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EXPERT OPINION

Research and Publication Ethics

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Summary

Research is an effort to seek the truth and communicate it. In the process, participants or subjects of research must be recognised and respected, and the principles of research ethics must protect the vulnerable from exploitation. The researcher must do the reporting of research findings with honesty and professionalism. Non-adherence to the above principles in the early research period resulted in gross abuse of personality and autonomy. Research is now subjected to rigorous scrutiny to stem the tide of abuse and ascertain and guarantee the sanctity of the research participants, process and product. These are the fundamentals of the practice of ethics in both research and publication. In effect, this paper aims to address ethics and its application to research and publications.

Introduction

The Era of Research without Ethics

It will appear that two propositions governed research in its early days, which are unacceptable today. One was the supremacy of certain members of the human race over the others, and the second was that 'the end justifies the means'. Celsius, in the First Century, justifying research experiment on condemned criminals, said:

"it is not cruel to inflict on a few criminals sufferings which may benefit multitudes of innocent people through all centuries." [1,2]

In other words, innocent people were superior to criminals, and anticipated benefit to multitudes justified whatever injuries 'criminals' suffered. Experiments on that principle included the Smallpox vaccination by Edward Jenner and the Rabies vaccine by Louis Pasteur. These were followed by experiments using the poor, orphans, mentally ill that we now know to be vulnerable. Should medical knowledge override the protection of the human subject? Going by the way early researchers carried on, concern for human subjects of research was their least concern. A brief reminder of activities done in the name of investigations will show why ethics had to take centre stage to stem the devaluation of the human subject as an instrument of research.

William Beaumont[3], an army surgeon, who pioneered gastric medicine through his studies of Alexis St Martin's post-traumatic gastric fistula in 1833, wrote the oldest American document on research ethics. His principles were:

a. The need for experimentation must be demonstrated
b. This need is justified when information cannot be obtained by other means

c. An investigator must be conscientious and responsible
d. Use a well-considered and methodological approach
e. Obtain voluntary consent
f. Discontinue studies when they cause distress to the participants
g. Abandon studies if participants become dissatisfied

The Tuskegee Syphilis Study (1932-1972 and World War II Abuses

Before World War II, experiments involved exposing subjects to gonorrhoea and syphilis without knowing they were participating in the research. The one on syphilis was particularly unfortunate because the trial, which started in 1932, continued until 1972 despite discovering Penicillin as a cure for syphilis in the 1950s. All they received were hot meals and burial facilities. In some cases, when subjects were diagnosed with syphilis by other physicians, researchers intervened to prevent treatment. Many subjects died of syphilis during the study. In 1973, the U.S. Department of Health, Education, and Welfare stopped the study only after its existence was publicised, and it became a political embarrassment. In 1997, under mounting pressure, President Clinton of America apologised to the study subjects and their families.

World War II abuses were the watershed in the annals of experiments on human subjects because of the unbridled atrocities perpetrated during the experiments. During this period, Nazi doctors performed horrific experiments on thousands of concentration camp inmates. These included deadly studies and tortures such as injecting people with gasoline and live viruses, immersing people in ice water, and forcing people to ingest poisons. Consequently, the American military tried and sentenced the German doctors involved. The verdict in 1947 included a section called "Permissible Medical Experiments", and this section became known as the Nuremberg Code, [4, 5] which stated that: "*The voluntary consent of the human subject is absolutely essential*". Since then, the quest for accountability in research has led to inquiries, litigations, and the development of several codes and regulations in the hope that its conduct will be just and the product dependable.

Continuing Abuses and Evolution of Codes of Ethics

In 1953, the World Medical Association initiated its own ethics guidelines by adopting resolutions that required consent by all participants or the person's next of kin. It also included qualification of researchers, responsibility or researchers, prudence, and respect for the subjects. All these did not stop unethical research and trials, as several still took place after that. The Thalidomide Study and the Milgram Experiment [6] still took place in 1958 and 1963, respectively. In the Milgram Experiment on obedience in psychology, the experimenter (E) orders the subject (S) to give what the subject believes are painful electric shocks to another subject (A), who is actually an actor (Figure 1). Many participants continued to "give" shocks despite pleas for mercy from the actor, as long as the experimenter kept on ordering them to do so. [6]

