

Module 1 – Refining a Research Question



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Overview

Introduction

Possibly the most difficult part of doing clinical research is selecting one of your clinical questions and shaping it into an answerable research question.

This module will help you work through the process of defining the goal of your research, identifying objectives, refining these into a question(s) that interests you (or your supervisor) and then refining your question, and refining it some more and then refining it even more until you have a neat, simple question that is feasible to answer.

As you go through this process, you should be asking yourself:

- What is the population I want to study?
- How do I describe it – age, sex, background?
- What is the intervention I want to study?
- Do I have all the details of the intervention?
- What is the outcome I want to achieve?
- How am I going to measure the outcome?

Objectives

At the end of this module, the participant will be able to:

- Recognize the features of a good research question
- Distinguish between descriptive, exploratory and testing questions
- Understand and actively create:
 - A list of specific aims
 - A research hypothesis that is testable
- Understand the terms “goal” and “objective” and how they are different in the context of research

Key Concepts

A couple of mnemonics help illustrate the key features of well-built questions. The first is the PICO format, borrowed from the Evidence-based Practice literature. This format lends itself very well to searching the biomedical literature for quantitative studies.

PICO

P - Population

I - Intervention

C - Comparison

O – Outcome Measured

The other mnemonic is more generally applicable to research. It comes from your text (Hulley) –

FINER Criteria:

F – Feasible

I – Interesting

N – Novel

E – Ethical

R - Relevant

Activities

To demonstrate that you have learned from the module, we are asking you to write a one page description of your research project including the question(s) in final format. For practice, list a Goal, Objective and then the questions. Check them against the FINER criteria specified in Hulley, page 19

- Write down the overall goal of your research project
- Break the goal into one or more objectives
- Think about the FINER criteria (page 19 Hulley) and start refining the question until you and others know what you are trying to do.
- Keep refining until you have satisfied the criteria above.

Highlighted Tools

Brainstorming Software: MindManager www.mindjet.com

Quick Links

- Hulley SB, Cummings SR. “Designing Clinical Research: An epidemiological approach.
- Centre for Health Evidence: “Users’ Guides to Evidence Based Practice”
<http://www.cche.net/usersguides/start.asp#Questions>
- Guidelines for graduate students: “Choosing and refining a research topic”
<http://www.fiu.edu/~kowitz/topic.html>
- How to write Specific Aims: <http://www.theresearchassistant.com/tutorial/4-4.asp>

Assignment

To demonstrate that you have learned from the module, we are asking you to write a one page description of your research project including the question(s) in final format. For practice, list a Goal, Objective and then the questions. Check them against the FINER criteria specified in Hulley, page 19.

Module 1: Refining a Research Question

Background

Possibly the most difficult part of any clinical research endeavour is to come up with a reasonable question and focus it to the point where it can be answered. This may sound stupid because “everyone” knows how to ask questions, don’t they? Alas, it would appear that many new investigators (and many established ones for that matter) want to answer the universe with one research project. This leads to a diffuse or extremely elaborate question that can not be answered. If we could answer universal questions easily, the understanding of medicine would be a great deal more advanced than it is today.

This module is to help you work through the process of defining the goal of your research, identifying objectives and then refining these into a question(s) that interests you (or your supervisor) and then refining it, and refining it some more and then refining it even more until you have a neat, simple question that is feasible.

The goal of the research is stated in broad terms and covers the topic that interests you. For example, one of the ongoing topics in recent years is whether medical marijuana has any place in the mainstream medical world. The goal of research in this area would be to assess whether medical marijuana is a useful treatment. The objective(s) of your research is more focused. For the marijuana topic, one objective of research within the goal might be to assess the efficacy of medical marijuana in the treatment of children with muscular disabilities. There could be more than one objective, but all would contribute to the overall goal.

Strategy for Module

Interactive Sessions will cover the steps in the process of defining the goal, breaking it into objectives and then finding a question, deciding what type of question it is, refining and focusing the question until it becomes clear to you and to your critics. You are then asked to consider the feasibility of the question you have posed before finalizing the topic. If you have a topic already in mind for your own research use it as an example.

