How to Conceptualize a Research Project

30

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For a research project to successfully advance medical and scientific knowledge, each component of the entire research process must be clearly and rationally conceived *before* proceeding with active research steps such as data collection and analysis [1]. The research process has three phases: the conceptual phase the empirical phase, which involves conducting the activities necessary to obtain and analyze data; and the interpretative phase, which involves determining the meaning of the results in relation to the purpose of the project and the associated conceptual framework [2].

The conceptual phase is the part of the research process that determines *which* questions are to be addressed by the research and *how* the research project will be designed to successfully find the answers to these questions [2]. Conceptualization involves simultaneously bringing together several considerations to identify a good research idea, i.e., an answerable research question that is worth answering. Components of this process include conducting a thorough search of the peer-reviewed literature, finding a mentor and other collaborators, considering methodology and study design, and assessing feasibility. It should be noted that although we describe these various components in a linear fashion in the text, in reality, the conceptualization phase is not a linear process and will require consideration of these components to varying degrees at various stages depending upon evolving circumstances and the early-career investigator's unique strengths and weaknesses (see Fig. 30.1).

Even though careful attention to all these components will require time and effort on the part of the clinician-scientist, it will be time well spent, as it is necessary to lay the ground for a truly successful research endeavor. Failure to plan thoroughly can result in wasted time, money, and, most important, unnecessary burden and risk for research participants if the project does not successfully answer the questions being addressed.

Embarking upon a Clinical Research Project

In the course of caring for patients, we frequently make observations that pique our interest and appear to be worthy of systematic scientific investigation. These clinical observations may be related, for example, to observing a particular pattern among patients with a common illness or disorder, individual outcomes of a new treatment that appears to be effective for a patient population, or factors related to where the patient lives, works, or receives care that appear to be affecting the clinical presentation.

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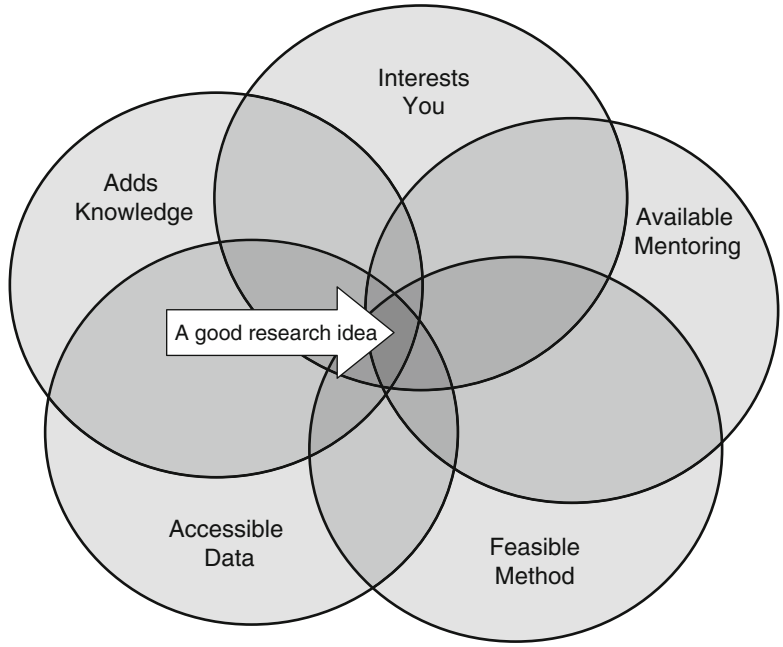

Fig. 30.1 Components of the conceptualization phase of a research project

Although the possibilities of such observations are numerous, underlying them all is a common theme—a notion that we have stumbled upon something worth knowing more about because we believe it could, potentially, enhance the care we offer our patients. Academic clinicians are, no doubt, well positioned to generate novel, exciting, and clinically relevant ideas for potential research projects, but although the two are closely linked, approaching a research idea is very different from clinical decision making. We suggest the following three considerations in this early stage.

Pursue an Idea About Which You Feel Particularly Inspired and Passionate. While there are many potentially interesting questions, the path toward setting up a systematic scientific investigation of an idea requires hard work, commitment, and time and may present frequent obstacles and dead ends. We state this not to discourage such an undertaking but, rather, to emphasize the importance of pursuing an idea about which one feels particularly passionate. This passion will provide necessary "fuel" for navigating the path ahead.