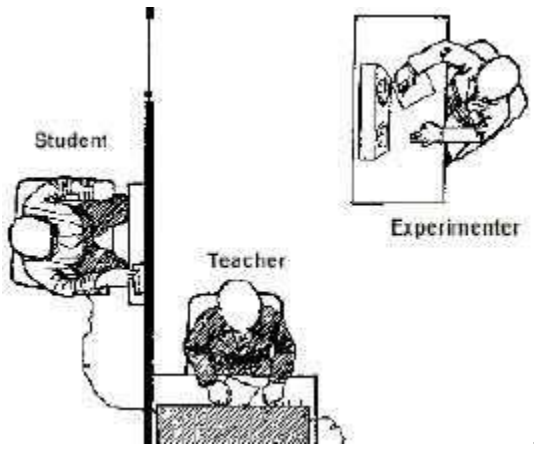

Figure 1: The Milgram Experiment
McLeod S. https://www.simplypsychology.org/milgram.html Accessed on 03 June 2021.

In response to the above abuses, and as part of her mandate, the World Medical Association

(WMA), in 1964, established recommendations guiding medical doctors in biomedical research involving human subjects. [7] The recommendations known as the Helsinki Declarations governs international research ethics and defines rules for "research combined with clinical care" and "non-therapeutic research." The declaration has gone through several revisions, and it remains the basis of Good Clinical Practice. Issues addressed by the declaration include the following:

a. Research with humans should be based on the results from laboratory and animal experimentation.
b. An independent committee should review research protocols before initiation.
c. Informed consent from research participants is necessary.
d. Research should be conducted by medically/scientifically qualified individuals; and,
e. Risks should not exceed benefits.

Beecher, [8] in 1966, published an article in the New England Journal of Medicine detailing 22 examples of research in which the human subjects never had the risks satisfactorily explained to them. Others did not know that they were the subjects of an experiment, although they had suffered grave consequences. Examples included withholding antibiotics from men with rheumatic fever, purposely infecting institutionalised children with hepatitis (Willowbrook), [9] injecting live cancer cells into nursing home patients (Jewish Chronic Disease Hospital). These abuses and exploitations happened despite codes of ethics.

In 1974, under the National Research Act, the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research was created and charged with the responsibility of identifying the basic ethical principles that should underlie the conduct of biomedical and behavioural research involving human subjects and developing guidelines which should be followed to assure that such research is conducted in accordance with those principles. The Commission drafted the Belmont Report or The Common Rule (45 CFR 46), [10] the principles of which included: Respect for Persons, Beneficence, and Justice.

In 1993, The Council for International Organizations of Medical Sciences (CIOMS), an international, non-governmental, not-for-profit organisation established jointly by the WHO and UNESCO in 1949, promulgated guidelines entitled *International Ethical Guidelines for Biomedical Research Involving Human* Subjects. [11] In the year 2000, Emanuel *et al*. [12] published an article titled: 'What makes Clinical Research ethical?', in which they highlighted ten ethical principles, including scientific value, scientific validity, a fair selection of participants, minimisation of risk and maximisation of benefits, independent review, informed consent, respect for persons, trust relationship, protection, and justice.

In Nigeria, a major example was the randomised clinical trial of Trovafloxacin [13], which was carried out in Kano, involving paediatric patients with Cerebro-Spinal Meningitis (CSM) in 1996. The issues raised on trial included the facts that: there was no proof of ethics committee approval, the trial was carried out during an epidemic, the dose administered was below the therapeutic dose, and the researchers did not adequately inform the patients of the risk. The outcry culminated in a court case, the setting up of the National Health Research Ethics Committee (NHREC) and the establishment of a code of ethics for biomedical research in Nigeria. [14] It then became mandatory that all research involving human subjects be reviewed and approved by the National Agency for Food and Drug Administration (NAFDAC) and the local HREC or NHREC before they are embarked upon.

Ethics, Research, and Publication

The nature of ethics

Ethics is different from Law, Regulation, and Policy. Law is mandatory and criminalising, being an act of the parliament, and breaking it will come with conviction and appropriate sentence. Regulations are subsidiary legislation because they often stem from existing laws. Policy is what must be done, and if not done, it will result in a sanction. Ethics, however, is what is generally agreed we ought to do, and repercussions for breaching them are enforced by the community and is limited to non-recognition or non-acceptability of what is presented. [15] Ethics guidelines are in the form of codes, and they are not actionable in the court of law. However, ethics assumes local and international importance as some institutions recognise their breach as grounds for disciplinary actions, including termination of appointment. It is essential, however, to state that a breach of the ethics guidelines can be the subject of litigation, particularly when it is research involving human subjects, if in the process, gross negligence can be proven, significant harm is done to the subject, or false claims are made which cannot be substantiated.

