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Perspective

FINER criteria – What does it mean?

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Received : 19 October 2022
Accepted : 07 November 2022
Published : 19 November 2022

DOI
10.25259/CSDM_123_2022

Quick Response Code:

ABSTRACT

The formulation of a research question in the appropriate scientific "syntax" is one of the vital steps in preparing a research proposal. Every research question should ideally have certain essential attributes which are represented by the FINER acronym. FINER stands for feasible, interesting, novel, ethical, and relevant. Ensuring that his/her research question meets these attributes is useful to the investigator, especially for those starting out in their research career. This article is a brief overview of these attributes which may assist an investigator to strengthen his/her research plan or idea.

Keywords: Research question, FINER, Feasible, Ethical, Novel

INTRODUCTION

Research is a systematic process of answering scientific questions to get an answer. The research question is the unknown doubt/curiosity that the investigator is trying to answer with his investigation.[1] The formulation of the research question in an "answerable" format is the first vital step in conducting research. It is said that the success of a research project can rely on how well the investigators can convert a clinical problem into an "answerable" research question.[2]

ESSENTIAL ELEMENTS OF A RESEARCH QUESTION

For descriptive studies, questions start with an interrogative adjective, that is, which, how much, who, etc. The essential elements of a research question in interventional and analytical studies are represented by the PICO framework, that is, population, intervention, comparator, and outcome.[3] Other elements such as time and effect size are sometimes added. For analytical studies, the elements are PECO, that is, population, exposure, comparator, and outcome. Population refers to the population that is being studied. Since there is no intervention done in analytic studies, it is the exposure that forms an important element. The detailed description of these elements is beyond the scope of this article.

A research question once framed should be assessed by the FINER criteria proposed by Hulley *et al.*[4] FINER is an acronym that represents the essential attributes of a research question. Careful consideration of these attributes will greatly enhance the possibility that the research question being investigated translates into a well performed study that adds to the knowledge used for clinical practice. FINER stands for feasible, interesting, novel, ethical, and relevant.

Feasible

It is very important that a study that is planned is practically easy to implement and is designed well. The study should be equipped with an achievable sample size with easily and reliably measurable outcome and exposure variables.[5] There should be sufficient resources in terms of time, trained manpower, and adequate funding.[6] The investigator should have sufficient expertise.[1] A well-designed study is more likely to get good funding. It is more likely to optimize use of human and technical resources. A robust methodology would ensure high adherence to the intervention, in interventional studies, and low rate of dropouts. The investigators can do a pilot study, if in doubt, to assess feasibility. If they feel that they would not get an adequate sample to answer the question, they can consider modifying the inclusion criteria. Other strategies that could be tried include reducing the exclusion criteria, increasing the time frame, planning multicentric studies, and changing the study design and source of patients. It would be also prudent to consult a biostatistician early to ensure that the study has sufficient power to answer the primary research question and to plan the analysis using crisply defined exposures and outcomes before data collection is commenced. Other technical experts or consultants too can be involved to shore up the expertise needed to conduct a study. It is important to comprehensively assess the funds needed at the beginning of the study, to avoid interruptions of the study for want of funds later in the study process. The time needed too must be estimated with a fair degree of accuracy. Investigators trying to answer too many questions can also make the data collection cumbersome. It would be wise to narrow the scope of the study and to answer only the most relevant questions.[4] For example, a study to compare the efficacy of adalimumab to isotretinoin for the treatment of hidradenitis suppurativa may be interesting to many investigators in dermatology. However, it will throw up multiple challenges with regard to feasibility if planned as a MD dissertation or a single-center project with a limited time horizon. It would be almost impossible to attain required sample size if it was to be conducted in a single center and the drugs to be used would be quite expensive, thus requiring substantial resources both in terms of manpower and funding.

Interesting

The research question should kindle the interest of the investigators primarily. Only if the question is interesting to him or her, would the investigator expend the effort required to overcome any potential challenges and bring the research project to fruition.[4] The project should also be interesting to collaborators in the case of multicentric studies. Sometimes, the projects must be relevant to the public health sphere to obtain funding from public health agencies. It falls on the researcher to be familiar with existing literature to achieve these goals. It is desirable to have a mentor and discuss with them if the topic is interesting, before spending a lot of time developing a project proposal that funding agencies may find dull.[2] One could also speak with representatives of funding agencies such as NIH project officers to ensure that funding agencies finds the project interesting.[7] Last but not the least, the proposed project should also be of interest to the readers of the published research paper once it is completed. Otherwise, the study results may never see the light of the day. For example, a study of the antifungal susceptibility of dermatophytes from a particular part of India would be of interest to all clinical dermatologists in the area and will be an interesting area to work on for a clinician researcher. Similarly, a study comparing Universal Multidrug therapy to Rifampicin, Ofloxacin, and Minocycline for the treatment of single patch Hansen's disease would be of interest to policy makers and could easily attract funding from public health agencies.

