

Research ethics

India is set to see a sharp increase in medical research. There has also been a rise in social science research in health. This raises a number of important ethical implications that merit serious discussion.

Research contains a number of inherent tensions: between the rights of the participant, the scientific interest of the researcher, the interests of commercial organisations, and the perceived social need. It often involves collecting personal information from people, submitting them to potentially risky situations.

Among the questions research poses are: is it acceptable to harm a few in the name of the larger good? And how do those who play the dual role of provider and researcher resolve the conflicts between their different obligations? How does the source of funding influence the choice of research question, the design of a study and the manner in which it is carried out? And how should research be conducted in settings where socio-economic inequities, resource constraints and other institutional limitations prevent the effective use of the knowledge gained?

Some of these problems are addressed by ensuring that all participants give their voluntary and informed consent, and by ensuring that research is conducted according to established guidelines, with ethical review and monitoring. And since the purpose of research is to add to the body of knowledge, fraud has implications for what is eventually practised. Fraud must be prevented by setting up institutional mechanisms. And research must be conducted in an environment of respect for colleagues and a fair recognition of their contributions.



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Research on hire

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Medical research has always been closely linked with business interests and these links are growing stronger over the years. Pharmaceutical companies have enlisted medical professionals in different settings, from general practitioners to consultants at large hospitals, in their research endeavours. Commercial medical research has proved lucrative for medical professionals and institutions. Universities view industry-funded clinical trials as a source of funds for their own research activities. However, such arrangements can compromise public interest. Moreover, 'collaborative' research is negotiated on terms unfavourable to the developing countries which serve as sites for research. The author describes the excesses of the industry and of physicians. He goes on to address the problems of out-sourcing research to developing countries with particular emphasis on India.

I recollect one of the first lectures in my first year of medical college where my venerable professor thundered: "... the first thing that a doctor should have is confidence. If you kill a patient, kill him with confidence." This is a classic expression of the necessity felt by the medical profession to maintain a veneer of confidence, even in the face of relative uncertainty.

In such a setting, medical technology is often used, not as a legitimate tool for diagnosis and treatment, but as a prop to hide inadequacies regarding knowledge about what constitutes the best course of action. In order to protect themselves from the anxieties that would otherwise accompany their relative ignorance, the profession seeks succour by immersing itself in the mindless pursuit of 'advanced' technology. The use of technology becomes an end in itself rather than a means to relieving human suffering. The last century has given us X-rays, ECGs, sonography, computerised

scanning and much more. Yet, instead of clearing the prevailing chaos in medical practice, many of these tools have compounded the chaos. Not because it was inevitable, but because control over these technologies has been the driving force behind the immensely profitable health care industry. Patients are over-investigated, over-diagnosed, over-treated and under-cared-for because the practice of medicine has to play second fiddle to large corporate interests.

Contract research

Medical research is often organised, paid for, commissioned or subsidised by the drug industry. The companies commissioning such research are only looking for conclusions that will enable them to market their product and reap profits. Nowhere is this more apparent than in the manner in which medical research is conducted in the 'seat' of the pharmaceutical industry, the United States.

An estimated 2 million Americans got hooked on to Redux (dexfenfluramine), a new anti-obesity drug marketed in the US by Wyeth-Ayerst, after it was approved by the US Food and Drug Administration (FDA) in April 1996. At the peak of its popularity, doctors were writing 85,000 new prescriptions a week. But a little more than a year after the drug's introduction, this craze collapsed, as patients began to exhibit symptoms of damage to their hearts and lungs. Fearing an epidemic, the FDA banned the drug in September 1997 (1). The manner in which 'scientific' evidence was created in favour of Redux is a shocking indictment of the system of medical research. In 1994, Wyeth had signed a \$180,000 contract with a medical publishing company called Excerpta Medica that offered pharmaceutical companies an invaluable tool: readymade scientific articles placed in leading medical journals and carrying the signature of influential academic leaders. Excerpta laid out for Wyeth a schedule of nine articles, each with a carefully crafted message aimed at a targeted audience, from primary care physicians to cardiologists to nurse practitioners to pharmacists. The articles had a 'writer' and an 'author', but they weren't the same person. The writer was a freelancer who was paid \$5,000 to actually write the articles. The 'author' was often a top university scientist who was paid \$1,500 to review the work and assign his or her name to it for publication.

