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Improving the Quality of Medical Research

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Abstract

A large number of medical research endeavors are made but only a few of them help in improving health. The primary reason for this dismal picture is the poor quality of most researches that increase the quantity but fail to make an impact. This communication suggests the steps that medical researchers can undertake to improve the quality of their research.

Keywords
- health research
- good quality
- improving medical research
- research methodology
- research data analysis

Introduction

What is a medical research without a new finding? This may look like a valid statement but is not more than rhetoric. A large number of endeavors is made around the world that do not succeed in reaching to new results but many leave a lesson for us. Failure to get anticipated results does not render the research useless. If we know the result already, there is no need for research. But there are several other "researches" that do not contribute anything to our knowledge. This can happen because their research questions are hazy, the methodology is sloppy, the results are vague, or the reporting is unclear. Perhaps "such space-occupying lesions" have proliferated more in medical research quagmire than any other discipline. Quality has taken a back seat amidst rush for quantity.

Medline added as many as 813,598 citations in the year 2017 to its database.[1] Perhaps there are a million other publications that do not make the grade for indexing. Of this enormous number, how many were able to contribute to our knowledge is anybody's guess but perhaps not more than 1% of these get the attention, while the others vanish into oblivion. If that is true, a lot of efforts and resources are going wasted. In the opinion of Ioannidis,[2] "most" papers out of nearly 1 million from clinical trials conducted across the world so far are not useful. Nearly 85% of billions of dollars spent each year on medical research go waste.[3] Thus, there is a desperate need to improve the quality of medical research. This communication discusses the common pitfalls and problems with medical research and suggests ways to improve quality.

This article starts with an explanation of the concept of medical research because the problem starts with inadequate understanding of what research is all about. The article subsequently discusses the ingredients of quality of research and provides advice on good reporting as an important constituent of quality.

What Is Medical Research?

Research is trying to discover new facts, enunciate new principles, or provide a new interpretation of the existing knowledge.[4] However, to qualify to be called valid research, the research question must have relevance to our well-being, it must contribute to the understanding of how and why of a phenomenon we come across in our life. Searching for answers to questions, such as what, when, and how much, is also a valid part of research endeavors.

Dealing with intricacies of life and well-being, the science of health and medicine has a special appetite for such inquiries. The objective of medical research should be a better understanding of how our body, mind, and soul function; why we get sick and what can be done to put the system back on the homeostatic state; how to minimize the adverse consequences; and how can we prevent such aberrations. In a nutshell, medical research is trying to find new ways to improve our health, not just physical but also mental, social, and possibly spiritual. On the ground, this is

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done through laboratory experiments or clinical trials for formulating or discovering new modalities, observational studies to identify and delineate new risk factors, or epidemiological surveys for assessing the current status and trends. With the gross functionalities of our body systems presently understood fairly well, the focus now needs to be on details at the micro level such as structure and function of DNA. At macro level, it can transgress into studying such minute details as the ratio of the length of two fingers for their possible association with coronary artery disease.[5]

As mentioned earlier, unsuccessful research that fails to come up with a positive finding is not waste so long as a useful hypothesis was examined with appropriate methodology. It generates lessons for us and gives the direction for future research. Miscues, such as finding that arthroscopic surgery for osteoarthritis of the knee is not better than placebo,[6] is also not a waste as they add to our knowledge. Wasteful research has one or more of the following ingredients:

- Irrelevant questions that do not need an answer or whose answers are already known.
- Unclear research question and tardy objectives that cannot be directly measured.
- Inappropriate design, such as using an observational study to assess cause–effect relationship, and studying an unrepresentative sample.
- Inaccurate data either due to use of unstandardized instruments (questionnaire, laboratory investigations, clinical assessment, scoring system, etc.) or due to ignoring fallacies and errors, sometimes even cooked up data.
- Superficial or wrong analysis such as using arbitrary categories of quantitative measurements, doing logistic regression where Cox's regression should be done, or ignoring confounders.
- Subjective or wrong interpretation of the results due to incomplete understanding or to serve a preconceived notion. Mixing of opinion with evidence-based results in reaching to a conclusion also compromises the integrity of research.
- Insufficient or unclear reporting of either the methods or results or conclusions.

The basic ingredient of quality medical research is that it should be well intentioned and should be performed with care and sincerity it deserves, done by using an appropriate methodology, and is honestly reported. The details are given next.

What Is a Good-Quality Medical Research?

Quality is a subjective term that takes varying meaning with different professionals and in different situations. Yet, the quality of a medical research can be assessed using the points listed in ►**Table 1**. These have been briefly presented by Indrayan[4] and Ioannidis[2] but in the present communication an effort has been made to provide a much more comprehensive list in a language conducive for medical researchers of all hues from postgraduate students to university professors.

