NATIONAL BIOETHICS CONFERENCE

Can virtue prevail? Safeguarding integrity in medicine and science.

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Introduction

I have been given the privilege and opportunity of summing up one of the major ethical issues that has been thoroughly explored in this scholarly conference. Can science and medicine retain or recover their ethical integrity? Let me start with a disclaimer: there are no easy answers to the dilemmas of unethical behaviour in contemporary medicine and science, and I certainly would not aspire to provide one. What I can offer, perhaps, is an international perspective on these troubling issues, issues that are by no means unique to India or to Asia, but are evident throughout the world. After briefly describing the range and depth of the problems, I shall offer a set of possible responses. However, how these might apply here in India will depend on both realism about what can be achieved and on the professional and political will to create genuine change. The prayer used by Alcoholics Anonymous perhaps applies here: we need "the *serenity* to accept the things we cannot change; the *courage* to change the things we can; and the *wisdom* to know the difference".

Let me begin by explaining the meaning of two key terms in my title: "virtue" and "integrity". There is a tendency to see virtue as some kind of exceptional characteristic, possessed by just a few individuals, the saints and heroes of our times (Aung San Su Kyi, perhaps, or Nelson Mandela). But this is not how I believe we should use the word. In my writings about virtue in medical ethics (1). I have started from the Greek word for virtue, *arête*. This term refers to the essential nature of a thing, be it a material object, a human being, or a human activity. Thus the virtue - the essential nature - of science is the honest and unbiased pursuit of the truth; and the essential nature of medicine is the committed and consistent effort to enhance the health and wellbeing of all. When these central purposes are ignored or betrayed, science and medicine become merely instrumental goods, without worth in themselves, merely subservient to other ends, such as economic gain.

Secondly, the meaning of "integrity" derives from its root, integer, that which is complete in itself or indivisible. Thus, "integrity" refers to wholeness, singleness of purpose, and so to trustworthiness and transparency. Conversely, integrity is totally sacrificed when there is deception, hypocrisy and fraud. I believe that the majority of doctors and scientists do show admirable integrity. They are committed to the welfare of patients ahead of personal gain, and to the disinterested pursuit of scientific knowledge without fear or favour. But, unfortunately, we are seeing increasing evidence of the destruction of such integrity, largely as a result of economic and political pressures on science and medicine. So I must now turn to the evidence for this tragic loss of ethical trustworthiness.

Virtue denied

I shall deal briefly with two different aspects of this betrayal of virtue: unethical health research; and fraud in scientific research and publication. Both of these have been fully explored in this conference, so I can summarise the main points quite succinctly.

Health research

There is increasing awareness here in India, and also in many other countries, that all is not well with many aspects of health research, especially with clinical trials. There are of course international declarations and guidelines designed to regulate health research, and several countries also have legislation specifically designed to prevent unethical clinical trials. But a number of factors have led to these guidelines being ignored or circumvented. The first is the *outsourcing* of trials to resource-poor countries by the major pharmaceutical firms. It has been estimated that after the US Food and Drug Administration (FDA) allowed companies to submit results from overseas trials in their applications for approval, about a third of Phase III trials by the major US drug companies are now conducted outside the USA (2). The impetus for this is clearly economic, since trials can cost as much as 10 times more in high income countries than in low income ones. A second factor is that the drug firms then hand over these trials to contract research organisations (CROs) to carry out all aspects of the work, including ethics approval and recruitment, thus staying at arm's length from what actually happens on the ground. A third factor is that many of the countries in which these trials are run do not have an adequate system for research ethics appraisal. (It has been shown, for example, that the Indian system is inadequately resourced, dominated by professional members and under the control of the institutions, rather being genuinely independent (3).) A fourth factor is that drug regulatory authorities in some countries lack genuine independence from the companies sponsoring the trials and so they grant licences too easily after inadequate trials in the location, or even after *no* trials! A damning report on this problem was presented to the Indian parliament in May of this year (4). Finally – and perhaps most significantly of all – there are major conflicts of interest in the

physicians, hospitals and private clinics conducting clinical trials, especially in resource-poor countries.