The Redux story clearly focuses on the growing reliance of university scientists on corporate funding. Clinical research is now a multi-billion-dollar industry, with hundreds of testing and drug companies working with thousands of private doctors. Patients have become commodities, bought and traded by testing companies and doctors. The number of private doctors in research in the US since 1990 has almost tripled, and top recruiters can earn as much as \$500,000 to \$1 million a year. Reports of fraud in drug trials are pouring in. Such abuses point to weaknesses in the new system that has developed in recent years for testing experimental drugs. No longer does the pharmaceutical industry rely on career researchers at academic medical centres, whose professional reputations are forged on the quality of their data. Rather, the industry has turned to thousands of private-practice doctors for whom testing drugs is a sideline for making money.

Research in developing countries

Medical research in the developing world suffers from the problems of underdevelopment, on which are superimposed the ills of a neo-colonial approach assumed by external research funding. In the developing world, research is poorly funded, monitored and prioritised. The situation is compounded by foreign domination in setting research priorities. While globally medical research is fuelled by corporate interests, the market for medical technology and pharmaceuticals in the developing world is very small. The size of the Indian pharmaceutical market, for example, is less than one-tenth of the market in the US or Japan. As a consequence, donor-driven research in developing countries (largely corporate-sponsored research) focuses on areas of interest in their home countries. Tropical medicine (itself a colonial construct) has a long history of descriptive studies that benefit researchers but have no direct implications for participants. For example, a bibliography of research up to 1977 in Papua New Guinea identifies 135 publications that describe Melanesian blood groups but only 25 concerned with treating malaria (2).

Different 'styles' of foreign donor-driven research are prevalent (3). There is 'postal research' where western researchers request colleagues in developing countries to courier to them biological

samples. There is 'parachute research' where researchers travel to developing countries for short periods and take back biological samples. The most prevalent is the practice of maintaining 'annexed sites' for field research, led and managed by expatriate staff. These annexed sites attract promising academics away from national institutions, and their research findings are infrequently translated into policy and practice. Research fellows in annexed sites may receive good training there but few return to national institutions. In a welcome development, India has recently forbidden annexed sites research and outsiders are now obliged to work through Indian institutions. However the long-term advantages of this move will, in all probability, be frittered away given the encouragement being provided to public sector R&D institutions to undertake contract research for corporate entities.

Drug companies have been known to perform research in developing countries that do not conform to the Declaration of Helsinki and could not be conducted in the developed world. Reasons quoted for conducting research in these countries, rather than developed countries, are lower costs, lower risk of litigation, less stringent ethical review, the availability of populations prepared to give unquestioning consent, anticipated under-reporting of side effects because of lower consumer awareness, the desire for personal advancement by participants, and the desire to create new markets for drugs. The commercial secrecy that surrounds early clinical research, and safety and dose ranging in phase 1 trials in paid normal volunteers (that is, poor volunteers), means that much preliminary research is unpublished, particularly when adverse effects are high and further development is abandoned (3).

Medical research in India

There is, however, no denying that India (as a consequence of its size and ability to pledge greater funds) is different from most developing countries. Real science and research is done mostly with public money and mostly in non-profit institutions. But such indigenous research funding is still too small and too badly organised to address local priorities. A report published in 1997 in *Current Science*, a journal of the Indian Academy of Sciences, suggested that most medical research in India is unrelated to the

country's major health problems. The report, based on an analysis of research publications from India indexed in the Medline database, said that achievements in research have "little influence" on health care delivery. It lamented that research seemed to be concentrated in the fields of tertiary health care and new biology (4).

There also exists a problem in defining local priorities. For long the two thrust areas for medical research in India have been vaccine research and research on contraceptive technologies (and, recently, reproductive health). Both priorities can be contested on the ground that they emanate from a view of public health that is technocentric – vaccines as 'quick-fix' remedies for communicable diseases and contraception to control population growth. Given the hype surrounding both these concerns, government-funded research in these areas has scant regard for standard ethical guidelines.

