



ARMY MEDICINE
Serving To Heal...Honored To Serve



Developing a Good Research Question

03 October 2018

Michael J. Morris, M.D.
Vice Chair, RHC-C IRB
SAUSHEC Assistant Dean for Research
Pulmonary/Critical Care



Disclaimer



- "The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Air Force, the Department of the Army or the Department of Defense or the U.S. Government."



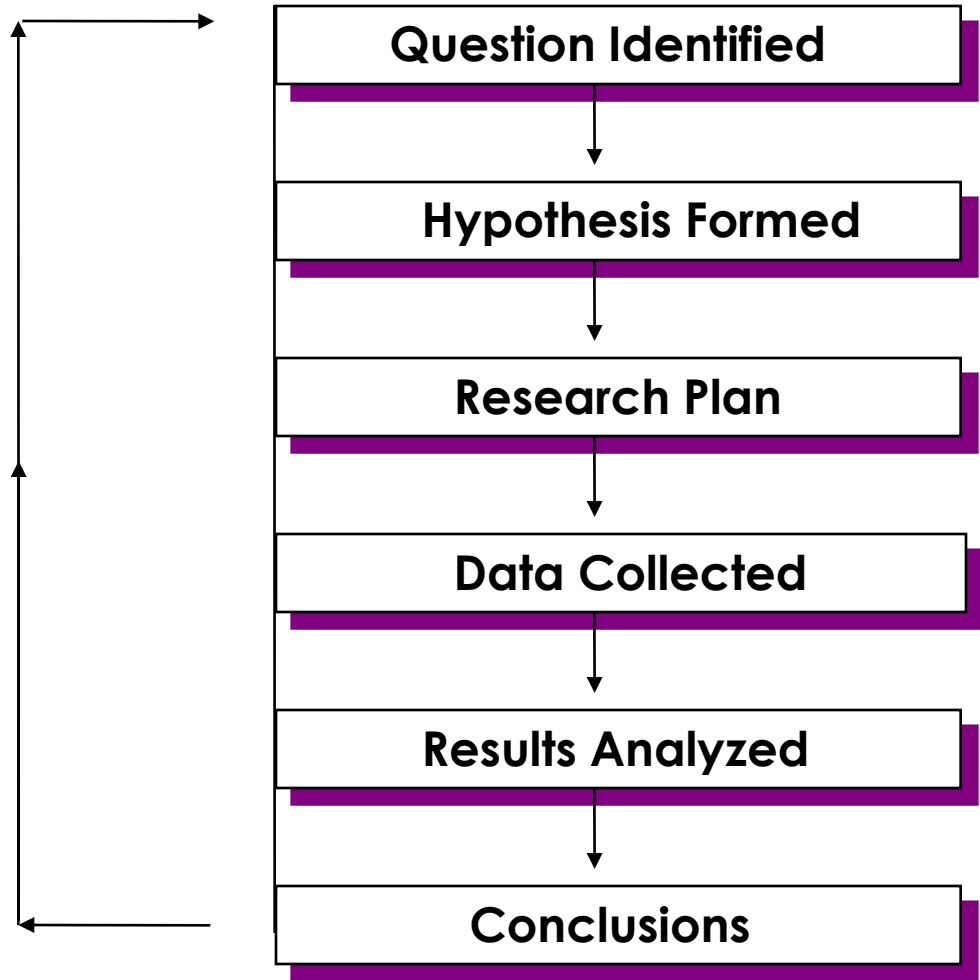
Objectives



- Describe principles of developing a project
- Developing a good research question
- Review basic research design
- Types of clinical studies



Stages of the Scientific Method



Steps within the research process



12 Steps of Research



1. Identify the research question
2. Initial review of literature
3. Distilling the question to a researchable problem
4. Continued review of literature
5. Formulation of a hypothesis
6. Determining the basic research question
7. Identifying the population and sample
8. Designing the data collection plan
9. Developing data collection instruments
10. Choosing the method of data analysis
11. Implementing the research plan
12. Interpreting the results



Research Question



- The foundation of your study
- The research question determines:
 - Study design
 - Subject selection
 - Methodology
 - Statistical analysis





Research Question



- Objective of the study
- Uncertainty about a health issue
- Begins as vague and general concern
- Narrowed to a concrete, researchable issue
- Question must be focused before planning
- The “So What” test

SO WHAT?



Research Question



- Narrow the question to a specific goal
- Which lung diseases are more common in the deployed population?
 - Is there a decrement in lung function based on change in FEV_1 in deployed asthmatics?
 - What are the various non-malignant pathological pulmonary diagnoses in military personnel and their relationship to deployment?
- The more specific your goal, easier it will be to answer your question





Research Question



- What are your clinical questions?
- What will keep your interest?
- What populations are available?
- What would you like to change?
- What doesn't make sense?
- How do I tell that staff attending they are wrong?
- What's for lunch at the Gateway today?



