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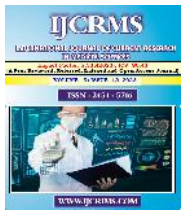

Review Article

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Scientific integrity issues in medical science and honorable solution

Dr. Anil Batta

Professor & Head

Department of Biochemistry

Muzaffarnagar Medical College, Muzaffarnagar

Abstract

Scientific practices, and medical and biological practices in particular, the persistence of certain moral values and/or standards and the priority attributed to them can change significantly, due to changes in society, people, the times, and/or environments, and they may be under strong tension. We therefore believe that a new theory of *ethics of science*, in a very specific teleological sense, may be required in this case, particularly in *medicine* and *biology*, in addition to *scientific integrity*. This ethical theory, through research, professionals, and structures in *ethics of science*— also called *medical ethics*, *research ethics*, or *bioethics* in the fields of *medicine* and *biology*—, should seek to identify and find specific ethical solutions to these tensions, applicable at a particular place and time, based on common ethical purposes and/or consequences. As a result, these specific ethical solutions may, or may not, lead to an evolution of common moral frameworks, which may or may not, be developed based on *scientific integrity*. In the fields of *medicine* and *biology*, this ethical theory is closely related to another theory, *global bioethics*, but with several new conceptual and methodological developments.