Unethical and dubious

The decades of the 1980s and 1990s have thrown up numerous instances of unethical and dubious research in the country. Research on long-acting hormonal contraceptives like Net-En, Depo Provera and Norplant have been conducted without observing ethical requirements like informed consent and the need to follow up participants.

A team headed by Dr G P Talwar at the National Institute of Immunology (NII) persisted for years with trials to develop a contraceptive vaccine despite criticisms that these trials were being run unethically. The vaccine passed through phase 2 clinical trials in the late 1980s. Only 80 per cent of the women who received the vaccine showed the adequate response necessary for contraception. More importantly, according to published reports on the trial, only 94 out of 162 women in the trial 'volunteered' for long-term follow-up. The Indian government did not give approval for phase 3 clinical trials of the vaccine but continued to fund the research on contraceptive vaccines. The trials were put into 'cold storage' only when Dr G P Talwar retired from the NII. In 1998 it was revealed that the Institute for Cytology and Preventive Oncology had left cervical dysplasia (a pre-cancerous condition) untreated in 1, 100 women to study the progress of the disease, without warning them or taking their consent. In at least nine women the lesions progressed

to invasive cancer, and 62 women developed localised carcinoma of the cervix before they were treated. The study had been sponsored by the Indian Council for Medical Research, whose function is to lay down the ethical guidelines for medical research. The investigators said, in their defence, that they did not obtain written consent because most of the women in the study were illiterate and also because written consent was not mandatory when the study was launched (5).

In 1997, the scandal surrounding trials on quinacrine sterilisation forced the Supreme Court of India to step in. Quinacrine was used in the treatment of malaria till it was replaced by better drugs. Some time back there was renewed interest in its use in a method of 'chemical' sterilisation. In June 1994, the WHO Consultation on Female Sterilisation Methods categorically stated that human trials with quinacrine should be stopped forthwith pending the outcome of toxicological studies. In India, quinacrine sterilisation was carried out in the 1990s with "hundreds of doctors involved" according to an early convert to the cause, Dr Biral Mullick. Coordinating the supply of drugs and equipment in the country was Dr J K Jain, former MP. There were widespread protests against these trials. The government of India denied granting approval. Finally, bowing to the public outcry, quinacrine sterilisations were banned by the Drug Technical Advisory Board in 1997 (6).

There is a discernible pattern in all the above instances. All of them pertain to research on contraceptive technologies, reproductive health and vaccine research. More importantly, all of them (except in the case of quinacrine sterilisation) have been conducted in public-funded institutions using public money. They point to the extreme laxity in existing regulatory institutions and mechanisms and also to the tendency of such institutions to submit themselves to pressures when faced with so-called 'national priorities'. Government-sponsored (or -approved) research in India seems to have been fraught with equally potent dangers as corporate funded research is globally.

The anarchy in medical research in the country is typified in three recent examples, only one of which has received some publicity. The last pertains to a clinical trial conducted on human subjects in the Regional Cancer Centre (RCC) in Kerala, with an experimental

drug in advanced oral and cervical malignancies. The trials were conducted in collaboration with the Johns Hopkins University in the US. The drug used, M4N, is an active principle of ‘chaparral tea’ made from leaves of the creosote bush, a common American desert plant. Although chaparral tea has been used over the years as an herbal remedy for cancer, it is also known for its toxic effect on the liver. While the trial was conducted in 1999 and 2000, the application for permission to conduct the trials was forwarded to the Drug Controller of India only in February 2001. Further, the Ministry of Health and Welfare states that the RCC was granted permission to import M4N from Johns Hopkins only in February 2, 2001. Apart from these procedural problems it now appears that the trials ignored basic norms regarding informed consent. Further, a preliminary enquiry indicates that subjects enrolled in the trial were given the experimental drug in preference to established treatment regimes, a clear violation of the Declaration of Helsinki on research on human subjects. The trials had not been approved or reviewed by any of Johns Hopkins’ institutional review boards concerned with the protection of human subjects, in spite of the Centre’s claims that the permission for the trials were granted on the basis of “pre-clinical and other relevant data”.