Resources

- Hulley SB, Cummings SR. “Designing Clinical Research: An epidemiological approach.
- Centre for Health Evidence: “Users’ Guides to Evidence Based Practice”
www.cche.net/usersguides/main.asp
- Guidelines for graduate students: “Choosing and refining a research topic”
<http://www.fiu.edu/~kowert/topic.html>
- ACHRN Health Research Network: “Combining Qualitative and Quantitative Research”
www.achrn.org/combining.html

Interactive Session: Setting the goal and finding the question

You don’t need to be an Archimedes or a Newton to come up with a fine idea that needs to be researched. Frequently, questions just pop off the top of your head as you go about your daily clinical practice. Sometimes it is the result of having a disagreement with a colleague about how a patient should be managed (You were trained in Toronto and your colleague in Vancouver and you have differing ideas). Sometimes, during your subspecialty training you wonder why on earth your centre uses that intervention or admits patients to hospital or uses two drugs when one might do. Possibly, you have just been to an international meeting of your subspecialty and were astounded to find that two eminent specialists were having a major disagreement over a particular issue. Or, you could just wonder what your patients think about the health care system or parts of it. Well, you can do something about all of these – do a study!

To get you started, let’s see what the inhabitants of Belltown are up to. Their activities, their follies and their misfortunes will frequently raise questions in your’s and others’ minds. **If you already have a question in mind, skip this section and move on to the next section (Assessing what you have written).**

The Belltown Beacon has a reporter who just loves to snuffle out stories which could potentially embarrass the local politicians, or raise local ire about the imminent closure of the local hospital or just help to sell the Belltown Beacon. This week’s story is about the health care (or lack of) for the women inmates in the local Federal prison. The reporter has found out that the women do not receive even a basic annual medical exam and that the only time a physician goes to the prison is when there is an emergency call. The Beacon trumpets:

“Doing Time is Bad for your Health”

The reporter claims that inmates use more drugs, are more obese than the general female population and writes that the women are denied routine pap smears and vaccinations for hepatitis. There is not even a needle exchange! Obviously, human rights concerns are not being addressed and these women are being treated as third class citizens! You are concerned about the truth of these statements. You have been told by one of your colleagues that the women do not want annual pap smears and wouldn't have one even if forced. **Can you identify a goal, objective and any possible questions here? Write them down for later use.**

Also reported in the Beacon are letters from irate citizens deploring the imminent closure of the acute care beds in the hospital, each citing an occasion when a family member would have died had the hospital not been close and also pointing out that to visit patients in the hospital in Belltown would require at least three buses. **Can you identify a goal, objective and any possible questions here? Write them down for later use.**

As you work through your evening shift as the physician on call in the emergency room of the hospital, the ambulance brings in Kyle from the skateboard park with a head injury. He had lost consciousness but is now awake, very confused about where he is and why he is there. This is the third head injury from skateboards that the emergency room has seen this month. **Can you identify a goal, objective and any possible questions here? Write them down for later use.**

On the same shift in emergency, Effie, an asthmatic, has been brought in by her distraught mother. You would normally give the child a dose of prednisone but wonder if you are doing the best for the child and perhaps you could use a non-steroid treatment instead. You know that a new drug has just been released by Novadrug and you think that this might be better, shortening the time in the ER and reducing the number of children who would require to be sent to the Children's hospital. However, you worry about whether this new drug might induce more exacerbations resulting in an increased number of visits to the ER. Can you identify a goal, objective and any possible questions here? Write them down for later use.

Assessing what you have written

Remember, the goal of any research is stated in broad terms. Many questions could be generated that would still fall within the goal.

Objectives (or Specific Aims) describe the areas you would like to explore in a more focused way. Defining objectives help you to decide what you really want to do and takes away some of the fuzziness in the initial thinking. For the marijuana topic, one objective of research within the goal might be to assess the efficacy of medical marijuana in the treatment of children with muscular disabilities. There could be more than one objective, but all would contribute to the overall goal. Other possibilities for objectives in the use of marijuana could be:

- “Objective 1 is to assess whether marijuana can alter spasm frequency in Cerebral Palsy”
- “Objective 2 is to assess whether medical marijuana alters spasm intensity in Cerebral Palsy”
- “Objective 3 is to assess the safety of medical marijuana in Cerebral Palsy”.