Keywords: scientific integrity, medical ethics, medicine and biology

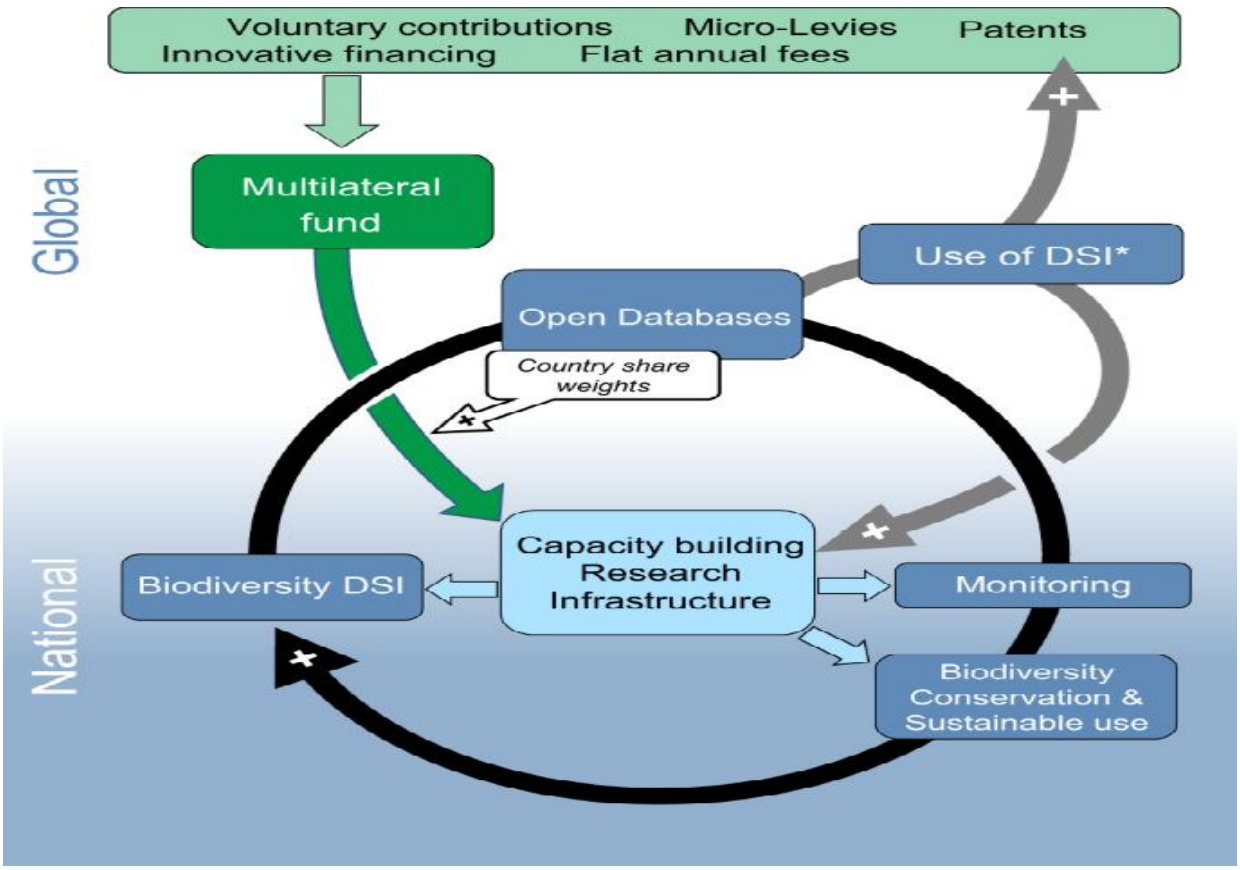
Introduction

It will be a daunting task to define the exact components of how reproducible research should be designed especially in the life and medical sciences. This is because of the great deal of variability in biological systems and the complex techniques employed in the design and execution of such studies. Although, it is not essential and expected to reproduce precise results, at least the major findings and underlining conclusions from research must be potentially validated from similar studies. Therefore, reproducibility is more or less the ability to draw similar conclusions from replicated studies. Also, in our field, reproducibility can be described as taking an existing dataset from a study, re-running the same analysis strategy that was used, and hopefully producing the same statistical findings, this is usually useful for spotting errors. On the other hand, replication is utilizing the same or very similar methods as an existing study to collect

new data, analyze it, and produce the same pattern of results to draw the same overall conclusions [8]. However, the last couple of decades have revealed shockingly the irreproducibility of several studies to validate their major conclusions. This was further heightened by the inability of the original authors to reproduce their experiments [2]. The manifestation of the reproducibility crisis became more visible in clinical trials of the increasing failure of novel treatment strategies, which were efficacious in diseased animal models [7]. A recent survey revealed that at least 70% of scientists were unable to reproduce studies from other scientists as well as the inability of at least 50% of researchers to reproduce their work [1]. The increasing concerns of this reproducibility crisis have triggered the implementation of policies and guidelines to safeguard research credibility and trustworthiness. Therefore, to provide solutions, it is important to identify the root causes of the crisis.

Factors that influence the reproducibility crisis

Scientific research is a complex process involving several stakeholders at multiple steps such as research design, ethics and legal framework, funding, methods, documentation, publication, and archival of research findings. Moreover, many scientists and researchers hope to reveal or identify novel findings and therapies [5]. Hence, multiple factors contribute to the irreproducibility of a study. These include but are not limited to, inadequate training of researchers in experimental design and methodology such as randomization, bias, replication, statistical analysis, variations in sophisticated medical techniques that are difficult to replicate, and variability in chemicals and reagents especially in experiments involving the use of antibodies. Additionally, the insufficient amount of time used for research, the bureaucracy and pressure to publish in high-impact journals to compete for research grants and positions as well as the lack of proper supervision and mentorship further exacerbate the reproducibility crisis [1, 3]. These may lead to researchers taking shortcuts, not transparently reporting their work, or even using questionable research practices.



Addressing the reproducibility crisis

Researchers are at the forefront of innovative findings. The same has been at the center of recent scientific misconduct in different scientific fields [4]. Although researchers and scientists play a dominant role in the research process, collaboration with multiple stakeholders such as academics, regulators, publishers, institutions, funders, and government is required to address the multifaceted reproducibility crisis. Moreover, the recent pandemic has exposed these issues, which indeed should be the foundation of science. We outline some suggestive remedies to this crisis by addressing the specific role of researchers and institutions.

