How to design and conduct research? – Research question & hypothesis

Ali Sabbour, MD
Department of General Surgery, Vascular Surgery Unit, Ain-Shams University, Cairo, Egypt

"In our country, real research is a luxury. We cannot afford its financial requirements, and this is the main reason we are not doing it."

You must have heard this statement –some time or another- from a colleague giving an excuse why we are not involved, or interested to be involved, in a real research project. Research is originally designed to answer questions about a problem that we face. If you want to solve your own problems, it is a must to conduct your own research. I would like to re-phrase this statement in a more realistic way. "It is true that finance is an essential component of any true research; it is a limiting factor, not only in our country, but all over the world –with respect to its relative importance."

In our country, we can direct our research to low budget projects. For high budget projects, we can apply for a fund or a grant if our research problem is well introduced and the research design is convincing –but this is another story.

The real problem –I believe- is that our junior staff doesn't know how to design and conduct real, sound research.

The objective of this series of articles is to try to simplify the basic concepts of clinical research to build your project step by step, because, if you have to do it, just do it right. Otherwise it is a waste of effort, time and money. The first article will deal with how to formulate a research question and hypothesis. Detailed description of the following steps will further be reviewed in separate articles.

The research question:

You can't start a research without having a clear question that you need to answer –otherwise, your effort will have no meaning and will be a waste of time. Think of what some of us are doing and you will get what I mean.

Research questions are usually found if you use your mind during clinical practice, teaching rounds, journal clubs, etc. Mind you, not all questions are worth research. Some questions may be answered by a simple literature search.

A good research question should be new (not answered before), interesting to the investigator (junior investigators should be involved in choosing their research topic), and ethical.

Research questions should also be feasible and relevant. Five years ago, one of our junior staff was planning to have his MD thesis on 'EVAR' [Endo-Vascular Aortic Repair]. At that time we neither had the prosthesis in Egypt, nor did we have the experience of how to put it in. If he is going to conduct his research in Egypt, his research question must be feasible. If his question is: "Are the radiological inclusion criteria for EVAR common among Egyptian patients?", then his question is feasible to answer because all what he has to do is to study the CT scan of patients with aortic aneurysms. But if the question is whether EVAR is better than classical surgery as regard short and intermediate outcomes, then it is not feasible to answer this question in Egypt yet, although it is definitely a relevant question.

Research questions can be classified according to the aim of the study. If your study aims to describe a disease or a problem, your question may be: "What is the incidence of congenital groin hernia in newly born infants?" If your study aims to know the etiology of a disease, then your question may be: "Is exposure to contraceptive pills associated with deep venous thrombosis?" If your aim is to know how to diagnose this disease better, then your question may be: "Is ultrasonography better than CT scan in the diagnosis of aortic aneurysm?" You may be interested to know the best therapy for a certain disease, then, your question may be: "Is surgery more effective than conservative treatment in the treatment of venous ulcers?" If you are studying

the prognosis of a certain disease after a given intervention, you may ask: "What is the 5 year survival of a patient with stage I cancer breast after simple mastectomy?" Finally, you may be interested to evaluate the impact of a certain program on your patient management. An example question is "What was the impact of the infection control committee protocol on the incidence of post-operative wound infection?"

Research hypothesis:

After you put your research question, you should formulate this question in a measurable form. That is the research hypothesis. It is this hypothesis that you will test through out your study.

For example, you are interested in new arterial imaging modalities. CT angiography is becoming more used as an investigation to delineate the arterial tree because it is less invasive. You would like to know whether this investigation should replace conventional angiography, so your research question would be: "Can CT angiography diagnose chronic lower limb ischemia as accurate as conventional angiography?"

To translate this question into measurable statements, the research hypothesis may be the following:

1- "CT angiography is as sensitive as conventional angiography in the diagnosis of stenotic and occlusive arterial tree lesions."
2- "CT angiography is as specific as conventional angiography in the diagnosis of stenotic and occlusive arterial tree lesions."

From these statements you can identify that the study variables you should measure are: sensitivity of CT angio, sensitivity of conventional angio, specificity of CT angio and specificity of conventional angio. You can also see that the proper study design should compare both investigations as regard these variables.

In general terms, the research hypothesis is a translation of the research question in a measurable form. It uses all study variables but tests only one relation at a time. It should reflect study design. It is obvious that any hypothesis should be based on a scientific background.

Examine the following statements then think why any of them can't be considered a sound hypothesis for the previous research question?

• "CT angio is safer than conventional angio in the management of chronic lower limb ischemia" – [this hypothesis is not related to the research question. It talks about safety while the question is about accuracy].

• "CT angio is accurate in the diagnosis of chronic ischemia" – [this hypothesis is missing an important study variable which is conventional angio.].

• "CT angio is as sensitive and specific as convetional angio in the diagnosis of ischemia" – [the hypothesis should examine only one relation. Use separate hypothesis for each studied association].

• "CT angio is better than conventional angio"– ['better' is not a measurable form. Would you consider it 'better' because it is less expensive, less invasive, and more tolerable by patients?].

What is next?

After formulating your research question and hypothesis, you will be able to choose the appropriate study design.

There are two major types of research designs; observational studies and interventional studies. The major difference between them is the role of the investigator as regard the control of the intervention or exposure he is studying.

Examples of observational study designs are; case control [retrospective] studies and cohort [prospective, longitudinal or follow-up] studies. The prototype of interventional studies is the randomized control trials.

The selection of the study design depends on many factors; the type of question you would like to answer, whether it is only describing a disease or looking for the effect of therapy, and the characteristics of the study variables. For example, if a disease is very rare, you can't use a cohort (prospective) study to know whether a certain exposure would cause it or not because you will need to follow-up a huge number of subjects.

A detailed description of different study

designs will be the topic of our next article.

The next step will be to define your study population, choose the sampling method and estimate the sample size.

Next, you should think about your main study variables, whether they are quantitative or qualitative, whether you have a confounding variable that may affect the relation between the exposure and the outcome and whether there is any effect modifier that interacts with the exposure factor.

Next, you should select the techniques and tools you will use to collect the data. You should identify the possible errors to minimize them or at least correct them.

Finally, you should know how to manage the collected data.

Following articles will deal with these steps in detail.

References:

1- Mishriky AM, Rizkalla NH: Research methodology course – designing and conducting research (Manual), Faculty of Medicine, Suez Canal University; 2005.

2- Good AMT and Driscoll P: Clinical research in emergency medicine: Putting it all together. *Emerg Med J* 2002; 19: 242-246.