Even more bizarre is the report of a trial of another ‘anti-cancer’ cure conducted in Calcutta in 2000. The trial was conducted on 24 patients by a team comprising a private medical practitioner and a group of non-medical scientists at the Indian Association for the Cultivation of Science (IACS), a non-clinical organisation. The results of the clinical trial have been published, of all places, in the *Indian Journal of Physics* (7). The journal, coincidentally, is run by the IACS. The paper acknowledges that the trial was conducted through funding from the Council of Scientific and Industrial Research (CSIR) and the department of science and technology and had the approval of the institutional ethics committee of the IACS. Clearly approval was not obtained from any body that is authorised to give such approval. The paper goes on to exhort that “We (authors) sincerely hope that researchers and clinicians with open minds will immediately make a concerted effort to use and to further improve the present formulation and treatment.” Worse still, the main ingredient of the drug formulation is a chemical

(methylglyoxal) purchased from the American warehouse supplier Sigma Chemical Company, whose chemicals are laboratory grade, not intended to be used as drugs, i.e., they are not biological grade.

The third instance is the permission granted by the Ministry of Health and Family Welfare to conduct trials of the long-acting hormonal contraceptive, Netethisterone Enanthoate (NetEn), in 12 medical college hospitals across the country in 2001. The ministry has not released any details regarding the purpose of the trial or the protocols to be followed. It is being presumed that the trials are a prelude to introduction of NetEn in the country's population control programme. Various health and women's groups have represented to the National Human Rights Commission (NHRC) against conduct of the trials on the grounds that the introduction of NetEn in the mass population control programme is unacceptable given the drug's potential toxicity and the absence of a monitoring mechanism.

What informs medical practice?

There is possibly an even more fundamental conundrum that faces medical research in a country like India. Research output is, as yet, too insignificant and too unfocused to inform the practice of medicine in the country. The latter continues to be largely determined by medical research conducted in the West. This situation has been given a novel twist recently by Dr Samiran Nundy in a letter to the *British Medical Journal*. He argued that given the state of medical research in the country it made more sense to first attempt to regulate medical practice in the country rather than regulate medical research: "That medical research in developing countries is meagre and of generally poor quality is well known, and it has not improved in the past 20 years. Should one therefore discuss research ethics in developing countries when they barely exist? In my view the ethics of medical practice is more important. To see how the public can be safeguarded from an inefficient and often corrupt medical system and receive comprehensive health care of a reasonable quality is paramount." (8)

Such issues arise today because the research institutions in the country have singularly failed to provide any cogent direction to the practice of medicine. It would almost appear as though the two

work in entirely different paradigms. Unless there is, at the least, an attempt to marry research with practice, public perception of medical research will continue to range from suspicion to derision.

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Ethical considerations in AIDS vaccine trials

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Medical research today has several stakeholders across the globe. And the developing world now encourages research done by these countries in collaboration with western governments or pharmaceutical companies. International research poses particular ethical challenges of distributive justice and protection of participants. Such concerns have also arisen in the context of AIDS vaccine trials. Are they testing HIV strains prevalent in developing countries? Will participants who turn positive during the trial receive long-term treatment and care? What are the standards of care that will be provided to the control groups? In this article written before the Indian government launched trials of an HIV vaccine, the author describes the problems anticipated and encountered and the ways to protect research participants.

The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated (1) at the end of 1998 that around 33.4 million people were living with Human Immunodeficiency Virus (HIV) infection all over the world, over 90 per cent of them in developing countries. However, in developing countries, promising newer therapeutic options for HIV/ AIDS are unaffordable, and prevention through behavioural change has not been successful due to illiteracy and low level of awareness. On the other hand, prophylactic vaccination has shown remarkable success in the control of many communicable diseases. Therefore global efforts are ongoing to develop vaccines (3) to prevent infection among persons exposed to HIV (prophylactic) or prevent HIV-infected persons from progressing to AIDS (therapeutic vaccine).

Present status of AIDS vaccine trials

Developing a safe and effective AIDS vaccine has been a challenge due to a lack of understanding of the correlates of protective immunity to HIV, the absence of an appropriate animal model, strain variation and difficulties in phase 3 evaluation of candidate vaccines (4, 5).

