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Research Notes

COMMON ETHICAL ISSUES IN RESEARCH AND PUBLICATION

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INTRODUCTION

Research is the pillar of knowledge, and it constitutes an integral part of progress. In the fast-expanding field of biomedical research, this has improved the quality and quantity of life. Historically, medical doctors have been in the privileged position to carry out research, especially in clinical research which involves people. They are able to control "life and death" of patients and have free access to their confidential information. Moreover, medical researchers have also enjoyed immunity from accountability due to high public regard for science and medicine. This has resulted in some researchers conducting unethical researches. For instance, in World War II, medical doctors had conducted unethical experiments on human in the name of science, resulting in harm and even death in some cases.[1] More recently, the involvement of pharmaceutical industry in clinical trials have raised issues about how to safeguard patient's care and to ensure the published research findings are objective.[2]

In the light of these ethical controversies, the Declaration of Helsinki was established to inform biomedical researchers the principles of clinical research.[3] This declaration highlighted a tripartite guidelines for good clinical practice which include respect for the dignity of the person; research should not override the health, well-being and care of subjects; principles of justice. Committee on Publication Ethics (COPE) was also founded in 1997 to address the breaches of research and publication ethics.[4]

How do we apply all these principles in our daily conduct of research? This paper will discuss different ethical issues in research, including study design and ethical approval, data analysis, authorship, conflict of interest and redundant publication and plagiarism. I have also included two case scenarios in this paper to illustrate common ethical issues in research and publication.

ETHICAL ISSUES IN RESEARCH

1. Study design and ethics approval

According to COPE, "good research should be well adjusted, well-planned, appropriately designed, and ethically approved. To conduct research to a lower standard may constitute misconduct."[3] This may appear to be a stringent criterion, but it highlights the basic requirement of a researcher is to conduct a research responsibly. To achieve this, a research protocol should be developed and adhered to. It must be carefully agreed to by all contributors and collaborators, and the precise roles of each team member should be spelled out early, including matters of authorship and publications. Research should seek to answer specific questions, rather than just collect data.

It is essential to obtain approval from the Institutional Review Board, or Ethics Committee, of the respective organisations for studies involving people, medical records, and anonymised human tissues. The research proposal should discuss potential ethical issues pertaining to the research. The researchers should pay special attention to vulnerable subjects to avoid breech of ethical codes (e.g. children, prisoners, pregnant women, mentally challenged, educationally and economically disadvantaged). Patient information sheet should be given to the subjects during recruitment, detailing the objectives, procedures, potential benefits and harms, as well as rights to refuse participation in the research. Consent should be explained and obtained from the subjects or guardians, and steps should be taken to ensure confidentiality of information provided by the subjects.

2. Data analysis

It is the responsibility of the researcher to analyse the data appropriately. Although inappropriate analysis does not necessarily amount to misconduct, intentional omission of result may cause misinterpretation and mislead the readers. Fabrication and falsification of data do constitute misconduct. For example, in a clinical trial, if a drug is found to be ineffective, this study should be reported. There is a tendency for the researchers to under-report negative research findings,[5] and this is partly contributed

by pressure from the pharmaceutical industry which funds the clinical trial.
To ensure appropriate data analysis, all sources and methods used to obtain and analyse data should be fully disclosed. Failure to do so may lead the readers to misinterpret the results without considering possibility of the study being underpowered. The discussion section of a paper should mention any issues of bias, and explain how they have been dealt with in the design and interpretation of the study.

3. Authorship

There is no universally agreed definition of authorship.[6] It is generally agreed that an author should have made substantial contribution to the intellectual content, including conceptualising and designing the study; acquiring, analysing and interpreting the data. The author should also take responsibility to certify that the manuscript represents valid work and take public responsibility for the work. Finally, an author is usually involved in drafting or revising the manuscript, as well as approving the submitted manuscript. Data collection, editing of grammar and language, and other routine works by itself, do not deserve an authorship.

It is crucial to decide early on in the planning of a research who will be credited as authors, as contributors, and who will be acknowledged. It is also advisable to read carefully the "Advice to Authors" of the target journal which may serve as a guide to the issue of authorship.