Before getting into the task of identifying and refining the questions within these objectives, it helps to look at the different types of information that could be obtained by each type.

Many research questions are posed just to describe what is going on. Questions such as “ What kinds of patients are we seeing?” or “ What treatments did the patients receive?” or “ Are the patients satisfied with the care they received?” are purely **descriptive (a1)** and designed to provide a background to how health care is delivered and how well it is accepted. The information helps to clarify what is going on but provides no details on why events happen.

Research questions which try to find out why things happen are **exploratory (a2)** and are written and conducted differently. Questions such as “Why do patients fail to take their medication as prescribed?” or “Why do inmates in prisons not attend for checkups when offered?” are two examples. Exploratory studies look for the how and why and who.

The third heading of research questions is possibly the most familiar and involves **testing (a3) hypotheses**. These questions try to explain the why and how and who or try to predict what will happen in the future if a certain clinical path is followed.

Descriptive research and exploratory research can be either **qualitative (b1)** or **quantitative (b2)** and are frequently used to generate hypotheses. Testing hypotheses require quantitative research methods. Questions need not be confined to one or other of qualitative or quantitative research but can use both **techniques (b3)** to find answers.

Now look at the research questions you have written so far to see if you can identify what type each one falls under. This will make life easier for you in the following modules.

Refine your questions

Now, refine the question(s) you asked. Usually, first attempts at defining questions result in vague statements rather than questions. For example, going back to the medical marijuana, attempt 1 might read: “Medical marijuana is useful in the treatment of cerebral palsy”. Is this clear? Trying to turn a statement into a real question and one which could lead to a good research project is more difficult than it looks. How to do it? Here are several ways

- You could start by writing it down, walk away and then come back and see if it makes sense to you.
- You could try the question out on colleagues
- Before you go further, do a **literature review (c1)** to find out if the question has already been answered! If it has been answered, but in a different population, then you have a guide to help you. If there is no information, and the question is analogous to some other area of research, do a literature search in that field to see what research has been done in that area. (For example, if you want to see whether there is a research question in the skateboard park incident, look at what research was done with head injuries for bicycles and inline skates).
- Finally, break down each section of the question and see if you have defined everything or if it still lacks clarity.

Let’s go back to the medical marijuana question and try again. What is it that medical marijuana is supposed to do? Reading suggests that it reduces spasms. OK, so the second attempt may result in: “Medical marijuana will reduce spasms in cerebral palsy” Is this clear yet?

Write down what is still not clear.

Take each bit of the question and keep going until you have a clear description of what you are looking for in a descriptive or exploratory study.

The questions you should be asking yourself are:

- What is the population I want to study?
- How do I describe it – age, sex, background (eg. prison)?
- What is the intervention I want to study?

- Do I have all the details of the intervention?
- What is the outcome I want to achieve?
- How am I going to measure the outcome?

After several attempts at refining and refining again, you may have a hypothesis. A **hypothesis** is a single statement that contains sufficient information that it can be tested using statistical methodology. Hypothesis tests are procedures for making rational decisions about what is real and what is opinion. So, if you believe that medical marijuana might be effective in the treatment of cerebral palsy, then you can set up a hypothesis which will allow you to test whether this belief is supported or not.

One possible hypothesis for the marijuana could be: **“Medical marijuana, given orally X mg q.i.d will reduce the frequency of spasms by 50%, as measured by the Tic spasm score, in children with cerebral palsy between the ages of 6 and 16 years.”** Have all the items been covered.

- Population - children with cerebral palsy
- Described - ages 6 to 16
- Intervention - Medical marijuana
- Details of intervention – dose and given orally
- Outcome – frequency of spasm by 50%
- Measure of outcome – Tic spasm score.

Note that this list is very much like the PICO methodology used in Evidence-based Medicine.

