Research in Respiratory Care

Introduction

Conducting research and publishing has become a necessity of the day. Although this concept has been prevalent for a few years now in the developed countries, the concept is catching on in many places across India. Universities have now begun to insist on publications in an attempt to detect and improve our practice. Unless the research mindset is inculcated in the young minds, this becomes a herculean task for them to understand and execute. This editorial is being written precisely for such individuals who are interested in research in respiratory care but do not know how to go about doing it.

What is Research?

First of all, it is important to know "What is research?" Research, as the name implies, is re-searching of solutions to the existing issues. Research is a relentless pursuit of new knowledge. It is important to recognize that science is ever evolving. Our knowledge is never complete and there are always unanswered questions, even in daily practice. Only an inquisitive mind will try to get answers to these so that the society can progress. It is questioning what is believed to be the truth. All of today's ease of living is attributable to the painstaking research conducted by our predecessors, and it is only our duty to continue with the process so that life becomes easier for the future generations.

The Research Process

The first step in the conduct of research is coming up with a good research question. This can pertain to a disease condition, a procedure, a device, or a complication. The research process consists of a particular sequence that begins with the understanding of the current knowledge and clinical practice and then formulating a hypothesis based on it.[1] The hypothesis should be formulated in such a manner that a clear answer is obtained from the research, clearly supporting or refuting the hypothesis.[2]

The first step to becoming a good writer is to become a good reader. Therefore, the topic of the experiment should be chosen after a thorough literature search to avoid repetition and ensure an innovative yet clinically relevant issue. Thereafter, one proceeds to formulate the study design.

One needs to decide whether the collection of data must be prospective or retrospective. Prospective data are more valuable because they are easier to control and eliminate confounding factors that may affect the result unlike in retrospective studies of events, where the event has already happened and the study is done from the records. A prospective clinical trial holds the greatest value in evidence-based clinical practice today.[3]

The sample size estimation, power analysis, and study and control groups must be clearly defined and should all be done while designing the study.[3] Blinding and elimination of bias improves the credibility of the study. In a single-blind study, the subjects are unaware whether they are in the treatment or control group, but the researchers are aware.[3] In a double-blind study, the researchers are also unaware of whether the particular subject falls in the treatment group or control groups.[3] At this juncture, consulting an expert in the field is invaluable to further refine our study question and methodology.[4]

Ethics Committee and Clinical Trial Registry

The patient is at the center of all clinical investigations, and it is important to ensure patient safety during the trials. Patient identity is also maintained confidential for obvious reasons. It is also possible that biological tissues are misused. Therefore, all clinical investigations are thoroughly scrutinized by a departmental and institutional ethics committee (IEC). Apart from the methodology, the ethics committee also scrutinizes subject information sheet that must be given to all participants before enrolling into the study. This is generally written in a simple language that can be understood by the lay people. It describes correctly their role in the study, what would happen to them, and what is expected so that they can make an informed choice regarding participation in the study.

Once the IEC clearance is obtained, the study is registered with the National Clinical Trial Registry. The first study participant can be recruited only after the trial is registered.[5] The participant is provided information about the study in a simple language for ease of understanding following which informed consent is taken from the subject for participation.

Actual Conduct of the Study

Conduct of the study, data collection, and data analysis follow. During and after the completion of the study, it is imperative that literature search is continued to look for reports that have been published on similar topics since the commencement of the study.[5] The data analysis is followed by manuscript writing and submission for publication.[1]

In the hierarchy of evidence-based medicine, meta-analysis and systematic reviews are placed at the top of the pyramid, followed by randomized controlled trials (RCTs) and then observational studies involving cohort and case–control studies. Base of the pyramid is formed by case series, case reports, editorials, and expert opinions.[6]

Types of Research

Systematic review and meta-analysis

A systematic review is a collection of all studies pertaining to a particular topic in medical literature and analysis of their results. A meta-analysis is a statistical analysis after an amalgamation of different results obtained from RCTs which have come out with a high level of evidence.[7]

Randomized controlled trial

RCT is a trial wherein the subjects are randomly distributed to two or more groups – the experimental group/s receiving the intervention which is being tested and the control group receiving the alternative treatment.[8] Randomization minimizes confounding variables, and the assignment to the study or control groups is ideally concealed from the investigator as well as the subject to eliminate bias.[8] Irrespective of what happens to the subject after initial randomization, even if there are dropouts, it is essential to keep them in the trial for outcome measurement. The analysis must also include those subjects who have dropped out after the initial randomization. This is known as "intention-to-treat analysis." It avoids bias as a result of selectively dropping patients from previously already randomized groups.[8] Training is essential to avoid interobserver variability while recording data during a RCT.

