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Invited Commentary

Conducting research at non-teaching institutions: Challenges and solutions

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ABSTRACT

Research is the basis of evidence-based medicine, which translates into better health care. While teaching institutions have traditionally been the hub of research activities, it can be carried out in other institutions too. There is no dearth of opportunities and material for research at the non-teaching health-care setups, but often the lack of know-how, workforce, and infrastructure hinder clinicians working in them from taking up research. However, with a systematic approach towards planning and conducting research and by acquiring the requisite knowledge of research methodology, these limitations can be effectively overcome. Not only the knowledge about what kind of research projects can be carried out with the available facilities but also about how to obtain the mandatory ethics committee approval is of paramount importance.

Keywords: Protocol, Meta-analysis, Research funding, Ethics committee, Institutional review board, Good clinical practice

INTRODUCTION

Research is important for bridging the existing knowledge gaps, and it forms the basis for the advancement of any science. Conventionally, for a long time, research has been conducted largely at medical schools and teaching institutions. Even though there is no dearth of opportunities or clinical material at public or private non-teaching institutions, often the lack of dedicated workforce, adequate time, infrastructure, know-how, and/or initiative hinders research at these centers. However, these constraints can be overcome by planning research which is feasible within the available infrastructure at the given center. In this review, we discuss some pertinent issues.

THE IDEA OF RESEARCH

The actual process of any research begins well before the research question is framed and is often unplanned and/or unintentional. It is through reading the existing literature and one's own clinical experience that any scientist identifies the knowledge gaps. The quest to fill up these gaps forms the basis of a research question. At this stage itself, potential researchers can consider performing a systematic review with or without meta-analysis which not only would be useful in identifying lacunae in the existing knowledge but are also well recognized forms of secondary research.[1] Research studies can be of various types. They can be descriptive, for example, case reports and series or survey and interviews. Analytical studies are either

observational or interventional. Cohort, cross-sectional, and case–control studies are observational studies. Interventional studies can be randomized or non-randomized clinical trials or community-based trials. Observational studies could be prospective or retrospective. Both have their advantages and have historically contributed to major advances in medical science.[2] The study design depends on the research question. For example, there are case reports of new-onset immunoglobulin G_4-related disease (IgG_4-RD) in patients with a history of seropositive rheumatoid arthritis. Since the occurrence is rare, it may not be feasible to follow-up a cohort of patients with rheumatoid arthritis for the development of IgG_4-RD. It would be more practical to do a retrospective analysis of patients who have developed IgG_4-RD. On the other hand, a cohort of patients with psoriasis may be followed prospectively for the development of psoriatic arthritis, as the occurrence of the same is much more common.

WHY RESEARCH?

Curiosity is inherent in human nature and critical thinking is a unique attribute that pushes us to quench this thirst. Research in the field of medicine has the potential to directly or indirectly make treatment better and improve patient outcomes. It also helps in advancing our understanding of the disease processes, patterns, and responses to the treatment. We depend on research to upgrade the quality of health care.[3] In addition, taking up research and publishing in reputed journals reaps rich dividends for the researchers. It brings respect and recognition for the researchers and consequently helps them build network, collaborate with other researchers, and also build a portfolio which helps them in procuring grants for future research projects.[4]

CHALLENGES TO CONDUCTING RESEARCH

There are several challenges to conducting research irrespective of the type of setting but these can be overcome by adopting a systematic approach.[5] It is paramount to be well versed with relevant regulations to begin with.[6] Once an area or a topic for research has been identified, it is imperative to scan, sieve, and extensively read up the available literature on the topic to frame the exact research question. Knowing how to critically appraise a scientific paper is essential to decide how valid are the conclusions of existing literature.[7] It is important to simultaneously take stock of the available resources. The methods needed for a study are guided largely by the research question and it is thus advisable to assess whether it is feasible to conduct the study at this stage itself. While deciding on the methodology, it is good to weigh up the skills, attributes, and limitations of the researchers, other personnel, and infrastructure. Workforce required for the research project must be identified in advance and appropriate responsibilities should be assigned to them.

