MODULE 2: THE RESEARCH QUESTION

INTRODUCTION

Designed in collaboration between Memorial University's Discipline of Pediatrics and Discipline of Obstetrics and Gynecology, this module is part of a series of teaching modules designed to augment residents' learning of the basic aspects of medical research and to prepare residents for conducting their own research projects.

This module is about ***the research question***. You may think that finding a research question is the first thing you do in conducting a research project. But a lot of work needs to go into developing a good and viable research question. A good research question is the foundation of a project and it needs to incorporate much of its planning.

In this module, you will learn:

- What a research question is and its role within a research project.
- The elements of a well-formulated research question.
- How to evaluate whether a research question is well-formulated and worth pursuing.
- Tips on developing a research question for your resident project.

CASE – PART 1

Alex is a second year pediatric resident who still does not have an idea for his research project. He knows that it is a requirement for his residency program, but he doesn't know where to start. He also feels a bit nervous because he does not have any experience in research. He meets with this program's research director, who tells him that research is driven by curiosity and that he should let his interests direct him to what he wants to study. They discuss his plans after residency. The research director says that "If you are leaning towards doing a fellowship after your residency, consider doing your project in that area. Publications will be very beneficial for fellowship competition." The research director also suggests he thinks about whom on staff he may want to work with or questions that he had in providing clinical care to help direct him to a topic.

Alex is interested in pursuing pediatric emergency or general pediatrics. While seeing a consult in the ER, he has a chat with the clinical chief of the ED. Dr. Williams says that she would be happy to work with Alex on a project. She said that she had a case earlier in the day in which a 4 year old who presented with severe hypoglycemia (unconscious, glu 1.1 mmol/L). She was concerned about how long it took to treat the hypoglycemia and that she would like to explore the issue more. Dr. Williams explains that she ordered D25 for the patient as per PALS protocol, however, the nurses had trouble diluting the D50. Alex knows that patients often have hyperglycemia with D25. Dr. Williams mentions that some adult centres are using D10 to treat hypoglycemia and suggests that this may be a good topic to study. Alex agrees. Dr. Williams says that he needs to develop a proper research question and get back to her.

Alex has a topic and someone to work with. But what does he do next?

WHAT IS A RESEARCH QUESTION AND WHY IS IT IMPORTANT?

A **research question** specifically states what a study is aiming to discover. It is very similar to a **research objective**, which formulates the research question as a statement. The research question gives direction and focus to the entire study. As Belgrave et al. point out, "A research question is an excellent way to pull things together. Writing a research question forces you to focus your thoughts and summarize your goals in a single interrogative sentence." It informs such things as who are eligible study subjects, what methods of data collection to employ, and the type of information to collect. It is also a succinct way to let others know what your project is about. In stating what the project is trying to discover, it can also be inferred from the research question what is not being studied. This information is important in terms of what inferences you can appropriately conclude from a project's findings.

A research question is different from your **research topic** or **area of research**. The research topic is the general area that you are interested in studying. The research question is more specific, relates directly to what is the aim of your specific research project, and is informed by a deeper understanding of the knowledge area. For example, you may be interested in studying maternal factors which put children at greater risk for a certain condition, e.g., type 1 diabetes. This would be your research topic. As you study this topic further, you will develop a more focused question which is answerable within the content of a study. Your ultimate research question maybe something like: "Which maternal factors recorded by the Newfoundland Neonatal Database are associated with the onset of T1DM in a cohort of children born at the Janeway Hospital between 2007 and 2012?" The good research question has to be narrowed to a concrete, researchable issue; it must be focused; it must be important; and it needs to be transformable into a feasible and valid study plan.

Some studies have a number of questions they are trying to answer. One question is usually identified as the **primary research question**, with the other question being secondary questions. If a study requires a **sample size calculation**, this calculation is usually calculated only using the primary research question.

FORMULATING A RESEARCH QUESTION

Formulating a research question is a process of taking your topic and sharpening its focus. In conducting research, we are trying to increase the amount of knowledge about a particular area. This can be done by conducting research done in other centres in your local context or studying something no one else has explored yet. In order to develop research questions that are novel and relevant, it is necessary to become familiar with background information as well as current knowledge surrounding the topic. The development of a research question takes time as it must identify the fundamental design, feasibility and relevance of the proposed idea. The research question must outline a study that yields important information in a given area, and must ultimately produce pertinent information that will broaden the scope and provide insight on the given topic.

The formulation of a research question is an iterative process, where you keep revising your initial ideas and plan for your project as it develops. The creation of a research idea must begin within the realms of a broad topic that is of particular interest. As a researcher inquires into more specific areas of the topic, the research question becomes clearer. For instance, one must ask whether there has already been substantial research done in the given area, and if so, it must be determined whether the given project will aim to confirm, refute or modify the major findings. Moreover, it is vital that researchers possess the means to complete their study in an effective manner and that they submit proposals to determine feasibility (i.e., funding, ethics). Start with a single primary question around which to focus the development of the protocol and sample size estimates. You can also identify secondary research questions, which related to the primary question or to other hypotheses. But a common error is overloading the study with too many objectives, which either cause the study to be unfocused or require too much data collection.