Take the Path of Least Resistance. Give preference to ideas that are synergistic with your clinical interests in addition to the mission and expertise of the department with which you are affiliated. For example, if your clinical expertise lies in serving patients with a particular illness, an idea which has that illness as a focus will be ideal. Or, if you work in a department with a tradition of conducting a specific type of research, e.g., health services research, an idea that approaches the particular illness from such a perspective may be more likely to blossom in a department that has the "built-in" expertise to support such an endeavor. One can also, of course, seek out clinical opportunities or affiliations with other departments that match one's research interests. But look to create as much synergy between your clinical life and research interests.

Identify Your Immediate Goals of Conducting a Research Project. Finally, we recommend identifying, early on, specific goals of the research project. In addition to answering the question that has piqued your interest, how will answering this question contribute to your field in a meaningful

way? Will the goals achieved justify the potential burden and risk to research participants or the cost and effort to conduct the research? How will you communicate to others what you have learned (e.g., produce peer-reviewed publications, present at professional meetings, or use this preliminary data to inform the writing of a grant)? Identify concrete goals that you wish to attain from embarking upon this project. Identifying such goals beforehand will assist in providing focus to your endeavor and lay a foundation for future work in this area.

Conducting a Thorough Search of the Peer-Reviewed Literature

Once you have decided on an area to pursue further, it is imperative to conduct a thorough search of the relevant peer-reviewed literature. This search will likely be different than searches normally undertaken to find an answer to a clinical problem. It should be substantial both in breadth and depth and, if necessary, also draw upon related fields. The goal is to get a complete picture of the current state of the knowledge in that particular area, including how others may have attempted to address this issue, limitations to previous research, opinions expressed in the literature about the problem, and approaches used in related areas that may have been successful. Once you have identified key articles, study and review them carefully. The goal is to emerge from this process with an informed perspective about the gaps and weaknesses in the current evidence base and how your potential research will contribute in some way to closing those gaps. Conducting a comprehensive view of the medical literature is no easy feat. If you are unsure of your search skills, enlist assistance from a medical librarian or take an online tutorial in how to conduct a search. Save your searches and sign up for weekly alerts to ensure you are staying abreast of the relevant literature and hence are able to adapt to accommodate cutting-edge findings should the need arise. At this stage you should begin refining your initial question into a clear, well-focused research goal or hypothesis.

Perhaps write up what you have learned as a review article, which may be a particularly useful exercise if a large body of literature is associated with your idea and an organizing review has not been previously published. Manuscript preparation will be a useful opportunity to concretize your thoughts, have your ideas undergo a critical expert review by the journal, and lay the foundation for future scholarly work in this area. Such a manuscript, when published, also adds credence to your expertise in this field, which is especially useful when seeking collaborative opportunities with other experts and writing for grant funding.

Finding a Research Mentor and Other Collaborators

After you have established a clear research idea, you will need some degree of expert supervision to guide you through the various stages of this project, depending on your previous research training and experience. Seeking mentorship from senior researchers at your institution will be key to enhance the scientific quality of your project and to provide assistance on practical elements such as helping you navigate the unique regulatory requirements of your organization and overcome unexpected administrative obstacles.

Ideally your mentor should have expertise in the area of research you have identified and have time to meet with you regularly [3]. If such a person is not readily identifiable, ask the leadership in your department to point you in the right direction. It may be that there is no one in your department who has a close alignment with your research interests, in which case you may have to be creative and seek out relationships with faculty in other departments or at other institutions. More often than not, you may need to assemble a panel of different mentors for various aspects of your project, e.g., an investigator with expertise in that disease to help refine the research question or a researcher with expertise in a particular methodology to help with study design.

Having a mentor who has an existing project in which you can get involved is a wonderful way

to proceed, especially if you are new to research or time is of the essence. Such a project could be a valuable opportunity to bypass many of the hurdles that frequently prevent a project from getting off the ground and also "test" some of your ideas and garner necessary research skills. Additional benefits of working as part of an established laboratory are possibilities of additional resources to assist you, such as office space or research assistant time.

