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 the first of two teaching modules designed to help introduce medical students to basic aspects of conducting medical research. This module is an introduction to why research is important to clinical care and reviews the basic aspects of the research process. The next module is focused on the development and evaluation of a research question.

In this module, you will learn about:

- The importance of medical research to clinical care;

- The main phases of a research project;

- How you can start to build a clinical research career.

CASE STUDY

Christine and Kamal are both first year medical students here at Memorial. Christine has an undergraduate degree in biochemistry, during which she had to complete her honours dissertation under the supervision of her supervisor. Kamal has a background in English and comparative politics from an American University. Both know that they have to complete a two week research block. Christine has selected to do her first two week project block with Dr. Richardson, conducting research on developing more effective ways to evaluate medical student performance. Kamal has selected a project with Dr. Kelly, performing a chart review on children affected in Newfoundland with a range of genetic syndromes. Both feel a little uncomfortable about their level of research knowledge and what they may be expected to know? Christine even questions why research should be part of her training to be a clinician? Kamal says to Christine that at least she has some experience with research through her undergraduate degree. He feels that he doesn't even an idea about how a research project is conducted.

SECTION A: WHY IS RESEARCH IMPORTANT TO MEDICAL EDUCATION?

Royal College of Physicians and Surgeons of Canada (RCPSC) have developed a framework of essential physician competencies (known as CanMEDS competencies), designed to address the growing complexity of clinical practice and the need for active, independent and lifelong learning. Among the various CanMEDS competencies is the physician as scholar, where physicians must "demonstrate a lifelong commitment to reflective learning, as well as the creation, dissemination, application and translation of medical knowledge" (2005, p. 21). This CanMed role is important as a means of maintaining one's knowledge and expertise as a clinician. Inherent to the concept of evidence-based medicine, is having an understanding of research and to apply findings to the care your patients receive. Ultimately, being able to access and appraisal research articles and reports is an effective way of answering your questions. It is also hopefully intellectually stimulating.

The best way to learn about research and different projects is to do it. But there are other reasons for conducting research. For many clinicians, making a contribution to their field becomes a reward part of their career. It is a way to get the respect of peers. For medical trainees, being involved in research is a great way at career advancement and can even be a requirement to work at an academic teaching hospital. If you are already leaning towards an area in which you want to do your residency, consider doing research in that area to demonstrate an interest and illustrates an added expertise in that area.

SECTION B: THE RESEARCH PROCESS

As Christine and Kamal recognize through their discussions with their class mates, it seems that research can be carried out on a wide array of topics. There are a number of different research designs and methodologies which can be employed. While it is not within the scope of this module to explore all of the different research designs, many research projects follow the similar research process, regardless of the designed employment. The process can be summarized in eight steps.

Step 1: Select topic. For many projects you work on, the topic may be selected already by a supervisor or research team. If you have a program of research, the topic for a study maybe derived from the findings of previous studies.

Step 2: Search literature / discuss with experts. Research is about providing new knowledge. The literature review is a process of identifying, evaluating and summarizing the literature relevant to a particular field or topic. Some aspects to consider when conducting the literature are: What are the research questions or objectives of the studies on your topic? What population did they study? Who didn't they study? Where did they conduct their study? How did they conduct the study? What were their conclusions and suggestions for future research?

Step 3: Formulate research question / objectives. Clearly identify what the study is aiming to discover. A research project can have more than one research question. This will be covered in the second module.

Step 4: Develop research protocol. This topic is covered in the Section C of this module.

Step 5: Apply to get institutional ethics proposal if required. This topic is covered in the Section D of this module.

Step 6: Conduct study / Collect data

Step7: Analysis data

Step 8: Report results

These last steps will depend on the methodological choices that are made in designing the study.

SECTION C: THE RESEARCH PROTOCOL

A research protocol is your blueprint for answering your research question. It sets out what and who is going to be studied, who is not going to be studied, the plan for studying, and how data will be analyzed. You should be able to justify the methodological choices you make in developing your research protocol. Use your literature review should inform the development of your research protocol.

There are various ways that research protocols can be structured, but they should also clearly include (if relevant to the study) information on:

1. Title

2. Background / Rationale for the study

3. Research question / study objectives

4. Study Population, Intervention, Control, Outcomes Measured and the Timeline for the study

5. Key Elements of Study Design
   1. The type of study
   2. How will data be collected?
   3. How will patients be contacted?
   4. How will consent be gotten?
   5. How do you plan to analyze your data?

6. Dissemination Strategy

SECTION D: RESEARCH ETHICS

Research ethics is a critical part of the research process. The three main federal research funding agencies have released a Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans which outlines many of the key principles that must be upheld when conducting research involving humans. A key aspects to ensure that the highest ethical standards are being met in your research project is the review of your research protocol by an institutional ethics review board. In our province, the institutional review board is the Health Research Ethics Authority of Newfoundland and Labrador (HREA). Its website: http://www.hrea.ca/Home.aspx.

Not all projects need HREA approval. Types of excluded projects are:

- ◦ Research using only publicly available information;
- ◦ Systematic reviews / meta-analysis;
- ◦ **Some** studies which rely only secondary use of data which would not allow attribution of personal health information to an individual
- ◦ **Some** quality improvement projects

Once you have your study protocol you should check the HREA website or contact them to determine whether on ethics application is required.

To apply for ethics review, you need to include

- ▸ The Appropriate HREA Application
- ▸ A copy of the Research Protocol
- ▸ And, if being used in the study, copies of the study's consent form, invitation to participant letters, and any data collection instruments.

Templates are available for helping to develop acceptable consent forms on the HREA website.

First time applicants need to also include:

- ▸ A copy of your C.V.
- ▸ A certificate of completion for the Introductory Tutorial for the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS), which can be found here http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/.

If you have a good research protocol, doing a HREA application is fairly straight forward. Many research projects raise minimal concerns from research ethics perspective and the review process can be fairly quick. HREA staff and your supervisor / mentor are available to give guidance and help assist you through the process.

REVIEW QUESTIONS

1. What is the purpose of a literature review in a research process? (Pick all that apply)

    a. **Build knowledge about the research that has been published to date on her research topic.**
    b. Help inform an evidence-based decision for a specific case.
    c. **Help focus and refine her research question.**
    d. To evaluate the quality and validity of research that has been done to date on her research topic.

2. Christine research is on developing more effective ways to evaluate medical student performance. Does she require ethics review before she starts her project?

    a. Yes.
    b. Only if there is an external funding.
    c. **Depends on the types of data she wants to conduct.**
    d. Only if she is a first time researcher.

3. As a first time researcher, if submitting an ethics application for a project on which he is the principal investigator, which of the following would Kamal not need to provide the HREA?

    a. The HREA Application.
    b. A copy of the research protocol.
    c. **A copy of his transcript.**
    d. The TCPS 2 certificate of completion.

4. If Christine does not have research ethics approval, she is only allowed to…

    a. Collect data that will be used to pilot the study design.
    b. Collect contact information for potential study participants.
    c. **Publish the research protocol.**
    d. Ask participants to be part of the study, without collecting their data.