P=Population; I=Intervention; C=Comparison Group; O=Outcome. The hypothesis is long winded, but now anyone reading the question knows precisely the hypothesis, the population, the intervention, the outcome and how it will be measured. The reader can criticize the choice but not the clarity.

Select and refine the key questions again

Now that you have dissected all your questions, check them against each item in the list in the table “Key points for a good question” and, if you are satisfied that you have all the components of a good question, come up with the final wording for each.

	Questions to ask yourself	Yes	No	Vague
	Is the question asked in a single sentence?			
	Is the question simple?			
P	Does the question specify the population?			

I	Does the question state the intervention?			
C	Is there a comparison group?			
O	Is there a clear outcome in the question?			
O	Has the measure for the outcome been specified?			
F	Is the question FEASIBLE?			
I	Is it INTERESTING ? to you? to others?			
N	Is it NOVEL? -- new? Innovative?			
E	ETHICAL? -- is there a state of equipoise between competing therapies? Will your investigations → harm?			
R	RELEVANT? To policy makers? To patients?			

Before you rush into choosing one or two as the key questions, think through each of the questions and try to decide where the problems would lie if you tried to conduct the research. It is not unusual to have a wonderfully clear and concise question only to discover that you will not be able to complete it. This is the **feasibility** stage of the decision making. Perhaps you will not have sufficient patients, the study will be too costly, or the ethics committee will frown on your idea.

Don't do anything more than think about the issues at this early stage:

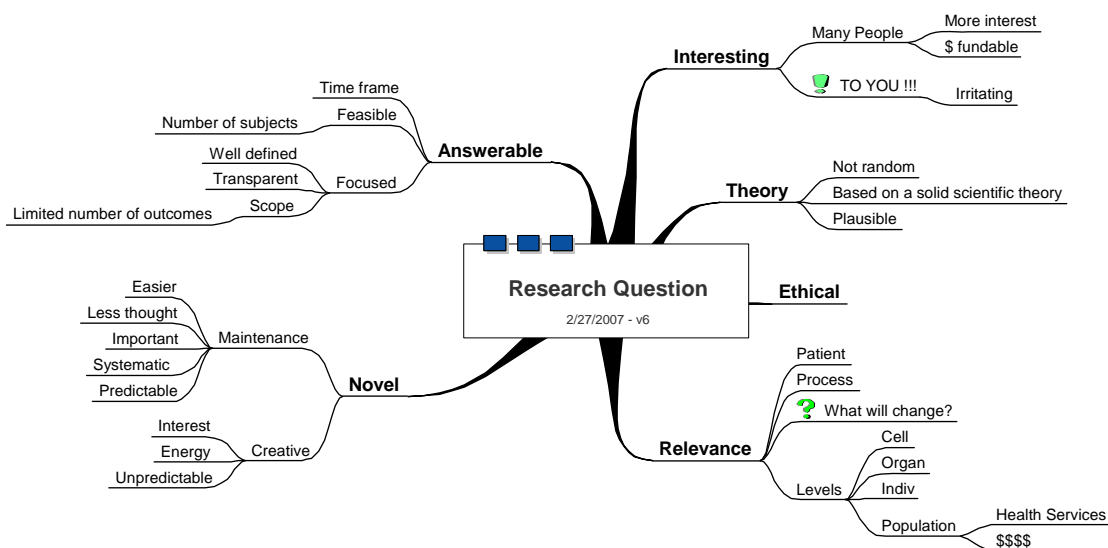
- What is the sample size you might be looking at for you to be confident in the answer? Q and D approach (ie "Quick and Dirty") If the incidence of skateboard injuries amongst all injuries coming to the ER is 1 in 1000, and there are 20,000 admissions to the ER for injuries then you would see 20 per year and would need to have a research project that will last more than 1 year to get a reasonable number of children to study. We will come back to sample size again in a later module.
- When you know approximately how many you would need, would you have access to the population you wanted? **Murphy's law states that any clinical problem will disappear the day you start to research it.** e.g. although there will be 20 skateboard injuries a year, you may not be on shift when each one comes in and although you have asked a colleague to collect information, he forgot or was too busy
- Would the selected population agree to participate? e.g. In the marijuana project, even if parents wanted to reduce their child's spasms in a CP study, they might not be so willing to use medical marijuana .