Novel

The point of conducting research is always to advance the existing knowledge. It is imperative that the investigators conduct a thorough literature review to assess the existing knowledge about the research topic. Consulting with experts in the field and searching for abstracts in the field of interest that has been funded using the NIH Research Portfolio OnlineReporting Tools (RePORT) website (http://report.nih.gov/categorical_spending.aspx.) can also be done before embarking on a new study.[7] The new study planned should ideally provide new results. It is understandable that, in some circumstances, research needs to be done to confirm pre-existing knowledge. However, this should not be misused to generate knowledge in each specific population subset when there is already reasonably generalizable knowledge available for the population. The project can instead attempt to improve on the methodology of similar studies conducted in the past and resolve a gap in the literature.[5] A confirmatory study may be useful when it eliminates weaknesses of the previous study.[4] For example, it has been established with observational and analytical studies that dairy intake can aggravate acne. However, since observational studies are only indicative of a possible association and may be false, the association needs to be proved by a controlled trial which can generate new information. Hence, instead of just repeating an observational study in more settings, to improve on this knowledge, an interventional study can be planned comparing standard treatment with dairy restriction to standard treatment alone in patients with acne vulgaris.

Ethical

Research projects should follow well-established ethical procedures as laid down by the Declaration of Helsinki.

Other guidelines to be familiar with would be the good clinical practices for clinical trials and the Tri-Council Policy Statement.[2] Research of any kind should be approved by the appropriate ethics committee constituted for that purpose. A prudent step would be discussing the protocol with a member of the ethics committee at the planning stage itself in case there are concerns about the balance of risk versus benefit for the participants. For many conditions with standard therapy available, it would not be ethical to administer only placebo to the patients in control arm though it may result in a more pronounced beneficial effect of the trial drug. Administering the placebo along with standard therapy would be needed. For example, in pemphigus vulgaris, if a trial is planned to study the effect of anticholinergic drugs, it would be advisable to provide standard treatment to both arms to ensure safety of the participants. Similarly, unnecessary investigations for the sake of documentation are better avoided. For example, for a condition that can be reliably recognized clinically such as psoriasis, alopecia areata, or dermatophytosis, it would be considered unethical to subject all patients to a biopsy before being enrolled in a study. If a particular intervention was found to be beneficial, it would be advisable to give the control arm the same benefit at the end of the study. This would be particularly relevant for split face studies as it would be unethical to provide the beneficial treatment to only one side of the face by the end of the study.

Relevant

The knowledge that would be generated by the study should be relevant to either current clinical practice or to current laboratory research. The study should ideally generate potential new avenues of research. In certain cases, it should be relevant to the public health aspects of the region. In such instances, it would be advisable to be familiar with the global and national burden of the disease. Having questions related to local problems would be more relevant than other questions. The investigator would do well to imagine the possible outcomes and think if each of them could change clinical practice, advance scientific knowledge, and/or guide further research. For example, for a practicing dermatologist, dermatophytosis has grown to epidemic proportions in India. Any information to address the issue will be highly relevant to the physicians. Hence, even a simple observational study assessing host and environmental factors that lead to chronic or resistant dermatophytosis would be very relevant to dermatology practitioners in India, so that they can have access to relevant information to address this vexing condition.

Assessing the research question using the FINER criteria and ensuring that it meets the criteria would instill ample confidence in the investigator to proceed with planning the study. The next step after this would be to make a study proposal to answer the research question. The research question developed based on the PICOT framework, and vetted by the FINER criteria, would then be used by the investigator to make the primary and secondary objectives. Based on these objectives, the exposure and outcome variables, previously judged to be feasible to measure (F of FINER), would be standardized, the sample size calculated (also judged earlier to be feasible to attain), and the statistical analysis planned. All this together with the potential plans for receiving funding would form a preliminary study plan, which when fine-tuned, would set the investigator on the path to successfully complete his or her project.

CONCLUSION

Assessing the research question by the FINER criteria is a vital step in research planning, and if dispensed with can lead to multiple challenges while executing a research project.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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How to cite this article: Mohanan S, Parameswaran N. FINER criteria – What does it mean? CosmoDerma 2022;2:115.