The research question guides the type of population that the study would include. However, ensuring that the desired participant numbers could be achieved is a challenge and thus the source(s) from where the participants would come from should be identified beforehand. It may require collaboration with other clinicians and departments such as pathology or radiology. Involving willing people in the team right from the beginning helps in remaining motivated, maintaining zeal and enthusiasm, and prevents attrition during the project.

"What to do with the data" is a common challenge faced by researchers who are early in their careers. Acquainting oneself with research methodology, statistical analysis, and remaining abreast with technological advancements is key to overcoming this hurdle. It is imperative that any questions/confusions related to the number of participants required to arrive at meaningful conclusion ("sample size") and statistical tools which shall be used should be discussed/clarified with a statistician with relevant experience at the start of the study.

The next hurdle is assessing how the finances will be taken care of. For example, in an observational study, it is unethical to have the study participant bear the expenses of any investigation which is not part of routine care. Apart from ethical considerations of any such investigations, provision needs to be made for the funding of the costs of such additional investigations. The researchers must, therefore, be aware of potential sources for the funding of research.[8]

Table 1 summarizes the solutions to various challenges in conducting research.

WRITING A RESEARCH PROTOCOL

Once the research question has been framed, a protocol needs to be formulated and written. A research protocol essentially provides an opportunity to lay down an action plan and also serves as a guide to prevent any deviations from the main objectives of the study. This exercise starts with the details of the principal and other investigators including their contact details and curriculum vitae. It then includes the details of the study center(s).[9] The title of the study is followed by an introduction. The introduction includes what is already known on the subject, what are the existing gaps in the knowledge and how the study will address the gap(s). It is important to clearly state the primary and secondary objectives of the study being undertaken. The research population is then defined and the inclusion and exclusion criteria are stated. No gender, race, and ethnicity should be excluded from a study without any valid justification. However, if vulnerable subjects such as pregnant women and children are included; justification and detailed explanation should be provided. Methods appropriate for the study

Table 1: Overcoming challenges to conducting research.

Challenge	Solution
Formulating an appropriate research question	• Thorough review of the literature with prior understanding of critical appraisal of a paper
Attrition during the study	• Choosing a topic of interest • Assessing the feasibility of the study by taking stock of the available manpower, infrastructure, and finances at the very initial stage
Unfinished tasks and missed timelines	• Once a team is identified, the members must be assigned clearly defined roles and responsibilities
Inadequate sample size	• Calculate the sample size required at the time of preparing the protocol • Identify where the participants will come from and if the sample size can be achieved from that source • Collaborate with other faculty and departments
Unable to analyze datasets	• Use resources (including online) to learn study design, the data collection required for the particular design and statistical analysis • Start by choosing study designs that do not involve complex datasets and analysis and once you are comfortable with other aspects of research, move on to studies that require advanced knowledge of statistics
Ethics approval and informed consent related issues	• When in doubt about any ethical issues, always include them in your submission to the committee • Whenever there is a doubt as to whether patient consent is needed, always take consent
Financial constraints and lack of adequate funding	• Assess beforehand if the study incurs any costs additional to the routine care and make provision for the same • Plan another study if funds are not available for research that incurs costs
Ethics committee not available at the study site	• The study site (hospital/clinic) can enter into a memorandum of understanding with another institute which has an ethics committee and use their services • The study site can enter into a memorandum of understanding with the governing body of an independent ethics committee and use their services • The study site can give a no objection certificate to be overseen by an independent or another institute's ethics committee and utilize their services

design must be stated clearly and must also include the plan for statistical analysis of the data. The protocol must also include the methods to be used for storage and maintaining the confidentiality of the data. The information sheet for the patients and informed consent forms are required for the approval of the ethics committee and must be attached with the protocol. The point where the protocol becomes different from a manuscript ready for publication is where the *expected* results are discussed, as compared to the *actual* results in the final manuscript. It is important to note that as the standard operating procedures of an ethics committee define the standard format of protocol that is required to be submitted for its consideration, it is necessary to adhere to them.