- Would you be able to obtain the marijuana? e.g. **Ask the researchers who tried to get it from the government!!**
- Think through what budget you might need. Details of how to do this will come later but it is worth considering ball park figures as you try to review the question.
- Will the ethics committee approve of your project? In the case of medical marijuana, it could be quite difficult to persuade the committee that the benefits outweigh the risks of giving marijuana to a pediatric population.
- How novel are the questions? Too often, research is conducted that is just a repeat of what someone else has done. If there is something different about your question that was not answered in the previous research, then the repeat part is acceptable.

Consider using brainstorming software

Generating a good research question is an iterative process that requires you to develop new conceptual schemes for the problem that you are wrestling with. Text is not necessarily the best way of considering these problems. Some of us find the generation of “Concept Maps” a very useful technique for keeping our thinking straight. Try out the following software:

- **MindManager** (www.mindjet.com): See the example below. Very easy to use and doubles as project management software. Wonderful for organizing your thoughts.
- **Inspiration** (www.inspiration.com) See Module 3 where this software is suggested for its flow-charting prowess. However, in recent versions the Concept Mapping capabilities of the software has been bolstered.



Summarize your progress

At this point you can write the one page description required for the assignment. In that page, you should write the goal of the research, what the general objective of the research is, try to formulate specific aims which can be your refined question(s) and then, if you have a hypothesis that can be tested, write that down. The rest of the page could summarize your thinking on the feasibility and general plans you have for conducting the research. If you are writing a Letter of Intent (LOI) to a funding agency, this is the information that would be required.

For a description of how to write a Specific Aims section, see:

<http://www.theresearchassistant.com/tutorial/4-4.asp>

Examples of questions from the 4 scenarios

Prison Scenario

Quantitative Questions

1. What proportion of the population has had pap smears within the last five years?
2. What are the three biggest health problems faced by inmates?
3. What is the coverage of vaccination achieved after introducing a vaccination program?

Qualitative Questions (list several questions you want to ask in order to learn about the problem and possibly what might be done about it):

1. What do you think are the biggest health problems facing inmates?
2. As an inmate, what kinds of things do you do to look after your own health?
3. What's your experience with the health care staff here in the prison?
4. Do you think would happen if clean needles were made available to inmates?

Hospital Scenario

Quantitative Questions

1. How many visits were made to the emergency room in 2002?
2. What proportion of these were pediatric (<16 years of age)?
3. What was the admission rate to hospital in 2002?
4. How many elective surgeries were performed over the past ten years, by year?

Qualitative Questions

1. As patient (or family member), how will closing the acute care beds in the hospital affect you and your community?
2. As a health care worker (Physician, nurse, pharmacist, social worker, etc.), how will closing the acute care beds affect the delivery of health care services?

Skateboard Injuries Scenario

Quantitative Questions

1. What proportion of injuries seen in the ER is due to skateboarding?
2. What proportion of skateboard injuries result in a concussion?
3. What is the economic impact of skateboard injuries – days off school, medical costs etc?
4. Are concussions from skateboarding more prevalent than concussions from playing hockey?

Qualitative Questions

1. When you first started boarding what did you do to protect yourself from injury?
2. As your skill improved, did your concerns about an injury change?
3. What do you (as a sponsored, advanced, intermediate, and beginner) do to protect yourself from a head injury?
4. What advice might you give to those with less experience that might help them avoid a serious injury?
5. When your child first started boarding what did you do to keep him or her from injury?
6. What do you do to protect your skateboarding teenager from a head injury?