Developing relationships with colleagues who share similar research interests can be highly beneficial—such relationships should be viewed as mutually supportive: you will need forums where you can brainstorm ideas with other researchers and you should also be ready to offer your services to your colleagues when the need arises. Once you have assembled a team of collaborators, you should be drawing on their expertise and experience to further refine your research question, goal, or hypothesis. At this stage, consider writing a draft proposal. It should not be longer than two pages and should include a title, rationale, objective, hypotheses, methods, data analysis plan, significance, and key references section. By keeping it succinct you will help maintain the focus of your project. Share this document with collaborators, and revise it after receiving their feedback. This draft will serve as a concrete representation of what you wish to do but will likely need to go undergo several revisions before arriving at a version that is complete. This refinement process is crucial; it will guide the next phase of conceptualization, methodological considerations.

Considering Methodology and Study Design

Before you can have a clear, well-focused research question, goal, or hypothesis, you need to think about selecting appropriate methodological approaches and study design. Careful consideration of study methodology will require knowledge of the fundamentals of key design approaches and issues. For the prospective researcher who feels inadequately prepared in this regard, we recommend specific texts at the end of this chapter. In addition, taking time to receive live instruction by attending relevant courses or seminars, if available, is strongly encouraged, especially for those who are new to research. As with clinical skills, some direct training from mentors and colleagues is an essential component to being a successful researcher. Here we offer a checklist of salient areas to consider as one goes about considering methodology and study design [4].

What Will Your Study Design Be?

The design of your study will be defined by multiple factors, including most particularly by the nature of the question you are addressing. For example, if you are the first one reporting on a novel new treatment, an open, non-randomized design may be an appropriate first step. But if your research seeks to provide a more definitive explanation or draw causal conclusions, your study will require an experimental design with randomization. Randomization comes in the form of random placement typically into a treatment or control group so that each participant has an equal and independent chance to be placed in either group [3]. If your research seeks to explore associations among naturally varying factors (e.g., how genotype relates to phenotype), you may be using a correlational or nonexperimental design. If your research explores epidemiological questions, such as disease prevalence, you will need to give greater consideration to sampling issues (e.g., whether your study participants are representative of a broader population).

Who Is the Target Population?

Clearly define the population of interest and identify an appropriate sampling procedure. Narrowing the population too much will hinder the generalizability of the findings; however, defining your inclusion criteria too broadly may make it hard to interpret your results. Consideration also needs to be given to calculating what the sample size needs to be in order for your study to have sufficient power to answer your research question. Because sample size is a critical factor in feasibility, it may

be worth getting some early consultation to estimate how large a sample you will need.

What Are the Key Variables?

A careful review of the relevant literature and clear articulation of the research idea will help ensure that the appropriate variables of interest are identified and controlled or accounted for in the design. It may be necessary to include certain variables as part of the randomization process. It is key to account for all major variables to ensure that subsequent data collection yields useful information for the analysis.

What Are the Outcomes of Interest and How Will They Be Measured?

Again, the research idea should guide what the primary outcomes of interest actually are. The literature review will provide ideas for how best to assess such outcomes and guide the selection of appropriate instruments and measures. There is often a balance between selecting the most sensitive and specific measure and the feasibility of administering a measure due to time constraints.

What Are Potential Confounders to Consider?

For studies that do not attend to sufficient randomization, the potential for confounding variables affecting outcomes, i.e., factors other than the experimental intervention is increased. As this can have a significant adverse effect on results and interpretation, it is vital to identify confounders and control for them beforehand.

Assessing Feasibility

A research study is rarely perfect; hence, the goal becomes finding the right balance between what is optimal and achievable given the practical limitations and the research idea [4]. Some questions call for a more definite answer than others depending on a variety of factors. We recommend assessing the following practical aspects before committing to a particular design or approach to a study.

Access to Data

Perhaps the foremost constraint on potential research is the sources of data that one can expect to access. For example, if your study will be based in your clinical setting, you need to consider what types and amount of data you can realistically expect to obtain from your participants, how patient flow limits the number of participants you can expect to recruit, and that your conclusions may be generalizable to people who seek treatment but not the general population.