When doctors' salaries are low and when hospitals are in need of extra resources to be viable economically, the money earned from clinical trials can provide a major inducement to recruit patients, who themselves can be enticed by the prospect of free medicine and medical care. Of course, *if* the trials themselves are safe and if the recruitment of patients genuinely respects the requirements of ethical codes for free and fully informed consent and for putting the welfare of subjects above any other factors, then this may not be quite such a major concern. Unfortunately, there is ample evidence to suggest that, worldwide, many clinical trials fail these minimum standards. Consent is not genuine and breaches of the guidelines are blatant (5). Thus, for those doctors and medical facilities involved in such activities, virtue has been denied – the welfare of their patients has not been their first consideration.

Scientific fraud

Turn now to scientific fraud- the betrayal of the integrity of the scientific enterprise itself. There have, of course, been some high profile cases, of which the best known is perhaps that of the South Korean stem cell researcher, Hwang Woo-Suk. In 2004 and 2005, he published claims that he had succeeded in creating the first cloned human embryo and had derived a stem cell line from it; and later, that he had established 11 "patient specific" cloned stem cell lines. These claims were subsequently shown to be totally false, since there was in fact no match between the allegedly cloned cell and the donor, and no match between the cell lines and the embryos from which they were said to be derived. Unfortunately, false claims of this kind, and other forms of cheating in science, such as skewing results, inventing data, plagiarism, and false claims to authorship, have been found in many surveys to be widespread internationally. In January of this year, a study was published in the *British Medical Journal,* which revealed that 13% of the 2,782 doctors and academics surveyed had firsthand knowledge of research misconduct and 6% had knowledge of misconduct in their own institutions that was insufficiently investigated (6). These findings have been replicated elsewhere. For example, an article in *Nature* published in 2005, under the title 'Scientists behaving badly', showed that the incidence of behaviours like changing the results of a study in response to pressure from a funding resource was as high as 20%, and inappropriately assigning authorship credit as high as 10%(7).

Why is this happening, and, most likely, happening to an increasing extent? We can see a whole set of pressures leading to such blatantly dishonest behaviour. The first is the growing tendency of governments to insist on early and economically beneficial outcomes from the research funding they provide. Very often economic gain seems to outweigh any interest in the integrity of the science, and this stress is increased by requirements to create partnerships with industry, whose aim is, of course, the maximisation of profit. Then there is the increasing competitiveness of science – the 'publish or perish' mentality – which makes people create phoney resumes and lists of publications in order to get ahead, or even to survive at all in academia. The influence of commercial funders can also actively encourage dishonesty (as illustrated by the survey in *Nature*). A powerful example of this is the practice of "ghost writing", when the funder writes the paper (supportive of course of its product), but a prominent person in the field has it attributed to him or her, often for a fee. Another example of industry pressure is control of publication to suppress or conceal unfavourable results. Finally, the media play a significant role here. Always hungry for a "break through"', they may tempt doctors and scientists to give (undeserved) glory to their native country by making false claims to novel discoveries. (This seems to have been the main cause of Hwang's fabrications.)

Can virtue prevail?

In face of such depressing evidence of the widespread betrayal of medicine and science, should we give up any hope of the restoration of virtue? The forces sustaining these vices in public and professional life are powerful indeed, so we cannot hope for perfect solutions. But we can try what the philosopher, Karl Popper, called "piecemeal engineering". Things will not change overnight, but we can take some steps to try to stop the rot. These are: better laws and tougher regulation; protection of whistle-blowers; consistent policies by scientific journals; and education of the young generation of doctors and scientists.