ETHICS APPROVAL OF RESEARCH

The Indian Council of Medical Research (ICMR) mandates that any and every research should be undertaken only after it is approved by the ethics committee. For a research that poses a less than minimal risk, for example, educational and practice surveys or quality audits, exemption from review can be requested.[10,11] It has to be noted that a researcher cannot himself/herself deem whether a particular study is exempt from the ethics review as this decision is the prerogative of the ethics committee and even in cases where an exemption is valid; a formal letter of such exemption has to be obtained from the committee. Research that poses no more than minimal risk, for example, a retrospective review of patient charts, may be taken up by the committee for an expedited review. Such expedited reviews may be conducted by the committee's secretary, chairperson, and one or two other members. For research on vulnerable subjects or any other research where there is even a minor increase over minimal risk, a review by the full committee is required. The member secretary of the ethics committee screens the proposals submitted for consideration and categorizes them into those for an exemption or expedited or full review. No retrieval of data or enrolment of subjects should begin before the ethics approval or waiver has been obtained.

In India, institutional as well as independent ethics committees exist. If an ethics committee is not available at the center where the intended research is to be carried out, an ethics approval can be obtained from a different (host) institutional or independent ethics committee. For this, the clinic/hospital where the study shall be conducted needs to

enter into a memorandum of understanding with the host ethics committee. Alternatively, the clinic/hospital where the study is to be conducted may provide a no objection certificate to be overseen by the host ethics committee. For multicentric studies, the ethics committee at one of the study sites may be designated as the coordinating committee and may take up the review of the protocol, but approval must be sought from committees at all the participating sites for implementation and monitoring of the process locally.[11]

FIRST 6 MONTHS OF RESEARCH PLANNING

It is essential to acquaint oneself with the basics of research to avoid any frustrations due to a lack of know-how at a later stage. There are various resources available to get a grip on research methodology, learn statistical analysis, understand ethical aspects of research, maintain good practices, and learn the usage of various research-related software.

National Programme on Technology Enhanced Learning is a project of the central ministry of Human Resource Development, which provides many web-based courses relevant to research. For example, it offers 16 weeks basic course in biomedical research.[12] Various societies such as Indian Rheumatology Association via its official publication; Indian Journal of Rheumatology runs regular workshops on scientific writing and publications,[4,13] and central organizations such as ICMR-National Institute of Epidemiology (www.nie.gov.in) run very useful health research fundamental course, both are open to everyone irrespective of where they work.

Good Clinical Practice (GCP) certification is a requirement for ethics committee members as well as researchers. A good GCP course acquaints one with, of course, good practices, but also relevant ethical aspects of research. While online GCP courses are yet not available from Indian providers, since the principles remain the same, the National Institute on Drug Abuse (NIDA) Clinical Trials Network GCP course may be considered.[14] The course includes modules on ethics, consent, participant safety, quality assurance, research protocols, documentation, recruitment, drug trials, roles, responsibilities, and misconduct.

There is software available for the analysis of data but it is important to have a basic knowledge of statistics to be able to use the various functionalities of these software correctly.[15] While using the software may seem difficult and frustrating initially, one eases into using these as they use it regularly. St. John's Research Institute, Bengaluru (www.sjri.res.in), and Indian Statistical Institute, Kolkata (www.isical.ac.in), conduct regular courses on biostatistics and epidemiology.

Researchers also need to keep a tab on the literature they have referred to at various stages. The reference manager software (such as EndNote or Zotero) is quite handy for this. While one still needs to manually ensure the correctness of the references and their conferment to the specific journal's style, reference managers help to organize them efficiently.

It is important for researchers to build up a profile which can help them in getting identified by other researchers and establish mutually beneficial networks. Examples include Research Gate, Academia.Edu, and Google Scholar citations and two scholarly profiling platforms with a bigger impact, namely, Open Researcher and Contributor ID (ORCID) and Publons.[16]

CONCLUSION

Research helps science progress in addition to contribute to the professional development. It must, therefore, be taken up by everyone wherever possible. While there are challenges to conducting research, they can be overcome by acquiring knowledge of methodology, logistics, processes, and then approaching the project systematically. Research at non-teaching institutions with adequate patient loads in our country has tremendous potential. Once the initial inertia is overcome, the process can become efficient and enjoyable.

Declaration of patient consent

Not required as there are no patients in this article.

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Conflicts of interest

There are no conflicts of interest.

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