Research

Merriam-Webster defines 'Research' as "careful, diligent, or studious investigation or experimentation aimed at the discovery and interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or revised theories or laws. [16] According to Wikipedia, research is "creative and systematic work undertaken to increase the stock of knowledge".[17] It involves collecting, organising, and analysing information to increase understanding of a topic or issue. A research project may be an expansion of past work in the field.

Publication is defined as: "the act or process of producing a book, or periodicals such as magazine, and making it available to the public". [18] (Merriam-Webster Learner's Dictionary).

Given the above definitions, it is evident that publication is the vehicle for making research and its findings available to the public, using channels such as journals, magazines and, other periodicals. In our tertiary institutions, the number and impact of publications are the major factors in appointment and advancement or promotion from one academic cadre to another, hence the hypothesis: publish or perish.

In the words of Stichler, "Nothing is more exciting than seeing your name in print as the author of a well-written article in a respected, peer-reviewed, scholarly journal". [19] A published article is the goal of a research project, an evidence-based design project, a case study, or an opinion or theory article that reviews and analyses previous literature and makes recommendations for future projects or research studies. Therefore, it is an instinct for academics to strive to increase the number of publications by engaging in one form of research or the other. As in other endeavours of man, sharp practices are now rampant. In the face of the temptation of people to multiply publications as quickly as possible, unethical practices have become rife, and so has the need to stem it become necessary. Therefore, research and publication ethics is mandatory to ensure that improper research is not conducted and, if conducted, are identified and denied access to the public domain and prevent the so-called researcher from benefitting from such products.

Biomedical research deserves a special mention because of the use of humans as research subjects or participants and the ability of the findings to influence healthcare services and patient care. Incalculable damage would be done to humanity if such changes resulted from unethical research and fraudulent publication. The potential harm to society is why research and publication communities have now

determined the standards expected from researchers and publishers in the form of ethics.

When is Research Ethical?

For research to be ethical, it needs to fulfil specific requirements based on the ethical principles of autonomy, beneficence (non-maleficence), informed consent, and justice. The conditions cover every stage from conception through formulation to implementation of the research process. They comprise social/scientific value, scientific validity, fair subject selection, risk-benefit ratio, independent review, informed consent, and respect for subjects. [16]

Social or Scientific Value

This aspect is important because resources are scarce, and it does not matter that the researcher bears the cost. Spending must still be justifiable. In addition, every community needs to be protected from exploitation. Therefore, the researcher must be sufficiently scientifically knowledgeable on the subject or research and be conversant with the social priorities of the community as perceived by them. Further, evaluation of the research, whether treatment, intervention or theory, must show that it will improve the community's well-being and lead to increased knowledge.

Scientific Validity

The research design must be scientifically valid for research not to be wasteful and community participation not futile. This requirement implies that the researcher should have adequate scientific and statistical knowledge of the condition to be studied and be sure that the study is feasible. The principles and methods to be used, including statistical techniques, must be scientifically acceptable and produce reliable and valid data. Any research design and methodology that are not scientifically sound cannot be ethical. In other words, the work of the Ethics Committee begins from the examination of the scientific basis of the research. Once this aspect is found wanting, it will be a waste of scarce resources, time, and energy to proceed.

Fair subject selection

It is a matter of justice that the selection of research participants be fair. This condition requires that the researcher has appropriate scientific, ethical and legal knowledge to make the selection fair. Often, minors, stigmatised, and vulnerable subjects are targeted for risky study in which they cannot benefit, while the rich and influential persons who stand to benefit are left alone. An example is to conduct the trial of an expensive medication in a rural community that cannot afford the cost, only for the drug to be marketed among the rich. Justice will demand that such a trial be conducted among those who can afford the medication or given free or at low cost in the rural community where the trial took place.

An example was the trial of antiretroviral therapy for Human Immunodeficiency Virus (HIV) infection in developing countries. Since there is no cure for HIV, the world understood that treatment would be for life. The point had to be made that for any patient with the infection participating in the trial, and there must be an assurance that supply will continue for life, even when programs by implementing partners had come to an end. This is justice and fairness.

Favourable risk-benefit ratio

The research must be seen to benefit subjects and society. This is the same as beneficence, non-maleficence, or non-exploitation. It requires that the researcher must minimise risk compared to the enhanced potential benefit of the research. It also requires that if a clinical trial of a therapy involves using a placebo as a control, subjects with the severe form of the disease cannot participate, or the researcher should test the new therapy against existing standard therapy. Doing otherwise will place those with a severe disease on placebo in great danger. This is the principle of Clinical Equipoise.

