- Explicit relevance to mental disorders/symptoms/related disability should be reflected in the title, abstract, theoretical framework, specific aims, measures and analyses.

## ***Example of small grant concept paper***

Comments from CPRC staff review:

- The section on significance and description of this “special population” was informative but need to describe types of incarceration a bit more e.g., difference between a jail, prison, detention in terms of how the individual moves through the system.
- Although the research questions are stated on page 4 and outlined in the Aims, some reviewers felt a defined hypothesis would help focus the study on outcomes.
- Always ask the question--so what? What difference will this research make in the health of the American public? Some thoughts--perhaps an outcome is a set of screening question(s) useful to primary care practitioners’ assessment of the patient. Or, if you decide to research and explore the impact on children as noted on page 3 of the concept paper, an outcome could be expansion of funding for support groups as part of the improved care recommendations.

### ***Revised specific aims***

- To estimate the percentage of adult female primary care patients with an incarcerated family member, and determine if practice-specific rates vary by practice characteristics such as proportion of minority populations served and proportion of underinsured patients
- To describe and compare adult female patients with and without the family incarceration experience with regard to biopsychosocial characteristics (sociodemographics, medical problems, physical/psychological symptoms, perceived stress, stressful life events, substance use, coping, social support, family functioning, presenting complaints, mental health symptoms, quality of life, and service utilization), and
- To investigate the relationship between family member incarceration and health outcomes (health related quality of life and its components) and service utilization.