Observational studies

It is not always feasible and ethical in medicine to conduct a RCT. Observational studies are considered the second best method to explore answer to questions in medical research.[9] Structured observational studies provide results assiduously comparable to RCT and are of similar importance in medical research.[7] In an observational study, the investigator does not intercede but just "observes" and then analyzes the strength of relation between an exposure or factor and disease. Observational studies are of two types – cohort and case control. They help in evaluating associations between diseases and causation or exposures.[9]

Cohort studies

Here, the subjects are initially identified by the exposure or event of interest and followed in time until the disease or outcome of interest occurs. They can be prospective or retrospective.[9]

Case–control studies

They identify subjects by outcome status at the beginning of the investigation process itself, and then subjects are classified as cases or controls. Controls are the subjects without the particular outcome but from the same population source. Data about exposure to a risk factor are collected retrospectively and analyzed.[9]

Longitudinal studies

They are a type of observational study which uses continuous or repeated measures to follow subjects over a prolonged period of time for evaluating the relationship between risk factor and development of disease.[10] They have the advantage to recognize and correlate events to particular exposures and establish a sequence of events.[10]

Cross-sectional study

It is also a type of observational study where the subjects are included based on distinct criteria, and the investigator studies the exposure as well as the outcome at the same time, calculates the odds ratio, and estimates the prevalence.[11] This is different from case–control studies (where the participants are included based on a particular outcome) or cohort studies (where the participants are chosen based on the exposure). Here, the participants are just selected based on particular inclusion and exclusion criteria determined for the study. As it is a one-time measurement of exposure and outcome, relationship to cause and effect is difficult to conclude from a cross-sectional study.[11]

Case report and case series

They are reports that illustrate rare, interesting cases in medical research.[6] Future investigations can be based on these interesting case scenarios. Case series provide stronger evidence with multiple cases. However, case reports are seldom accepted for publication by high-impact journals as they are not ranked highly in the hierarchy of evidence-based medicine.[6]

Legal and Ethical Concerns

Legal and ethical concerns are the core components of modern research. Most of the institutes have institutional review board or IEC which is an administrative body that protects the rights and welfare of human research subjects participating in research conducted under the institution with which it is affiliated. Approval from these bodies mandates an informed consent from participants. Informed consent contains a statement that the study involves research, the complete study information, the duration and purpose of study, responsibilities of participant, risks involved, any benefits from the study, details regarding compensation for injury, participant's rights, any extra cost for participation, the contact details of whom to contact for queries, and signature for consent by participant.[12]

If the institute does not have an IEC, then the proposal has to be approved by independent ethics committee (external ethics committee) that is outside the institution. In India, to conduct a clinical research, it is mandatory to have IEC approval and Clinical Trials Registry-India registration.[12]

The Funding Opportunity

Once the research idea is formulated, it is transformed into a proposal and a fund may be essential for execution of the research idea. Identifying the funding opportunity is a great challenge for young researchers. Most of the funding agencies typically call for applications once a year or twice and hence the researchers must be aware of the call for duration. It is important to note the eligibility criteria by the funding agency mentioned. To mention few funding agencies that support *Respiratory Therapy Research* are American Association of

Respiratory Care, Canadian Lung Association, and Indian Council for Medical Research.

To obtain a successful grant, the instructions given by the agency in the website must be followed. This gives an insight about the vision and scope of the grant agency and also the components of the proposal. Most agencies ask for a letter of intent or a preproposal before the full proposal. The key components of a grant consists of (a) research question; (b) project summary; (c) ethical concerns; (d) study methodology; (e) study timeline; (f) study budget; (g) expected outcome; (h) infrastructure and resources; and (i) details of the applicant and the team.