Remedies

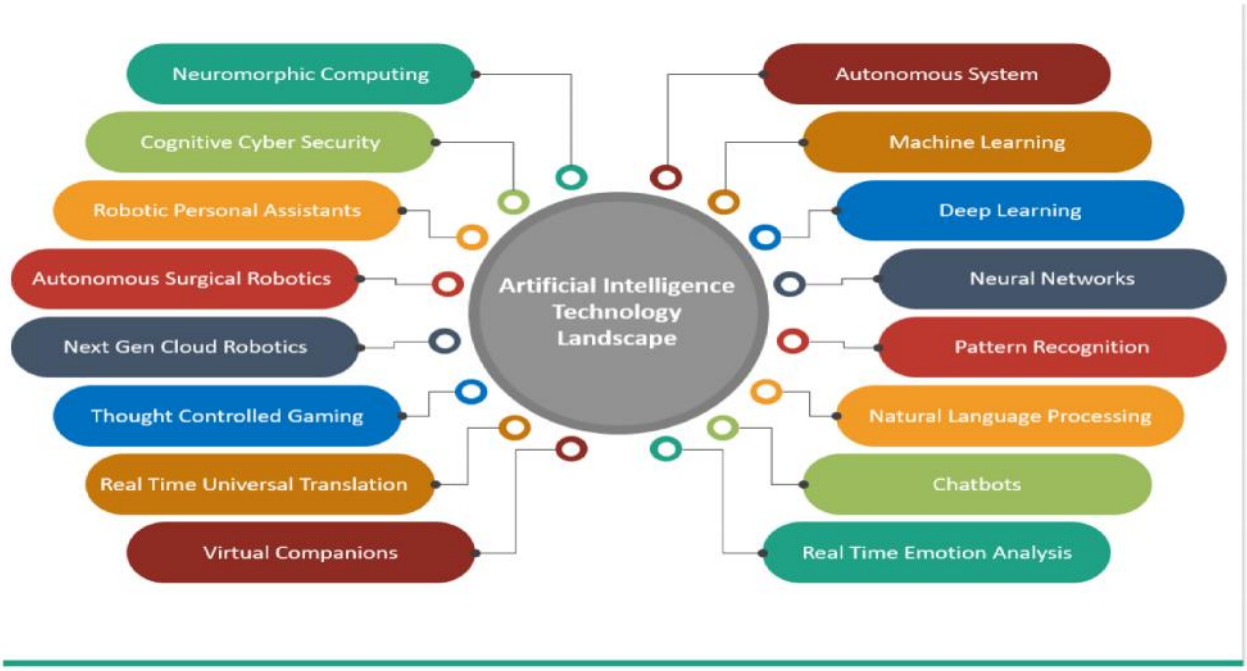
1. First, researchers should be more open to sharing ideas, methods, and data with thematic colleagues and the public. Researchers should devote more time to careful planning, design, and execution of scientific research including the use of appropriate experimental methods and statistical analysis, which are necessary to arrive at a good and reproducible research outcome. Though most researchers would probably like to do these things, they feel overburdened to the point that systemic pressures and misplaced incentives prevent them from doing these things.

2. Research group leaders and supervisors must provide adequate supervision, mentorship, and training to early career researchers to design good experiments from the onset. All research authors must be able to provide the raw data used in their study and should be made accessible to everyone without barriers. Possibly setting up and making accessible data repositories for published papers will allow for transparency and integrity in the research arena. Primary data is very crucial in research findings, hence avenues to store and avoid manipulation is essential. One way to ensure reproducibility of results is to have a clear and concise documentation. This could be done electronically or manually as in safe book-keeping of research data and findings which are openly accessible. Documentation could include open workflows, registered study protocols and methodology. These are important since documentation can be misrepresented if not accessible as part of shortcuts and poor research practices, thus maintaining the crisis. Within research groups, group leaders or supervisors must recheck storage of experimental results and when in doubt, experiments must be repeated by individuals or others in the laboratory to confirm breakthrough findings.