Independent Review

Independent Review is required for public accountability and to reduce the influence of conflict of interest (COI). Conflict of Interest may be personal, financial, or professional. Special care must be exercised in be in industry-funded research in which the researcher may be tempted by financial gain. This is the job of the Institutional Review Board (IRB) or the Health Research Ethics Committee (HREC). Members of such a board/committee should be intellectuals, financially or otherwise independent, have scientific and ethical knowledge, and are not affiliated with the research. They are to examine the design of the research or trial, its proposed subject population, and the risk-benefit ratio. The committees should only be subject to review by regional or national boards and not the institution's management.

Informed (and Understood) Consent

Informed Consent is based on the principle of autonomy or respect for persons, which is the hallmark of research involving human subjects. Subjects must be provided with information on the nature and purpose of the research, its procedures, potential risks, benefits, and possible alternatives. The individual participant needs to understand this information and make a voluntary decision on whether to participate or continue with the study. In the case of minors, consent should be given by the parent or guardian, and assent should be obtained from the child who is old enough (older than six years). The Community-Based Association (CBA) should be invited to represent the community where a community is involved. Unfortunately, it is still common to have our patients used as research subjects without being informed, simply because they are 'captive'.

Respect for Potential and Enrolled Subjects

This involves the autonomy and welfare of the participant. Subjects enrolled in a study following informed and understood consent should be assured that they are at liberty to withdraw from the study without negative consequences. The researcher should protect their privacy through confidentiality during and after the study. If new risks or benefits are discovered during the period of the research, they should be informed. The results of the research should also be made available to them. The researcher is obligated to see to the welfare of the subjects during the period of the study.

Research Involving Animals

Interest had developed around the protection of animals used in the early phases of biomedical research. Particular areas include the welfare of the animals, ensuring that only the minimal number of animals required for research are recruited, and regulating the sacrificing of the animals after the research. Health Research Committees are now to include specialists in the care of experimental animals.

Material Transfer

Due to the globalisation of research, it is common for a researcher to ship blood, other body fluids and tissue abroad for research. Ethics demand that there must be evidence that such research will have clear and identifiable benefits for the community or country from which the material originates. Otherwise, such research will not be just. Secondly, such tissue transfer should involve Material Transfer Agreement (MTA) that will specify what the materials are to be used for and that new documentation will be necessary if the materials were to be used for additional purposes. Ordinarily, the ethics committee should review such an agreement before approval is given.

Publication Ethics

It is a wasted effort if research is concluded and there is no means of disseminating the results or findings. Ethics of publication should cover the following areas: Approval and Consent, Data Accuracy, Plagiarism, Submission, Authorship and Conflict of Interest. [20]

Approval and Consent

Researchers may need to show evidence if required that the protocol for the study received approval from the IRB or Ethics Committee before its commencement. Where the research involves a therapeutic trial, approval should generally be obtained from NAFDAC, especially when an existing agent is to be used for conditions for which it had not been approved. Depending on the materials to be used, approval may be required from appropriate regulatory agencies. An example is radiation. If journal editors suspect that necessary permissions have not been obtained, they reserve the right to request proof of such approval.

Just as for research ethics, informed consent is required for publication, particularly with research on human subjects, and journal editors may wish to confirm in case of suspicion. Furthermore, competition among journals and the classification of some as predatory has informed that journals are careful about their editorial processes. Researchers, therefore, have the responsibility to identify and avoid predatory journals. In determining predatory journals, pointers include: [21,22]:

a. Does the journal address align with the country of origin, or are mails professional and journal-affiliated written outside working hours or the country of origin?
b. Are members of the editorial board professionally aligned with the speciality of the journal?
c. Is the peer-review process clearly described on the journal's website?
d. Does the peer review process have rapid timelines?
e. Does the journal require payment of publication fees before acceptance of the manuscript?
f. Are the articles published consistent with the stated journal speciality?
g. Are the journal's claims of indexing by associations or committees on publication such as Committee on Publication Ethics (COPE) or the Directory of Open Access Journals (DOAJ) correct?
h. Is the advertised 'impact factor' accurate?