Ethical Guidelines

Research involving the participation of living human volunteers is carefully regulated and monitored both locally via the vice-chancellors of research and institutional review boards and federally by the office of human research protection. Nonetheless, it is vital that as the one who is most intimately acquainted with the nuances of the proposed study design and population, you give careful consideration to ethical issues raised by your research and how you will ensure that appropriate safeguards are implemented. Such consideration will be shown in the writing of a well-informed grant and IRB protocol.

Buy In from Key Stakeholders

Who are the key stakeholders in your study? Do they agree with your plan? Perhaps the most obvious stakeholders can be found at the clinical site from where you intend to recruit participants. Have you spent time communicating with staff at the clinical site about the purpose of the study? Do they have suggestions about the design or confounding variables that you may not have considered? Do they have other reservations or concerns that need to be addressed? Do they think

your line of inquiry is relevant and useful to their program's goals or mission? If your study involves, for example, access to administrative datasets or lab results, do you have the relevant permission and expertise to access this data? Partnering with key stakeholders, prior to starting the study, will provide an additional source of invaluable input to further sculpt your research idea. Such a relationship will also facilitate a smoother implementation phase of the project.

Costs and Funding

Will your project need funding? If so, how will you go about obtaining such funds? How long will this take? What is your backup plan if you are unable to obtain funding? Can you obtain sufficient release from clinical duties necessary to conduct the study? Will you need to ask for support from other clinical staff, e.g., nursing or laboratory service? Costs and funding will likely be a major rate-limiting step in the early phase of your project; if funds are elusive, you may have to think creatively—perhaps your project needs to be done on a very small scale first, i.e., as a pilot, then, if successful, you can use your data to inform the writing of a grant. Alternatively, you may consider designing a project that has little costs other than your time and negotiate for "protected time" to devote to the project.

Does the Research Project Timeline Fit in with *Your* Timeline?

A research project will require your devoted effort over a substantial period of time. It is important that you are able to meet this commitment, as it is integral to the successful execution of the project. Ensuring you have this time may involve negotiating with supervisors that you be alleviated from other duties or reprioritizing personal or other professional goals for the duration of the study.

Careful consideration to all these components is an iterative process from which, it is hoped, the reader will emerge with a good research idea, i.e., an answerable question that is worth answering. Such an idea will represent a successful conceptualization phase and will serve you well as you proceed with the next stages of the research project.

Words to the Wise

- Be respectful of collaborators' time. Be ready to adapt your schedule to fit theirs, even at the last minute.
- Keep collaborators appraised on the status and outcomes of the project at timely intervals, e.g., if a collaborator provided you with feedback on one or two occasions in the earliest phase of the project, be sure to keep him or her in the loop of subsequent positive progress, even if it is several months after the fact.
- Be respectful of the feedback process. Give people time to respond and do not ask them to adhere to unrealistic deadlines; acknowledge their input right away; if you decide not to follow their advice or suggestions, let them know why.

Ask Your Mentor or Colleagues

- Can my proposed study contribute to the field?
- What departmental resources exist to help with my research project?
- What institute or funding agency might be interested in funding this project?
- How much protected time can I obtain to pursue this project?

References

1. Rose AM. Sociology: the study of human relations, 2nd ed. New York, NY: Alfred A. Knopf; 1965, p. 9
2. Batey MV. Conceptualizing the research process. Nurs Res. 1971;20:296–301.
3. Sambunjak D, Straus SE, Marušic´ A. Mentoring in academic medicine: a systematic review. JAMA. 2006;296:1103–15.

4. Horn C, Plazas Snyder B, Coverdale JH, et al. Weiss Roberts L: educational research questions and study design. Acad Psychiatry. 2009;33:261–7.

Additional Resources

Chapters 8, 10, 19, 20, and 24. In: Roberts LW, Hilty D, editors. Handbook of career development in academic psychiatry and behavioral sciences, 1st ed. Arlington, VA: American Psychiatric Publishing, Inc.; 2006.

Hulley SB, Cumming CR, Warren S, et al. Designing clinical research. 3rd ed. Philadelphia, PA, USA: Lippincott Williams & Wilkins; 2007.

Kraemer HC, Kraemer KL, Kupfer DJ. To your health: how to understand what research tells us about risk. New York: Oxford University Press; 2005.

Motulsky H. Intuitive biostatistics: a nonmathematical guide to statistical thinking. New York: Oxford University Press; 2010.