Fellowship Question



- If pulmonary HTN is increased in patients with ILD (50%) and pulm HTN is a contraindication to transbronchial biopsy, why am I doing this procedure?
- Developed 2 research studies and publications from this question.





Research Question



- Medical literature
- Journal clubs
- National meetings and conferences
- Application of new methods or concepts
- Observations during patient care
- Ask questions!!!





Literature Search



- Discover what has already been done
- Helps define & refine study topic
- Update your knowledge
- Needed for protocol application
- Sources
 - Textbooks
 - Google Scholar
 - OvidSP
 - SCOPUS



Research Question



The backbone of the research

The uncertainty the investigator wants to resolve

F – feasible

I – interesting

N – novel

E – ethical

R - relevant





Feasible



- Adequate number of subjects
- Technical expertise
- Time during training
- Monetary support
- Manageable



Interesting



- Investigator
- Mentor or program director
- Your peers
- Funding agencies
- Specialty



Novel



- Explore new information
- Confirm / refute previous findings
- Extend results
- Examine a different population



Ethical



- Ethical principles
 - Beneficence
 - Autonomy
 - Respect for persons
- IRB approval
- Consent process



Relevant



- Advance knowledge
- Impact clinical management
- Impact health policy
- Guide future research
 - Pilot study
 - Confirm clinical question





Patient Population

Target Population (Research Question)



Accessible Population



Intended Sample (Study plan)



Actual Subjects (Actual study)



Patient Population



- Are the patients appropriate to answer your question?
- Deals with feasibility, ethics, and relevancy
- Avoid pitfall of performing study “in a military population”
- Sample of convenience



Exclusion Criteria



- High likelihood of being lost to follow-up
- Inability to provide good data
- Ethical barriers (increases risk)
- Subject's refusal to participate
 - Too complicated
 - Too many visits
 - Prolonged duration



Limitations



- Sampling problems (representativeness of subjects)
- Uncontrolled factors and extraneous variables
- Faulty research design and techniques
- Reliability and validity of measuring instruments
- Compromises to internal/external validity



Further Questions to Consider



- Who will be studied?
- What intervention will be made?
- When will the study take place?
- Where will the study take place?
- Why do I care about this question?
- How will I evaluate the results?

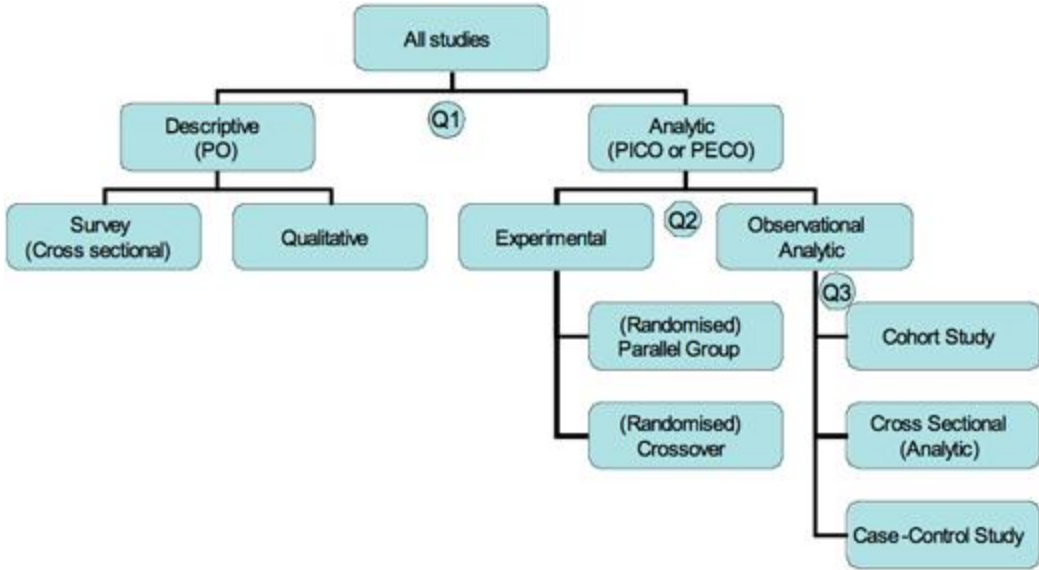




Study Design



- Explain step by step what is to be done
- Several designs for the same problem
- What method works best for your question?
- Can you reasonably achieve the goals of your research?