3. In ensuring the completeness of data in the context of publication, scientists and journal editors must ensure that data should be contextualized instead of over-generalized. Since good data also depends on proper laboratory management, established and standardized protocols as well as good and calibrated equipment with required standards must be routinely checked. With chemical analyses, standards may be analyzed together with the samples. By so doing errors could be detected and corrected. A periodic interlaboratory analysis to compare results in case of doubts is also helpful as this will help to ensure the reproducibility of results. Managers of research laboratories must ensure the implementation and enforcement of these measures.

4. Furthermore, research institutions must establish and allocate more training and teaching resources, particularly for early career researchers on the scientific research process including the experimental design, methods as well as analysis, management, and publication of data [7]. However, the training should not be limited to early career scientists alone but to technicians, mid-career, and senior researchers. Since much of the crisis can also be traced to mid-career and senior researchers engaging in questionable practices and shortcuts out of habits, because they have benefited from these over their longer careers. Hence, training should be provided across the board and can be incorporated into the mentorship training of young scientists, tenure positions, or funding schemes which will be crucial in helping scientists understand the ethical implications of their work. This allows researchers to dedicate and focus on the essential details of their study and eliminate research bias [2, 7]. In line with this, the United States National

Institute of Health developed and implemented a mandatory training course to promote reproducibility and transparency of research findings with a special focus on good experimental design for its fellows [3]. Also, extensive platforms must be provided to train researchers on the implications of research integrity as well as avenues to discuss challenges.



5. Research institutions must ensure the transparency and accessibility of research by incentivizing researchers who promote open science through the publication of open data of their research findings. These incentives could include long-term research contracts, promotion, assigning tenure positions, and providing easily accessible research grants. This will ensure a clear and focused direction in doing better and more productive research since withholding important data that may be timely and innovative to secure promotion, tenure position or funds to sustain their career could hinder innovative progress. Additionally, institutions must endeavor to have and implement policies on good scientific practice with a special focus on reproducibility. This includes putting in place measures that allow research employees to submit raw data upon request, which promotes transparency. Over-reliance on publication in high-impact journals to assign tenure positions and promote researchers to a higher career level must be reduced. Instead, institutions must establish standard structures focusing on research integrity and quality in assigning these positions. In addition to providing resourceful tools and materials such as online storage servers, and electronic laboratory notebooks, research institutions must reward, promote, and provide guidelines on the publication of negative results [2, 7].

Finally, publishers must promote the publication of unexpected data and findings. This is very important as within the scientific fraternity so-called novel results are awarded by fast publication whereas those which have so-called negative results are not published. Also, grant-awarding institutions should be open to giving different teams resources for the same work. In so doing one team becomes a check on the other. However, this can be very costly and difficult but the need to ultimately save more lives outweighs the cost when for instance many lives depend on research findings that could be translated into new therapeutic findings like breakthrough drugs. Giving different teams resources for the same work could also deny other researchers the opportunity to explore new areas of research and prevent the possibility of diversity in exploring new frontiers of research.

Conclusion

Scientific negligence should be problematized much more than it currently is in codes of conduct for scientists. Problematizing negligence is part and parcel of the logic of professionalism and is key for keeping and deepening the trust of the wider society in the scientific community. If the scientific community is to genuinely adopt professionalism as an organizational structure, it must find a way to include negligence provisions in codes of conduct. Without these provisions, the rationale for trust in the scientific community and for scientific autonomy cannot be justified.Yet at the same time, it is not easy to discern what precisely should be the path towards including negligence provisions. For some scientific activities—following procedures, or support activities such as reviewing—it may be relatively easy to identify standards compared to the core activity of innovative research. Nonetheless, even then there are considerable pitfalls, because, if done poorly, negligence provisions can lead to a drive towards control, which in turn can damage trust between scientific agents (both individuals and institutions). In this article we discussed pitfalls regarding the sanctioning system and expectations of precaution. In sum, negligence provisions should be included in scientific codes of conduct, but it is paramount that this should be done reasonably, as a means to enhance rather than diminish trust between scientists.

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