Disseminating Research Finding

Communicating the research finding to peers is most important as it contributes to the knowledge base. Most scientists communicate their findings in either of the following three ways: (1) publishing in peer-review journals; (2) presenting in conferences; and (3) publishing in popular media such as magazines, newspaper, or blogs.

Communications through journal papers may be in the form of letter to editor/commentary, short communication, case study/case report/case series, original research, review articles, and systematic reviews/meta-analysis.

Which Journals Should We Select for Publication?

For the publication of original research articles in journals, we must select the appropriate journal with utmost sagacity. In September 2015, the Medical Council India (MCI) had issued a "clarification" on what constitutes "research publications" for the promotion of teaching faculty of medical colleges/institutions in India. Indexing agencies which are accepted by the MCI are Scopus, PubMed, Medline, Embase/Excerpta Medica, Index Medicus, and Index Copernicus.[13] The MCI guideline states that only "Original Research Articles" and "Original Research Papers" will be eligible for consideration.[13]

The Journal Citation Reports database provides information on the most renowned journals in each discipline as well as the highest impact journals. Impact factor of a journal is calculated by the total number of citations a journal receives to its articles over a period of 2 years divided by the total number of articles published by the journal over the same period. The higher the impact factor of a journal, the more is its importance in medical literature.[14]

PubMed and Scopus are the two highly reputed indexing bodies in biomedical research. PubMed is a database of biomedical journals in the National Library of Medicine, United States.[15] Scopus is Elsevier's abstract and citation database, and all the journals which are included under Scopus database ensure that the highest quality standards are maintained. It offers more coverage than Web of Science as well as PubMed and covers a wider journal range and citation analysis.[16] Scopus-indexed journals are ranked as quartiles on the basis of their impact factor by Scimago Journal Rank (SJR). However, SJR uses a 3-year period for the journal article ranking, as compared to a 2-year period used for impact factor. Q1 comprises of the top 25% of the journals and Q2 consists of 25%–50% of the journals.

Predatory Journals

To increase the world ranking and promotion or hiring of individuals, many academic institutes insist on the quantity of publications than quality. As a result of this, young researches often succumb to predatory journals. As per an article authored by Jeffrey in journal *Nature*,[17] "disreputable journals that make aggressive publishing pitches to academic researchers." This was called "predatory publisher." Predatory journals actively ask researchers for manuscripts. They have no peer-review system and may have a fake editorial board. A young researcher must have a proper insight to identify a predatory journal. To avoid such pitfalls in India, the University Grants Commission (UGC) has come up with the Consortium for Academic and Research Ethics (CARE) to ensure the prevention of academic misconduct. The UGC-CARE website may provide better insights to young researchers.

Manuscript Writing

Manuscript is an unpublished version of a research that is being sent to editors for publication. Effective writing of a manuscript is most crucial because even a novel result with creative experiment will have dull impact if not written well. A separate article published in this journal focused on scientific writing in detail.[18]

O'Connor and Holmquist[19] published an algorithm for a scientific manuscript which said "the writing should start with making figures and tables, and then proceed with summary statements (the conclusions summarizing the major contributions of the manuscript to the scientific community), identification of the audience, materials and methods, results, discussion, references, introduction, title and conclusion."

A few tips to remember while submitting a manuscript is (a) before submitting, know the journal and the editors, (b) avoid spelling mistakes, pay attention to the language and grammar, (c) references should be written correctly and in appropriate style as instructed by the publisher, and (d) one must comply with the instruction to the authors.

Any manuscript requires multiple revisions by all authors. Once a manuscript is ready, it is submitted to the editor-in-chief of the journal. The editorial team decides on the manuscript whether to send out for review. If not, the author will be contacted with the decision. The manuscript is then sent to potential reviewers (peer-review process) while the author is notified about the process. The reviewers review and submit the reports to the editor. Finally, the editorial team decides

on the final decision after discussing the review report and notifies the author.

Responding to Reviewers

Most manuscripts undergo revision. A good review process provides an opportunity for the author to learn from the reviewers and improve the readability of the manuscript. It is important to respond to every query and comment that has been raised. The author must make the changes as suggested and resubmit for further review.

To conclude, this editorial has briefly covered the basic essence of research for health-care personnel involved in respiratory care. We hope this article could inspire many young minds to inculcate the tradition of research in their career and add to the ever-expanding universe of knowledge.

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