Legislation and regulation

Laws governing clinical research and the conduct of science vary greatly from country to country, and even when there are laws they are often breached because of inadequate regulation and monitoring, or the absence of effective penalties. We need greater international effort on this, looking at best practice and getting some real control of the multinational research industries. One model could be the setting up of national Offices of Research Integrity (on the American model), but, of course, if these monitoring bodies have no real powers to penalise or are inadequately resourced, then it will make no difference. Equally, professional bodies that have statutory powers need to use them! Poor research practice seems to be rarely, if ever, properly exposed and penalised. Why, for example, are prominent academics not punished for agreeing to the outright deception of ghost authorship, when their own students are punished for the same misdemeanour – plagiarism? (Goldacre makes this point very effectively in his new book (5).)

Protecting whistleblowers

Those who have the courage to expose corrupt or dishonest practices are often subsequently ostracised and may lose all career prospects. Thus the problems will never be fully dealt with so long as it is easier and safer to keep quiet about what is going on. So every institution must have a clear and effective policy for protecting such people, as well as having mechanisms to prevent malicious and unfounded accusations.

Journal policies

Although journal editors have made promises to more rigorously detect and expose scientific fraud, there are still too many instances of this not being done effectively. The website, Retraction Watch (http://retractionwatch.wordpress.com/), has revealed the astonishing numbers of papers retracted from academic journals (over 200 a year at least), yet some journal editors refuse to publish the reasons for the retraction. This volume of retractions suggests that the peer reviewing process is significantly flawed, and that some journals are failing to ensure the highest standards in the papers they publish. So long as false claims and deceptive trial findings continue to get published in high impact journals, these dishonest activities will continue to corrupt both medicine and science.

Education

Finally, there needs to be a consistent effort to prepare young scientists and doctors for the ethical hazards that lie ahead for them. It is only recently that modules on research ethics and research integrity have been introduced into medical and scientific courses, and they are still far from universally present. Unless the problems I have identified are to be allowed to increase exponentially, such educational initiatives should become mandatory worldwide. Then we might at least place some hope in the future generation acting more ethically than is now the case with many of their mentors.

Conclusion

So, can virtue prevail? We have to believe that it will, for, otherwise we will witness the increasing corruption of medicine and science by practices which undermine their very *raison d'etre*. In that doomsday scenario, all that will matter is commercial gain, and institutions which are fundamental to our civilisation and to our health and welfare will lose all credibility.

It is up to us never to let this happen.

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Questions of ethics in public health policy

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Most discussions in public health policy revolve around the setting of priorities and issues of technological choice and programme design in achieving these prioritised outcomes. Priority setting and choice of strategy are political choices. They are negotiations between what the public perceives, what public health experts pronounce, and the perception of interest groups – or stakeholders, as they are more often referred to – of the impact of any particular choice. Here, I set out to examine the choices of priorities and strategies using an ethics lens.

I use the term "strategies" to be inclusive of choice of technology, programme design and systems designs. And when applying the ethics lens, one does so while being careful to note that questions of ethical values are historically and culturally determined and vary across contexts (but there is clearly a gradient) between what would be completely acceptable or unacceptable except to a small minority of fundamentalists at either end. So this discussion is situated in our context today, in early 21st century India – a rising economic and political power - which also remains one of the nations with a large burden of poverty and ill-health.

Questions of ethics in public health policy can be analysed from the relationship of the state to the individual and the community. One dimension of this relationship is the state as a coercive instrument. Classical neoliberal thought will see this role as predominantly negative and as an interference in market mechanisms – but inevitable and to some extent necessary – for safeguarding property and ensuring that contracts are adhered to, and so on. At the other end, socialist perspectives see the role of the state as a coercive instrument wielded by an economic elite to secure both its own interests and the consent and obedience of the majority.

The other dimension of this relationship is the state as accountable for the health of its citizens. This was so clearly articulated by the Alma Ata Declaration: "the attainment of the highest level of health is a most important worldwide social goal… Governments have a responsibility for the health of their people which can be fulfilled only by the provision of adequate health and social measure". The accountable state matches with the rights perspective, though it is only in a socialist or social democratic persuasion that it would be seen as the purpose of governance. In the neoliberal state, where huge economic