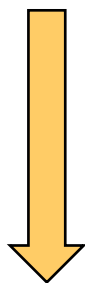
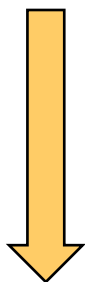
Research Ladder



Descriptive

Reviews

Observational



Analytical

RCTs

Cause and Effect



Types of Research Questions



- Conceptualize that a research study can ask three types of questions:
 - Descriptive question
 - Relationship question
 - Difference question
- This general classification scheme helps not only with the design of the study, but also in choosing the type of data analysis procedure



Descriptive Question



- Seeks to describe phenomena or characteristics of a particular group of subjects being studied
 - Answers the question “what is”
 - Asking questions of the research participants
 - Testing or measuring their performance
 - Survey research



Relationship Question



- Investigates the degree to which two or more variables are associated with each other
 - Does not establish “cause-and-effect”
 - Only identifies extent of relationship between variables



Difference Question



- Seeks to make comparisons between or within groups of interest
 - Often associated with experimental research
 - Is there a difference between the control group and the experimental group?
 - Comparison of one group to another on the basis of existing characteristics





Study Types



- Questionnaire
- Secondary Data
- Cohort (Incidence)
- Cross-Sectional (Prevalence)
- Case-Control
- Observational
- Randomized Controlled Trials (RCT)



Questionnaire



- Clear, accurate and reliable
- Existing, validated instrument
- Self-administered vs. interview
- Open-ended vs. closed-ended
- Simple, easy to read
- 100% complete and error-free collection of data





Descriptive Studies



- Descriptive Studies
 - Prevalence Study
 - Case Report
 - Chart Reviews
 - Surveys





Descriptive Studies



- Goal - typically no hypothesis – goal to report observations (not causal)
- Outcome – report novel cases, report epidemiologic findings, report distributions
- Statistics – means, percentages



Descriptive Studies



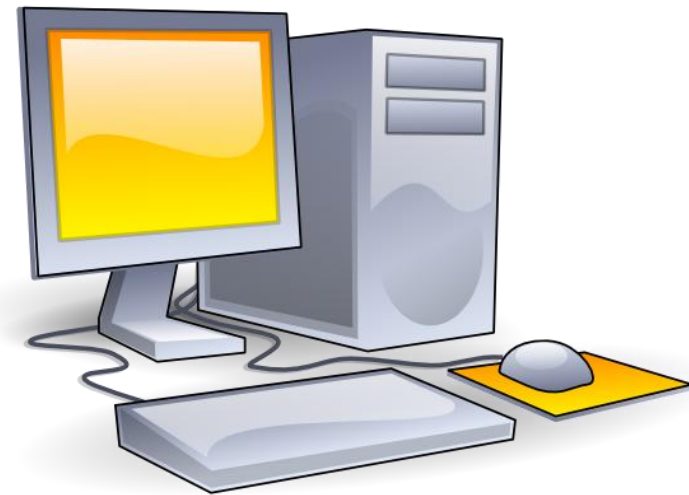
- Chart Review – How many active duty have deployment-related dyspnea?
- Prevalence Study – What percentage of active duty recruits have asthma? What is the relationship to deployment?
- Case Report – Patient who developed diffuse alveolar hemorrhage during deployment



Secondary Data



- Reduces cost and time of research
- Existing project
- Computerized databases
- Trauma, tumor registries
- Hospital records
- Discharge diagnoses, clinic visits
- AHLTA, M2, Essentris

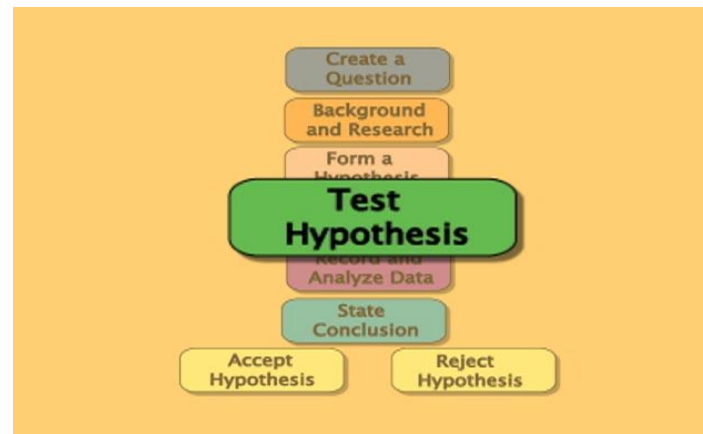




Analytic Studies



- Analytic Studies
 - Test a hypothesis
 - Establish relationship
 - Deals with associations of variables





Analytic Studies



- Observational
 - Cross sectional
 - Cohorts
 - Case Controls
- Experimental
 - Clinical Trials
 - Systematic Review





Questions?