Those who have conducted research and published their findings may like to introspect and reexamine their papers

Table 1 Steps to conduct research of good quality

Step	Details
Step 1: The problem under research	Clear specification of the research question. Justify the research question and consider how it will contribute to improved health in real-life situation. Assess the feasibility after considering the available resources such as time, expertise, and material. Review all the relevant literature without leaving out the opposite view and underscore the lacunae in the existing knowledge. State the hypothesis, if any, and list the objectives in measurable format with a specification of the outcome and antecedents under investigation.
Step 2: Complete specification of the methodology	Choose the appropriate setting (clinic, laboratory, and community) that can elicit the correct answer to the research question. Include the right type of subjects or patients, adopt a procedure for their unbiased selection, and determine the sample size in consideration of the reliability of the estimates or power to detect a medically important effect. Devise a suitable design for selection/allocation of the patients keeping in view of the possible confounding factors. Use data collection tools (questionnaire, clinical assessments, investigations with their units expressed clearly and correctly, scoring systems, etc.) with established validity and reliability. Ensure that the data obtained are correct and complete as much as possible. Use the appropriate method of statistical analysis considering the type of data and the research objectives.
Step 3: Obtain evidence based results	Obtain the results exclusively from the data obtained in the study without imputing any opinion to keep the focus on the research question. Take care of the missing values, outliers, confounders, and interactions, and do the required analysis to minimize their impact on the results. Prepare the right type of the tables and illustrations that can improve understanding of the results. Assess internal and external validity of the findings, and try to detect possible fallacies that can affect the findings.
Step 4: Study the implication of the results	Evaluate the results in view of the current knowledge as available in the literature and take inputs from colleagues and experts. Explain the rationale of any variation from the existing knowledge and resolve any conflict with other internal findings or external knowledge. Explore the possible alternative explanation of the results and provide sufficient arguments against it. Consider how the associated uncertainties (in the data) and the limitations of the methodology can affect the results.
Step 5: Draw modest conclusion	Draw conclusions based on the results and other corroborative or conflicting evidence. Be modest in conclusions because of the all-pervasive uncertainties in a medical setup.

in the light of these criteria and assess the quality of their research. The most important aspect that defines quality is not the result but the methodology. When a relevant question is examined with appropriate methodology, the research is likely to have a good quality irrespective of the result. However, a research that reaches to an unexpected result has wide ramifications or the one that contradicts the current understanding has much more impact than a research with a routine result. But, for this too, the methodology must be appropriate because only then the result can be believed.

Quality of Reporting

There may be instances where a research is performed with utmost care as provided in the rule books[7] but it fails to be noticed because of sloppy presentation. This is not just language deficiency but some of us are not able to prepare a draft in a manner that can make an impression.

Much of how a manuscript should be prepared should be clear from the details provided in ►**Table 1**. Excellent texts such as by Indrayan[4] and Ray et al[7] are available that can help. In brief, the manuscript should contain the following:

- Convince the reader that the research question is such that its answer will help improve health in one way or the other. A novel question attracts widespread attention. The statement of research question should be unambiguous and accompanied by a full justification of the choice of topic with citation of the literature pointing to the lacunae. The lacuna could be in terms of conflicting or inconsistent reports or near complete absence of the kind of thinking now is being explored.
- Crucial for the credibility of the results is the methodology. This should be described in detail so that nothing is left to the imagination of the reader or reviewer. Convince yourself and the reader that you have used appropriate tools to obtain correct data. The method of analysis should be focused on the stated objectives. The methodology should be stated in a manner that anybody with sufficient resources can replicate.
- State the result with complete clarity and all the results should be supported by the evidence collected during the study. Make sure that the results are reproducible. A recent BMJ Open Science blog[8] gives details of how reproducibility has become an overriding consideration. For this, demonstrate reliability and validity of the findings (reliability and validity are two different aspects of quality and should not be mixed). Demarcate the medical significance of the results from their statistical significance. State any coincidental findings as hypotheses and not as results of the study.
- Discuss the findings honestly in the light of the findings of the others without leaving out inconsistent or conflicting reports. Resolve such conflicts by providing holistic arguments. Do not gloss over the errors and limitations but, instead, state them frankly that will increase the credibility of the paper.
- Make a distinction between results and conclusions. Results are what your data say whereas the conclusion is based on the results plus other evidence available in the literature and a plausible biological explanation of the results. Results tend to give too much importance to the statistical *p*-values, sometimes even ignoring the multiple *p*-values that compromise statistical significance. There is a great discussion going on these days regarding the validity of the results based exclusively on *p*-values.[9]

Conclusion

Medical research is on cross-roads and is being intensively scrutinized for validity and reproducibility. Errors and fallacies are common that can jeopardize the health of a large number of people when such results are applied to millions.[10] Sloppy research is wastage of resources.

Researchers have the responsibility to produce research of high quality that can be believed and can be applied to improve health. This can be done by following the advice provided in this communication.

Conflict of Interest

None declared.

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