Any new vaccine has to be evaluated at many levels: Phase 1: safety, Phase 2: safety and immunogenicity, Phase 3: large-scale trials for efficacy and Phase 4: post-marketing surveillance. Over 34 different HIV candidate vaccines have been tested in phase 1 trials and three in phase 2 trials (6). Difficulties in initiating large-scale efficacy trials of preventive AIDS vaccines include unanswered ethical issues regarding how such trials would be conducted, fear that trial failure would make successive trials impossible to conduct, and controversy among the scientific community regarding the usefulness of the available vaccines to protect against HIV infection (7).

However, with the continued spread of HIV despite educational efforts, and evidence of the safety and efficacy of many products to elicit immune responses among vaccinees (8, 9), it is increasingly felt that Phase 3 trials of such vaccines are necessary. Therefore, despite an incomplete understanding of HIV pathogenesis and correlates of protection, large Phase 3 efficacy trials have been initiated in the US, Thailand and Uganda (10). Cohorts are also being established, and sites prepared for efficacy trials when appropriate vaccine candidates become available (8).

Deciding when and how to proceed to Phase 3 trials is often complex (6, 11). Some scientists in developing countries are concerned about the deteriorating HIV/ AIDS scenario in their countries and the long time required to complete clinical trials in developed countries. They argue that as the beneficent intent in conducting vaccine trials is clear, trials could be initiated simultaneously in developing countries (12, 13).

There are several reasons to consider conducting trials of AIDS vaccines in developing countries (14, 15). A majority of HIV infections occur in developing countries where an effective vaccine will be most beneficial. The high incidence of HIV infection makes it easier and cost effective to assess trial end-points. It is easier to

assess vaccine efficacy of therapeutic vaccines among HIV-infected people who have not received anti-retroviral therapy. Different routes or co-factors in HIV transmission and the presence of various HIV subtypes may have a differential influence on vaccine protection in developed and developing countries.

To conduct an AIDS vaccine trial, the developing country must have a cohort with defined epidemiologic characteristics, and the technical and scientific capacity to perform clinical procedures and laboratory assays. But such a trial can also raise ethical controversies, as critics, investigators, volunteers, sponsors and regulatory agencies may have conflicting opinions, mandates and expectations. Open communication between the organisations involved and the participating community can minimise this possibility (16).

Trial-related concerns

Participants may fear developing adverse reactions or HIV infection; a post-vaccination positive HIV test result and consequent discrimination; and problems in freedom of travel, insurance, employment and immigration. They may also worry that spouses or partners informed about their trial participation will stigmatise them. The participating community will ask if investigators can ensure adequately informed consent; if trial participants will face discrimination; and if they will receive post-trial benefits. Countries participating in vaccine trials will expect to discuss and approve trial protocols. They will expect that researchers will adhere to the highest scientific and ethical standards, that regulatory bodies will do periodic monitoring, and that the population will get substantial post-trial benefits. Researchers can refer to various international ethical guidelines while planning AIDS vaccine trials (17-20).

Ethical issues in the pre-trial phase

Before selecting a candidate vaccine, and deciding whether or not to initiate a vaccine trial, policy makers, experts and community representatives must have a national discussion on the trial's scientific justification, the clinical and laboratory expertise available and the community feasibility of a vaccine trial. Most current vaccines are based on subtype B of HIV-1.

Testing subtype B-based vaccines in countries where other subtypes are predominant raises ethical questions, though evidence of cross-clade immunity may justify such a trial. Separately, industries in developed countries may not be interested in developing non-B type of AIDS vaccines for countries who cannot buy them. Capacity-building efforts must therefore be made to develop vaccines in developing countries with the help of competent industries in developed countries.

Developing countries may ask if the vaccine has been tested in the country of manufacture. Why should the research be carried out in developing countries? The rationale for conducting the trial must be explained to the community. A network of community-based organisations, people living with AIDS, local medical practitioners, leaders and the media can ensure that the trial is in the community's best interest. It can help disseminate information on the proposed vaccine trials, clear doubts and ensure public support and participation in the proposed trial. Specific cultural, clinical and economic settings influence local ethical expectations and must be addressed while designing field trials (21). Qualitative research should be used to identify the community's fears, so that correct information can be provided in an ongoing manner.