4. Conflicts of interest

This happens when researchers have interests that are not fully apparent and that may influence their judgments on what is published. These conflicts include personal, commercial, political, academic or financial interest. Financial interests may include employment, research funding, stock or share ownership, payment for lecture or travel, consultancies and company support for staff. This issue is especially pertinent in biomedical research where a substantial number of clinical trials are funded by pharmaceutical company.

Such interests, where relevant, should be discussed in the early stage of research. The researchers need to take extra effort to ensure that their conflicts of interest do not influence the methodology and outcome of the research. It would be useful to consult an independent researcher, or Ethics Committee, on this issue if in doubt. When publishing, these conflicts of interest should be declared to editors, and readers will judge for themselves whether the research findings are trustworthy.

5. Redundant publication and plagiarism

Redundant publication occurs when two or more papers, without full cross reference, share the same hypothesis, data, discussion points, or conclusions. However, previous publication of an abstract during the proceedings of meetings does not preclude subsequent submission for publication, but full disclosure should be made at the time of submission. This is also known as self-plagiarism. In the increasing competitive environment where appointments, promotions and grant applications are strongly influenced by publication record, researchers are under intense pressure to publish, and a growing minority is seeking to bump up their CV through dishonest means.[7]

On the other hand, plagiarism ranges from unreferenced use of others' published and unpublished ideas, including research grant applications to submission under "new" authorship of a complete paper, sometimes in different language.

Therefore, it is important to disclose all sources of information, and if large amount of other people's written or illustrative materials is to be used, permission must be sought.

CONCLUSION

It is the duty of the researcher to ensure that research is conducted in an ethical and responsible manner from planning to publication. Researchers and authors should familiarise themselves with these principles and follows them strictly. Any potential ethical issues in research and publication should be discussed openly within the research team. If in doubt, it is advisable to consult the respective institutional review board (IRB) for their expert opinions.

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Case Scenario 1:
"A community survey on prevalence of domestic violence among secondary school students."

Question:

1. Who should we obtain the consent? Students, parents, teachers or Ministry of Education?
   - To conduct this study, we need to seek approval from the Ministry of Education and permission from the school principal. However, consent should be taken from parents, who are the legal guardians of the students.

2. If the results show that 50% of the students have ever been abused, should I report them to the police?
   - These ethical issues should be discussed at the proposal stage, and the participants/guardians should be informed about the decision to report to the police while taking the consent. This will potentially affect the response rate; but this is also the responsibility of the researcher to protect the participants and their families.

3. I have decided to publish it. Can I send an abstract for presentation as part of the conference proceedings, and later submit similar abstract with the full text for publication. Is that redundant publication?
   - Yes, you can. However, you need to declare to the publisher that you have presented the paper in the conference. Redundant publication happens when an author has submitted two papers with similar objective, methodology and results, without cross referencing.

4. Can I submit the same paper in a different language?
   - Yes, you can. However, you have to declare to the publisher that you have published an identical paper in a different language.

Case Scenario 2:
"Does HRT improve vasomotor symptoms among menopausal women in a Malaysian primary care clinic?"

1. Some people say it is "unethical" to do this study because it has been proven in many studies. But no such research has ever been done locally!
   - HRT has been proven to be effective in relieving vasomotor symptoms in many well-designed studies. It is inappropriate for the researcher to repeat an established therapy which may potentially cause harm to them (e.g. deep vein thrombosis and breast cancer). However, it is appropriate to repeat research if the researchers feel that it may yield a different outcome in the local setting based on a firm theoretical basis.

2. Do we still need to obtain ethics approval if it is part of daily clinical practice?
   - Yes, even though it is part of our normal practice, all research involving human subjects, especially when it involves drugs, should be subjected to ethics approval. (E.g. "How did the researchers ensure that they explain to the patients fully about the potential harm of HRT?")

3. I'm worried that if I start explaining to the participants about the possibility of Ca breast, they won't want to participate. How can I "play down" this possible side effect?
   - As mentioned earlier, it is the duty of the researcher to ensure that the participant understands the benefits and risks of the treatment. The information should be conveyed in an objectively manner in the patient information sheet. Any queries from the patient should be answered truthfully, and it is the patient's rights to refuse to participate in the research.

4. While writing the introduction and discussion of my paper/thesis, I copied sentences from some papers. But I referred to them in my reference. Is that acceptable?
   - It is acceptable to quote sentences from a paper as long as they are duly referenced.