Some helpful steps to follow are:

1. Write down the question…
    - What is the uncertainty that you want to resolve
    - Begin with a general concern then narrow down to a concrete, researchable idea.

2. Master the literature in that area
    - Read, read, read…
    - Focus on studies that support the *need* for *your study*

3. Establish a single primary research question which you will use to develop study plan and estimate sample size.
    - You can supplement with secondary questions as the study develops.

THE ELEMENTS OF A RESEARCH QUESTION

A good research question needs to be specific about what the project is aiming to achieve. But what elements does it need to be specific about? A helpful mnemonic of the elements that should be part of a research question is **PICOT**:

1) **P**opulation: Who are the subjects the project hopes to recruit?
2) **I**ntervention: For studies which have an intervention, what is being administered to subjects to examine its effect?
3) **C**ontrol or **C**omparison: Who are the people the study group is being compared with?
4) **O**utcome: What is the main outcome that is being measured to compare the groups?
5) **T**imeframe: What is the time period being studied?

Example of a Bad Research Question:

Is vaginal rejuvenation safe and effective?

Population: Women who want/have had "vaginal rejuvenation"? Too general

Intervention: vaginal rejuvenation (not a specific procedure, too general)

Control: none

Outcome: too vague, there is no standard definition of "effective" in this case. Large numbers required to demonstrate safety may affect study feasibility.

Timeframe: since vaginal rejuvenation has been available?

Example of a Good Research Question

Will administration of continuous OCP result in better pain relief than cyclic (21 days of active pills and 7 days of placebo pills) administration to women with primary dysmenorrhea?

Population: women with primary dysmenorrhea

Intervention: continuous oral contraceptive pill

Control or Comparison: cyclic oral contraceptive pill

Outcome: pain relief

Timeframe: *assumed to be over the study period

REVIEW QUESTIONS – PART 1

Try to find the various PICOT components in the following research question:

Is tonsillectomy preferable to nonsurgical treatment for children under the age of 12 who have severe recurrent throat infections?

1) What is the study population for the research question?

a) Children who have had tonsillectomy

Answer: The study population refers to everyone who the study aims to recruit. The children who have had tonsillectomy may be may be part of the study population, but they do not make up the whole study population.

b) Children under the age of 12

Answer: While it is true that the study population includes children under 12, a proper description of the population should be as specific as possible.

c) Children under the age of 12 who have severe recurrent throat infections

Answer: Correct. The description of the study population should reflect the inclusion criteria for the study.

d) Children under the age of 12 who have had either a tonsillectomy or nonsurgical treatment for severe recurrent throat infections.

Answer: This may be the study population for a retrospective study, where you are looking back for cases that include either the intervention or the control, but would not be the study population for a prospective study that recruits patients and then assigns them to a specific treatment.

2) What is the intervention for the research question?

a) Tonsillectomy

Answer: Correct. Even though it is a common procedure, in the context of this study, it is the intervention that is being examined.

b) Recurrent throat infections

Answer: Incorrect. This is one of the selection criteria for the study population.

c) Nonsurgical treatment

Answer: Incorrect. As the research question is written, patient who received nonsurgical treatments are the control group.

b) Rate of throat infections for children under 12

Answer: Incorrect. This is the outcome measure for the study.

CASE PART 2

Alex searched Pubmed and the Cochrane databases. He did not find any studies published in children using D10 in the emergency treatment of hypoglycemia, but 3 recent publications in the adult population. He also reads some information about conducting a research project and found out that a randomized clinical trial is the gold standard for research. He meets with Dr. William to discuss the project further. He proposes doing a randomized clinical trial to study the efficacy and safety of using D10 versus D25 for the treatment of hypoglycemia in children presenting to the emergency department. She asks him that given that he is now at the end of second year, whether her will he be able to finish this project during his residency? What are the potential obstacles?

She suggests a more manageable approach would be to consider a chart review of patients with hypoglycemia to determine their number at their centre annually and how they are currently treated. Other approaches Dr. Williams asks Alex to consider include interviewing the staff on their thoughts, frustrations, and ideas about the problem or conducting a simulation study to compare the time required and the confidence of staff administering D10 versus D25. She tells him to start writing up some of his findings from the literature review and to start thinking what aspect of the problem they should aim to study and to write down how he would propose to do it.

EVALUATING A RESEARCH QUESTION

Now that you know what a research question is supposed to do and what it should specify, you can start to use this knowledge to evaluate whether a research question is well formulated. The PICOT framework sets out aspects of a proposed study that should be specified in a research question. But there are other aspects to consider in evaluating whether a research question is a good question. Another mnemonic that is sometimes used to define this aspect of a research question is **FINER**: Feasible; Interesting; Novel; Ethical and Relevant.

