Medical Research Misconduct Need Regulatory Reforms

Neeraj Bedi
Professor. Community Medicine, Bundelkhand Medical College, Sagar, Madhya Pradesh. Ex Associate Professor, Community Medicine, Gandhi Medical College, Bhopal, Madhya Pradesh, India

ABSTRACT
The medical research misconduct has become a global problem. Except from countries like the USA, China, and Germany the exact figures of misconduct are not available. The research misconduct include fabricating the data, falsifying data, and plagiarism. The irresponsible research practices are publishing research data more than once, conflicts of interest is not declared, selective reporting of data and including an author who has not contributed at all and many more. About 2% of scientists have been found to admit the fabricating the data and 33% researchers were involved in irresponsible research practices. There is no formal regulatory programs available to monitor the research projects. Few developed countries like the USA, Germany, and China tried to develop programs which can monitor the medical research misconduct. There is a need to develop a regulatory system at national and institutional level to regulate the research activity to ensure that good ethical and scientific standards are practiced by medical researchers.

Keywords: Ethics, irresponsible research practices, plagiarism, research misconduct

Definition
Research misconduct is being defined as the “Behavior by a researcher, intentional or unintentional that do not meet or fullfill the scientific and ethical standards.” While USA has a detailed research misconduct definition other European countries adopted shorter definitions. However, in 2010 in Singapore a second World Conference on Research Integrity attended by more than 50 countries resolved the definition of research conduct as “Researchers should report to the appropriate authorities any suspected research misconduct, including fabrication, falsification or plagiarism, and other irresponsible research practices that undermine the trustworthiness of research, such as carelessness, improperly listing authors, failing to report conflicting data, or the use of misleading analytical methods.”

The exact wordings of adopted conduct are quoted here highlighting the importance of good ethical and standardized practices during research in medical field.

It is generally agreeable that research misconduct includes fabrication i.e., cooking up results, falsification i.e., manipulating results and processes and plagiarism i.e., stealing work of others. It is also evident that medical research record may be more damaged by “irresponsible research practices or practices of questionable nature” than by the fabrication, falsification and plagiarism issues. The irresponsible research practices include publishing research findings more than once in pieces, not declaring the conflicts of interest, selective reporting of data by excluding outlying data, including an author in paper who has not contributed and many other things.

Problem of Research Misconduct
As research is a global activity so research misconduct is also a global problem. Wherever there is human activity there will be misconduct. There is often suspicion about the quality and results of research work done by some researchers. However, there is a lack of reliable data on the prevalence and incidence as well extent and distribution of research misconduct in medical...
field. Most of the countries have no formal regulatory programs available to monitor the research activities or research projects.\(^{(6)}\) Only a handful of developed countries have responded to research misconduct issues by developing programs for prevention, investigation, punishment, and correction. The United States of America, Germany and the Scandinavian countries have formal programs to deal with for research misconduct issues but still country like United Kingdom is not being able to respond in adequate manner.\(^{(1,7)}\)

Reliable data is not available about incidence/prevalence of research misconduct in different countries. Few systematic review and meta-analysis studies have tried to find out the problems of the research misconduct. According to one study 2% of scientists had themselves fabricated or falsified and 33% are found to be indulged in irresponsible research practices. Surprisingly, when they were inquired about other researchers’ misconduct it was interestingly answered that 14% of researchers fabricated, falsified the data and three quarters researchers did act for irresponsible research practices.\(^{(8)}\)

These data are mostly from the developed countries like USA, UK and others. Evidence based studies are not available from the developing and underdeveloped countries. But few reported sporadic incidences of ethical and research misconduct from developing and underdeveloped countries reflect the seriousness of the problem. A public interest litigation in Supreme court of India has highlighted the issue of illegal and unethical clinical trials resulting in deaths of 1727 between 2007 and 2010 in about 3138 clinical trials that took place in India.\(^{(9)}\) It also highlighted various irregularities in drug trials as the principal investigator (PI) of clinical trial was also the ethical committee member against the norms. There is no role played by ethics committees and no compensation offered to patients in case of development of side or adverse effects of the trials.