Ethical considerations in an ongoing trial

All the fundamental ethical principles (22) – beneficence, non-maleficence, autonomy and justice – apply to AIDS vaccine trials. For the researchers, this includes ensuring that the study is in the participants' best interests; ensuring that all participants (24) give their informed consent without coercion or inappropriate inducement (19); using comprehensible and informative consent forms and procedures meeting international guidelines and also approved by the Ethical Review Board (ERB); and getting modifications of the protocol and the consent form re-approved by the ERB (23).

Participants should include all groups who may benefit from the vaccine, in particular those with a high incidence of HIV infection. Though children are not included in Phase 1 or 2 vaccine trials, it may be ethically justified to do Phase 2 trials on children (with their guardians' consent) if a therapeutic vaccine shows evidence

of working. Most AIDS vaccine trials will enrol HIV sero-negative persons, which would necessitate a two-step consent procedure with initial consent and counselling for HIV testing and later for trial participation. Respect for local standards such as by taking permission of community leaders does not eliminate the need for individual consent. Investigators must clearly inform trial participants that the vaccine may not work, and provide risk reduction counselling for AIDS prevention. If there is a placebo arm, potential participants must be told about the placebo, and that they could receive either the vaccine or the placebo.

It is absolutely essential to safeguard the confidentiality of trial participants. Researchers' responsibility to maintain confidentiality (with coded forms and samples de-linked from the participants' names) is particularly important in trials relating to HIV/AIDS. Maintaining confidential records may be complicated by the fact that since participants could develop complications in the long term, trial records may have to be preserved for an extended period.

Earlier, randomisation was equated with clinical equipoise – no arm in a trial is known to have an added benefit – making it impossible to test products with some favourable data in randomised clinical trials. This was later revised to suggest that randomisation could be ethical if there were overall uncertainty about the product's utility. Also, in the context of AIDS, behavioural factors and STDs are known to affect HIV transmission and only randomised controlled clinical trials can provide substantive evidence about vaccine efficacy.

Regulatory mechanisms

The Ethical Review Board, which includes experts in pharmacology, pathology, clinical medicine, social science and law (25), should not only review the research proposal but also guarantee that the trial proceeds according to plan and fulfils ethical requirements. The Scientific Advisory Committee's review should cover issues such as the need for the trial, capability and infrastructure at the site, choice of candidate vaccine, methods and appropriateness of selection of subjects, plan for recruitment and retention, mechanism for reporting and management of adverse events and quality control procedures. The Data Safety and

Monitoring Board, which may include some trial participants, should periodically review performance reports, protect participant safety, and define criteria for vaccine or trial failure for which it has the authority to stop the trial. The community advisory board, composed of local workers and community representatives, should liaise between researchers and the community; advise on study procedure and consent and data forms in order to protect the community, play a significant role in community information and education, and help in recruitment and retention of study participants.

The post-trial phase

Once a vaccine is proved to be safe and effective, the vaccine trial sponsors and the host country are morally and ethically obliged to make a commitment for a continued supply of the vaccine in the post-trial phase. The community where the trial was done must either continue to receive the vaccine or be helped to develop the capacity to produce a sustainable supply of the vaccine. This point can be negotiated with the manufacturers before initiating the trial. International agencies can play a major role in this regard (26). Post-marketing studies and surveillance should be undertaken to consider the vaccine's inclusion in ongoing prevention and control programmes.

HIV-uninfected persons considering participation in a prophylactic vaccine trial will be anxious on finding out that as a result of the vaccination, they will always test positive for HIV. This can create problems of discrimination in insurance, travel, jobs and housing. To tackle this problem, those conducting HIV tests for insurance, employment, health care or other reasons should be made aware that HIV vaccines can cause false-positive HIV test results, and trial participants should receive documents confirming their participation in vaccine trials. Social risks and harms to trial participants should be monitored as seriously as physical harms (27).

Some researchers feel that if countries cannot afford to give three-drug therapy to vaccine recipients who develop breakthrough HIV infection, they should not take up HIV vaccine trials. Other researchers from developing countries feel that this is not financially

sustainable; giving the three-drug regimen to vaccine trial participants in a country where it is not otherwise available is unethical because it can be an undue incentive itself. One suggested option is to treat breakthrough infections with two drugs without a protease inhibitor. However, most researchers agree that therapy for breakthrough infections should be given for life and should be on par with the best standards of locally available care. The sponsors and ERB should ensure that such provisions are made and actually followed. However, it might be important to clearly explain to the participants that if they acquire HIV infection and if the vaccine fails, compensation can't be given.