Feasible

There is no sense proposing a research question you cannot answer given your level of expertise, amount of available time or available resources. Another important issue is whether you have access to enough study subjects to collect the amount of data that you'll need. In evaluating your research question and your proposed project, you need to consider:

- Is the scope of the project manageable?
- How many people will you need to answer your question and will you likely be able to recruit that number of participants?
- Do you have (or your research team) have the necessary expertise?
- Do you have adequate resources (time, money, personnel, equipment)?

Novel

All research aims to add new knowledge to a study area. When evaluating a research question, you need to consider whether your project will add anything new to the subject area. Making a novel contribution may include confirming or refuting previous findings or discovering new findings. Determining whether a research question has the possibility of making a contribution to the topic requires a review of the academic work that has already been completed on the topic.

Interesting

Similar to whether it is novel, is the question whether a project is interesting. Is your question interesting to your peers and colleagues who work in the subject area?

Ethical

Your study should not pose unacceptable physical risks or invasion of privacy. You should check with your supervisor or the Health Research Ethics Authority to see if there are issues with your project and whether it will need approval from your institutional ethics board.

Relevant

It is likely that the proposed study will influence clinical management and health policy; or guide future research.

REVIEW QUESTIONS – PART 2

1) A research question specifically states what a study is aiming to discover. A good research question:

    a. Only provides the general topic of study
    b. **Identifies which study subjects are eligible**
    c. Identifies who is going to conduct the study
    d. Does not require extensive knowledge of the literature on the topic of study

2) A helpful mnemonic of the elements that should be part of a research question is **PICOT**. Which is **NOT** an element of PICOT:

    a. Population
    b. Intervention
    c. **Conclusion(s)**
    d. Outcome
    e. Timeframe

3) A common error in choosing a good research question is overloading the study with too many objectives. What problems would this cause?

    a. Causes the study to be unfocused
    b. Causes statistical analysis to be too complicated
    c. Makes the study less generalizable
    d. Makes it impossible to prove cause and effect

FORMULATING A RESEARCH QUESTION FOR YOUR RESIDENT RESEARCH PROJECT

So far in this module, we have talked about the importance of the research question and how to construct a good research question. In this final section, you will focus on developing a research question for your resident research project. Based on the information provided so far, complete the following questions. Once completed, print the session and review it with your research supervisor.

Section A: Resident Worksheet

1. What is the topic of research project?
2. How have you searched for information about your topic so far (e.g., PubMed, Google)?
3. List any relevant articles that you have found so far.
4. What type of study are you thinking of conducting (e.g., chart review, survey)?
5. Is there an intervention you plan to give, and if so, what is it?
6. What is the specific population you want to study?
7. Who is the control / comparison group for your study?
8. What specific outcome(s) are you interested in tracking?
9. What is the time frame that you are study your subjects for?
10. Please formulate your initial research question(s).

Reviewing of Your Research Question

1. If you have multiple research questions, have you identified your primary research question?

2. Are all your research questions unambiguous?

3. Do all questions accord with the PICOT framework to the extent that it is appropriate?

4. Are all of the questions supported by a review of the academic literature?

5. Is it feasible for you to answer your proposed question?

6. Who would be interested in the findings if you successfully answered your research question?

7. What contribution would you see answering your question having?

8. Can you answer your questions in accordance with the ethical conduct of research?

Suggested Further Resources:

Belgrave L, Zablotsky D, Guadagno M (2002). How do we talk to each other? Writing qualitative research for quantitative readers. Qualitative Health Research. 12. 1427-1439.

Fineout-Overholt, E., & Johnston, L. (2005). Teaching EBP: Asking searchable, answerable clinical questions. *Worldviews on Evidence-Based Nursing*, 2, 157-160.

Guyatt G. Clinical Epidemiology.

Rios LP, Ye C, Thabane L. Association between framing of the research question using the PICOT format and reporting quality of randomized controlled trials.

Vaillancourt C. Conceiving and formulating the research question. Royal College.

Glossary

Research question(s) - Questions which specifically ask what a study is aiming to discover. A research project can have more than one research question.

Research objective(s) - Similar to a research question, research objectives are statements which state what a study is aiming to discover. A research project can have more than one objective.

Research topic – A general identification of the focus of a research project, which is generally less specific than a research question. For example, you may be interested in studying maternal factors which put children at greater risk for a certain condition, e.g., type 1 diabetes. This would be your research topic. As you study this topic further, you will develop a more focused question which is answerable within the content of a study. Your ultimate research question maybe something like: "Which maternal factors recorded by the Newfoundland Neonatal Database are associated with the onset of T1DM in a cohort of children born at the Janeway Hospital between 2007 and 2012?

Area of research – Same as the research topic.

Primary research question – The main research question that a study is trying to answer. It is used to calculate the sample size of a project.

Sample size calculation – A calculation of the required sample size that a study needs in order to answer a specific research question with a desired level of statistical confidence.