Data Accuracy

Data can be manipulated through equipment, materials, and processing. This manipulation constitutes research fraud. Research must not present data that do not exist either as fabricated data or falsified data. Images must not be modified to conceal the truth or give a wrong impression. Data must not be modified to produce *p* values that are not consistent with the original data. Some researchers who recruited fewer than the required sample size are in the habit of fraudulently multiplying the number of samples to achieve the required size and power. Experienced reviewers can detect fabrication and falsification, and journal editors have the right to request data sheets if they suspect manipulation or doubt is raised. Therefore, researchers must cultivate the habit of preserving all data from their studies.

Plagiarism

Researchers are not allowed to use previously published work of another author as their own without crediting or acknowledging the original author. When a large portion of another author's literal text or data is reproduced, it is known as clear plagiarism. Minor copying, on the other hand, is the reproduction of phrases from other people's texts. It is also possible to plagiarise yourself. These days, there are software that assists journal editors in checking manuscripts for plagiarism. The Committee on Publication Ethics (COPE) [19] views plagiarism as a serious offence whether detected in the review process or after publication. Researchers should acknowledge any public works referred to in their work.

Simultaneous Submission

Manuscripts should not be submitted to two journals simultaneously, particularly after

submitting a declaration to one that it has not been sent to another journal. This usually occurs when the author suspects another journal might publish the work quickly, but the danger is that the two journals might publish the manuscript. This type of scientific misconduct is better prevented by the author responsible for sending out the manuscript.

Duplicate Submission

Duplicate Submission occurs when a new manuscript is submitted containing the same hypothesis, data, discussion, and conclusion as previously published ones. Sometimes data are split for use in a second manuscript and sent to a journal outside the region of the original one or in another language. This is usually observed during assessment for academic promotion when all publications are presented. When detected, it leads to a reduction in the number of published articles to be assessed.

Unnecessary Self-Citation

Researchers should avoid the temptation to cite themselves unnecessarily to increase the citation index. While self-citation is expected if the subject of the new article is continuous with previous ones, it should not be done on unconnected works just to increase citation.

Authorship

Authorship of a research article is a significant achievement and prestige in the scientific community. Therefore, every author or co-author should have a substantial contribution to be accorded that role. To qualify for authorship status, one should have performed in one or more of the following roles:
conception and design of experiment; execution of the experiment; collection and storage of the supporting data; analysis and interpretation of the primary data and preparation and revision of the manuscript. Authors should read the section on 'Preparing a Manuscript for Submission to a Medical Journal' on the website of the International Committee of Medical Journal Editors (ICMJE). All collaborators must agree on the authorship from the onset, and authorship should be offered to all those who meet the criteria, including trainees. In certain circumstances, trainees and students are denied authorship, even of articles arising from their research that forms the basis of their dissertation. In some cases, supervisors unfairly assume lead or sole authorship. This should typically be seen as research misconduct.

Three types of authorship recognised as scientific misconduct include (a) Ghost Authorship, (b) Gifted Authorship and (c) Guest Authorship. Ghost authorship refers to one who contributed substantially to preparing a manuscript but is not credited with authorship or acknowledged. This may be because the individual was paid to perform that role, but there must be acknowledgement even then. Gifted authorship refers to giving co-authorship to someone who did not participate in the research because of affiliation to the department or the institution, such as head of department or friendship, or to assist in speeding up qualification for promotion. Guest authorship is according co-authorship to someone because his/her inclusion may facilitate acceptance of the manuscript by a journal.

Conflicts of Interest

As stated under research ethics, conflicts of interest could be personal, financial, social, or industrial. Journal editors expect all authors to declare known conflicts of interest so the editor can use discretion on how it can affect publication when it comes to publication. Failure to disclose conflicts of interest may jeopardise the success of the manuscript. This is particularly important where grants are involved or pharmaceutical companies have paid honoraria to the researcher.

Conclusion

The upward academic carrier movement is a natural impetus for research and publishing, so we will publish and not perish. But the speed

with which we want to arrive has given rise to the temptation to do it quickly and anyhow. Some academics easily fall for the cash-and-carry publications because they think the end justifies the means. The multiplicity and duplicity of journals and publishing houses have produced unhealthy competition and a "rat race" for predation in publishing. Naturally, academic institutions, in order to maintain their integrity and avoid predatory promotions and advancements, are generating criteria for acceptance of published works, and some are doing it in a way that impedes genuine advancement. In addition, the COVID-19 pandemic has highlighted the fact that science is not sufficiently insulated from politics and commerce. In the end, what we appear to be losing in the speed of advancement, hopefully, will be gained in greater integrity and confidence in the products of our research efforts.

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