Feedback

Adequate feedback must be given to the community in which the trial was conducted. This could be done through the Community Advisory Board. Effective communication is essential to ensure sustained public support for research.

Conclusion

According to India's Parliamentary Standing Committee on Dreaded Diseases, an estimated eight million people are infected with HIV (28). The Prime Minister has stated that developing an AIDS vaccine is a top national priority. A formal AIDS vaccine development programme in India will probably be implemented through the coordinated effort of the government of India (28). International agencies have stated that they will help strengthen vaccine development capabilities in developing countries (29). These efforts must be supported by advocacy for a clear governmental policy on AIDS vaccine development, identifying and training researchers for vaccine development and evaluation and testing, and public education for future community support to vaccine trials.

AIDS vaccine trials may soon commence in India. While we must ensure that the various codes of research are observed in such trials, research participants' protection ultimately depends on the ethics and commitment of individual investigators (30). Indian researchers should ensure that all future AIDS vaccine trials conform to the highest ethical standards.

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Ethical and methodological conflicts in sexuality research

Leena Abraham

Ethical discussions in biomedical research are based on a fairly well-established understanding of benefit and harm. Social science research in health raises new questions of what constitutes harm. Newer areas such as sexuality research are particularly complex and concepts such as stigma and confidentiality are of critical importance. Research on sexuality frequently focuses on vulnerable adolescents who are in unequal relationships within their families as well as in educational institutions. Here, a researcher explores some of these issues while describing her experience of conducting a study on sexuality among college students, with equally young investigators. Social science researchers are attempting to devise their own equivalent of 'post-trial benefits' to participants.

This essay is based on issues relating to a study of sexuality among low-income college students in Mumbai. Low-income students were made the focus because existing urban studies are on English-speaking students in 'elite' colleges; sex education programmes had not really started in 'non-elite' colleges, and these students' behaviour could be affected by their lack of resources. Data were collected during 1996-1998, from four colleges catering to low-income students in the city. Boys and girls in the 11th standard in high school and in third-year undergraduate college were interviewed. In the first phase, qualitative data were gathered using 10 focus group discussions and interviews with 87 students. This was used to design a survey which used a self-administered questionnaire. A total of 966 students participated in the survey.

A novice in sexuality research may not seriously consider the ethical dimensions of such an enquiry. S/he is usually more concerned about conceptualising the study, choosing the appropriate

methodology and working out the logistics involved in executing the study. The question that haunts the researcher is: “Will people talk about their sexual experiences, especially about taboos such as premarital sex?”

Having no prior experience in such research, I, too was troubled by this question when starting off, but I was not unduly worried because sexual experiences were only one part of my study which was meant to explore a range of issues related to sexuality – sexual socialisation, knowledge and attitudes to sex, peer socialisation, erotic exposure and so on. I reassured myself that if people did not share their sexual experiences with me, I still would have a lot of useful data to analyse. Besides, the refusal to respond tells you whether a group is willing to disclose personal information. It can also tell us the strengths and weaknesses of methodologies for sexuality research.

A review of existing sexual behaviour studies showed that a percentage of young people report pre-marital sex and that more young men report pre-marital sex than young women. Some authors attributed this gender difference to over-reporting by boys and under-reporting by girls, but did not state the evidence for this belief. They apparently assumed that girls refrained from admitting pre-marital sex, fearing the possible negative consequences of such a disclosure. On the basis of my study, I now believe that fewer girls than boys actually engage in pre-marital sex, in order to avoid various negative consequences: a ‘bad name’ for themselves and their families, the possibility of future marital discord and domestic violence, and so on. While one must be aware of the possibility of over-reporting and under-reporting, it may be best to base one’s beliefs on sufficient evidence. At the beginning of the study, therefore, I was mainly concerned about the methodological aspects of gathering reliable data, and how to gain students’ confidence and trust. However, I was not fully prepared for the consequences of people disclosing their personal experiences. While methodological aspects of the research were considered in detail, the ethical aspects were considered only briefly. This has changed in the last five years. Sexuality research has tackled many methodological issues and is now discussing ethical dimensions

more seriously. Our experiences may be useful to ongoing discussions.

