

# The crisis of ethics and integrity in Evidence Based Medicine and scientific practice

AMAR JESANI

This issue of *IJME* carries three essays and a letter on the current crisis in Cochrane, earlier known as the Cochrane Collaboration. Cochrane expelled one of its founder members, Peter Gotzsche, on September 13, 2018, and in protest, four other Governing Board Members resigned. The essays show that what happened was not merely a clash within an organisation, but involved some basic differences on approach to Evidence Based Medicine. While these issues had been simmering for a long time, the expulsion brought them sharply into focus in the public domain.

Peter Gotzsche represents an ideal example of a highly competent and committed scientist, acclaimed for the body of biomedical scientific literature he has produced. At the same time, he has had a very tense relationship with the biomedical establishment over the years because of his outspokenness, the courage to shout that the emperor has no clothes.

## Everything is not rosy in the “Republic of Science”

In the body of Gotzsche’s scientific work two strands are palpable:

First: the strict adherence to scientific methodology, scepticism and the bold pursuit of the evidence which are the hallmark of good science, and must not be allowed to be compromised. Throughout the current controversy I have not seen any evidence advanced by his critics to show that he compromised science in any of his work. The systematic reviews done with his contributions and under his leadership are still highly respected.

Second: that in the social and economic environment determined by the quest for higher and higher levels of profit by the companies sponsoring scientific research, scientists must have the courage to examine all data and information, not just what is made available in the public domain. They must also seek what is not made available, in order to make a balanced assessment of the evidence. This aspect is important because the use of scientific methodology is not a mechanical process but a tool for discovering the truth.

Both these aspects must be satisfied for good science. And yet, these aspects could be a source of tension, more so if science is losing the courage to pursue the truth.

I was reminded of the famous 1962 essay in *Minerva*, titled “The republic of science” by Michael Polanyi (1) where he argued: “The Republic of Science shows us an association of independent initiatives, combined towards an indeterminate achievement. It is disciplined and motivated by serving a traditional authority, but this authority is dynamic; its continued existence depends on its constant self-renewal through the originality of its followers.”

The dynamism of scientific authority is determined by the space that exists for scientists to ensure that the evidence being dealt with is not manipulated and that they have the liberty to challenge the existing evidence. No self-renewal is possible if evidence is controlled by the marketing divisions of companies, and is only selectively brought into the public domain and manipulated. That would violate the integrity of science and inhibit the dynamism of science.

## Evidence and ethics

Tom Jefferson and Lars Jorgensen (2) in their editorial in *BMJ Evidence Based Medicine* argue that the paradigm that relied on the evidence of clinical trials reported in the biomedical scientific journals “has begun to creak”. For journal publications compress the actual data more than ten times. Citing evidence from studies comparing the actual data of the research with the data in the articles published in the journal, they assert that “Evidence of distortion in the results of research is now overwhelming.” The meta-analysis and systematic review of the data published in journals, instead of providing critical original insights into the evidence, often end up reiterating and reinforcing the bias. The result is: “garbage in and garbage out” (2).

Indeed, evidence is the ethics of biomedical science. If insufficient evidence is made available, and whatever is made available

Author: **Amar Jesani** (amar.jesani@gmail.com) Independent Consultant Researcher and Teacher in Bioethics and Public Health, 310 Prabhu Darshan, 31, Swatantrya Sainik Nagar, Andheri West, Mumbai 400 058, India

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is selective and manipulated, then there is a violation of science as well as ethics. The powerful companies sponsoring research and controlling the healthcare industry have done a disservice to science by not making all the data of clinical research public by calling them “trade secrets,” and sometimes deliberately suppressing data to protect the profits of commodities marketed by them.

Since its establishment in the early 1990s, Cochrane has emerged as an authority in the science of Evidence Based Medicine (EBM). The science of EBM is determined by the methodology it uses to assess evidence from the data generated by multiple studies using different kinds of methods. The demand that all research data be made available in the public domain is, therefore, meant to strengthen the science of Evidence Based Medicine and institutions such as Cochrane.

Unfortunately, the current leadership of Cochrane has chosen to weaken its commitment to the transparency, openness and integrity of evidence by expelling the key dissenting voice, Peter Gotzsche.

### **The Cochrane crisis and bioethics**

The ethics of evidence and the integrity of scientific practice are at the core of the discipline or sub-discipline of research bioethics. The exposition and elimination of forces vitiating them are, therefore, legitimate areas of intervention for bioethics or for practitioners of bioethics.

While scientists and editors of biomedical journals have hotly debated the current crisis in the biomedical journals, I was surprised and disappointed not to find mention, let alone analysis, of this crisis in most of the leading bioethics and medical ethics journals. We hope that in the coming times, this situation will change.

*IJME* believes that bioethics publishing cannot be an indifferent witness to the events changing Cochrane because they involve issues of ethics, integrity, freedom and the openness of science. The material published on this subject in this issue is only a modest contribution to the bioethics debate. We hope that more scholars – observers as well as protagonists of these events – will write on this subject. *IJME* is, of course, keen to publish more such discussion.

As this editorial was being written, news came in that Peter Gotzsche, in spite of his expulsion from Cochrane, removal from the Nordic Cochrane Centre he headed, and dismissal from his position at the hospital in Sweden, will be launching a new institute for scientific freedom. (3) We hope more such efforts will be made by scientists to protect scientific freedom and integrity.

### **References:**

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