Key Concepts

- Quantitative or Qualitative Research or both
- Aim of study - Goals and Objectives
- Type of study - Descriptive/Exploratory/Testing hypothesis
- Simplify and clarify question

a1: Descriptive

Descriptive research provides data about a population. It can only describe the “who, what, where and how much” of a topic and is useful for generating hypotheses. Descriptive research would be used to measure how many skateboard injuries the emergency clinic sees in a year, or who the prison physician sees when she holds a clinic for inmates. It cannot be used to test a hypothesis. Ergo, it cannot be used to investigate causal relationships; no matter how hard many investigators

try!! Types of studies in descriptive research are observations and surveys. Also retrospective chart reviews would fall into this category.

a2: Exploratory

Exploratory research seeks to understand a new problem. It is used to try to find out why there are so many skateboard injuries, why the teenagers view helmets the way they do or how parents try to protect their children from injury. Exploratory research can lead to a better choice of design for further research and can suggest whether qualitative or quantitative methods or both would be the most productive.

a3: Testing

One result of descriptive or exploratory research is the generation of hypotheses that could be tested. Examples of testable hypotheses from Belltown are:

- The frequency of skateboard injuries seen in the emergency room has doubled in the past five years
- Educational interventions using rock music videos will increase the proportion of teenagers wearing helmets when skateboarding by 25%.

NOTE: there is a division between hypothesis testing studies and other types. Some of your colleagues will try to tell you that you have to have a hypothesis in every study. However, in most cases the word “**hypothesis**” is used in place of “**specific aim**”.

For example, if we go back to the medical marijuana study, the initial statement: “**medical marijuana is useful in the treatment of cerebral palsy**” cannot be tested. The second attempt at refining the question was: “**medical marijuana will reduce spasms in cerebral palsy**”. You could take a group of subjects with cerebral palsy and provide them with medical marijuana and ask them if it has reduced their spasms and then do a statistical test to see if there has been a change. There are problems with this approach, not the least of which is that you did not specify what reduction in spasms was **clinically important** nor did you decide how many **subjects would be required** to show a reduction. Thus, hypothesis testing research is reserved for questions that are clear cut with detailed information to allow a test to be conducted and interpreted.

b1 : Qualitative research

Qualitative research works on the assumption that our view of the social world is dependent upon how we are able to make sense of the phenomena we experience and the way in which we are able to give meaning to our experiences. Qualitative research has the broadest denotations and is perhaps better understood by the characteristics of its philosophy and methods.

A list of the common methods used in qualitative inquiry include: case study, content analysis, ethnography, narrative analysis, phenomenology and grounded theory. The unifying characteristics of qualitative research are:

- qualitative research uses an interpretive approach;
- events can be understood adequately if they are seen in context;
- the context of qualitative research is 'natural', e.g. data collection takes place in people's houses or in places of their choosing;
- the social world under study is not pre-defined;
- qualitative research is an interactive process in which the researcher is an integral part of the research process;
- qualitative research is multi-method in focus. There is no one general method, e.g. methods may include interviews, observations or documentary analysis;
- qualitative research attends to the experience as a whole, not as separate variables;
- qualitative research addresses issues related to process, beliefs, meaning or experiences.

b2 : Quantitative research

Quantitative research seeks to establish facts, make predictions and test hypotheses about the world around us, based on sampling a small portion of that world and then extrapolating from the sample to the total population from which the sample was drawn. Thus it is extremely important that the sample be representative of the population. The second characteristic of quantitative research is that it involves turning all observations into numbers that can be manipulated statistically. For example a myocardial infarction will be described as having occurred or not. The details of the ECG will be presented in numbers, not narrative descriptions. The reason for the statistical approach is to determine whether the observations gathered could have resulted from chance or not.

A list of the common methods used in quantitative research include: randomized clinical trials, cohort studies, case-control, surveys (or analytical studies) or case series. These will be covered in more depth in the next two modules.

Characteristics of quantitative research include:

- Stating an objective or hypothesis before starting the study plus the research procedures that will be followed in the study
- Attempting to minimize bias throughout the study, either through the design or by identifying and measuring confounding factors and taking account of these in the statistical analysis.
- Estimating the sample size required to provide statistically meaningful results.
- Conducting a rigorous statistical analysis, defined a priori.

b3 : Comparison of qualitative and quantitative research

- http://www.personal.psu.edu/txl166/kb/Research/quantqual.html#_ftn1
- <http://www.rdinfo.org.uk/flowchart/Characteristics.htm>

c3 : Searching the literature (module 2)