One private practitioner of India published dozens of papers in prestigious journals like BMJ, Lancet, Circulation and the American Journal of Cardiology. He was the first author on 28 full articles. Five large intervention studies were also published by him within 18 months.\(^{(10)}\) The editor of the BMJ was cautioned about the work by several researchers. The research misconduct was never investigated as author was self-employed and no organization came forward to investigate the matter. So British Medical Journal and Lancet in 2005 published “expressions of concern” about the studies in their journals.\(^{(11,12)}\) The work was ignored by the academicians and researchers but it illustrates the need of national and international mechanisms for investigating the research misconduct.

Similarly, a systematic review study for authorship misuse showed a 23% misuse in USA and UK while India, South Africa and Bangladesh showed authorship misuse in 38%, 64% and 60% of cases, respectively.\(^{(13)}\) Similarly retractions data form different countries provides ratio of data retracted for fraud to the papers published for some selected studies shows similarity patterns between developed and developing countries indicating that medical research misconduct is a serious global problem.\(^{(13)}\)

An interesting article belonging to South America discussed plagiarism from a different perspective. A study found that only ten research papers to be of research misconduct out of more than 190,700 papers search from 594 journals in 2008.\(^{(14)}\) However, the focus group discussions with researchers revealed that copying and pasting “text” was not taken as a very serious matter than copying “data” as English language was a communication barrier for publication in English journals. It was never thought to be against research integrity. Similarly a Chinese journal also found 31% of papers submitted was plagiarized but much of the unoriginal texts was referenced or standard definitions or others indicating not be plagiarized.\(^{(15-16)}\)

In 2009, in China the authors claimed in a randomized controlled trial that that transarterial chemo embolization together with radiofrequency ablation therapy was better than either treatment alone in patients with large hepatocellular carcinoma.\(^{(17)}\) This article was retracted from JAMA and readers raised serious concerns about the study. The investigations by the employer disclosed that the study neither had ethical committee approval and nor a well conducted randomized trial and that “conclusions drawn from the study are also not valid.”\(^{(17)}\)

China is the one of first countries to take the research misconduct very seriously and investigated all cases of alleged misconduct. In 2005, the National Science Foundation of China investigated 542 allegations of research misconduct. Evidence of misconduct was found in 60 cases. The main issues were data falsification (40%), plagiarism (34%), and data fabrication or theft (34%).\(^{(18)}\) Thereafter, the Ministry of Science and Technology of China took action and established the Office of Scientific Research Integrity Construction. This body is empowered to investigate cases of research of misconduct and take preventive and corrective actions.

A survey in non-communicable disease research centers in developing countries viz. China, Peru, India, South Africa, Nigeria, Costa Rica, Guatemala, Bangladesh and Tunisia, about research misconduct has shown little response to research misconduct. Only few countries like China, South Africa has both national and institutional systems to deal with research misconduct.\(^{(19)}\)
Research is being regarded as the essential focused area for development of medical field and most of the developing countries are now spending heavily on research in medical field. The international health policy also recommends the ‘health’ as core issue in every policy of country to achieve the universal health coverage. Thus it is imperative to assess the trust worthiness of the findings of the medical research conducted.

Conclusions — What Action Next?
Generally it is now felt among the academicians that there should be a national systems to deal with research integrity and misconduct. Although now many countries have ethics committee systems for approval of research proposals, but they are not very active. Their constitution is also very defective and researchers often influence the acceptance and lack technical expertise to deal with research misconduct. However, the countries also require well-managed health research systems to prevent, investigate, punish and correct any allegation of research misconduct and keep a strict vigilance on research activities. The main responsibility not lie only with research departments of Universities, but even big research institutes lack the technical expertise how to deal with research misconduct. All academic institutions must have teaching and training sessions for research methodology/ethical issues to update the students and staff at regular periodical intervals. Curriculum of undergraduates and postgraduates must contain the topics of research integrity and ethical aspects. Often the research institutes have profound conflicts of interest even if one researchers is accused of research misconduct. Therefore, a body at national level may help in providing research leadership and manage the conflicts of interest. They should be delegated powers to deal with any research misconduct. Awareness to various aspects of research misconduct and integrity is also required at different levels as most research institutes have a denial tendency. There should be exposure of research misconduct cases to entire research world. The beginning stage should be discussion and recognition of the problem of research integrity and misconduct. There cannot be a single system to deal with all types of research misconduct and every country has to develop its own system. The national and institutional systems can ensure that the ethical and scientific standards are being adhered by the researchers during research.

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