The research team's concerns

Our first concern was to deal with the methodological and ethical problems at our end: Are we comfortable asking those questions? Is our language appropriate? What are our prejudices? Are we sensitive to young respondents' anxieties? How much should we probe into their lives? Working on these was a protracted exercise.

The research team consisted of young men and women just out of postgraduate or undergraduate courses – almost a sub-sample of our study sample, similarly biased and ill informed on sex and sexuality. But they were very enthusiastic and, above all, well informed about the social and cultural milieu in which the study was located. Prior to data collection we had meetings on the objectives, methodologies and logistics of the study. We spent considerable time talking about sex and sexuality, clarifying misconceptions and filling in information gaps. We also held a two-day workshop on conducting group discussions, interview techniques and note-taking and transcribing. The only ethical issue that the workshop resource people discussed was to 'respect' and be 'sensitive' to the respondent's views. More detailed discussion on ethical issues should have been an integral part of that workshop.

The returns of research

Although ethical issues were not at the forefront of our research concerns, they kept cropping up. During our meetings, research staff raised the question of appropriateness of our research. They perceived it as a one-sided relationship in which respondents 'give' and the researchers 'take'. "Are we providing them nothing in return?" they asked.

In the tradition of social science research that I was trained in, researchers did not provide anything in return to respondents. The returns of research were not perceived in terms of their immediate benefits. Benefits accruing from such research would result from a lengthy process: research findings would enhance our understanding of society, which circulates to benefit the whole group. In other

words, the job of the researcher is to generate critical 'knowledge' that has some value for society as a whole.

Such arguments were not acceptable to my young staff. They raised several questions: "Why should people spend their time and put themselves at risk talking to you if you are not going to give them anything in return?" "Is it morally correct?" "It is only natural that they expect something from you."

Intervention research

Looking for a solution to this dilemma, I came across several research protocols prepared by international agencies in the area of health research, advocating what they call an "intervention component" as part of the study itself. This intervention could be by way of services provided after the completion of the study, or basic services such as health care, counselling, awareness programmes or information, education and communication materials provided during the study itself.

Our study was one of four studies on adolescent sexuality in India, funded by Rockefeller Foundation. The others were conducted by agencies already providing services, for whom the studies were to feed into their services, making 'intervention' the overall aim. Our study was to generate understanding that would feed into programmes organised by various agencies, both government and non-governmental, for youth groups, especially school- or college-based programmes.

The intervention component is increasingly becoming part of research conducted outside traditional social science research institutions such as universities and special centres. I believe that this 'new perspective in research' arose in the context of two developments. First, voices were raised against the use of the bulk of research funds on researchers' comforts even as the respondents lived in abject poverty or in stigmatised conditions. Second, as non-governmental organisations (NGOs) became increasingly involved in research, some of them criticised 'ivory tower' research in favour of more humane research that took into account some of respondents' immediate needs. My gut feeling was that this trend of having a built-in intervention has more to do with the politics of large international funding for research in poor countries. While

this approach seems logical and also reflects some ethical concerns, I am not sure of its methodological appropriateness or its resolution of ethical issues. Could it amount to an inducement to participate? And could the anticipation of a reward, however small, alter the nature of data? I am still not sure.

Social science research has generally held that data gathering should avoid any form of inducement as it can seriously affect the data. However, researchers are expected to intervene in life-threatening situations and other serious crises involving respondents, their immediate families, or the community, and not remain dispassionate observers to document the outcome. It seems ethically correct to provide services to respondents suffering from reproductive tract infections in a study of reproductive health. But what do we do in studies of voting behaviour, or of employment outcomes? Much social science research is seen as a collaborative effort of the researcher and the researched. It is true that research findings often do not get translated into benefits for the respondents. In many cases, no one pays heed to the researcher's findings or the respondents' interests, unless the researcher is backed by influential agencies. However, the 'intervention component' may thwart the efforts of small-budget studies carried out by individuals in lesser-known institutions. Is this a way to make 'ivory tower' research redundant, and to promote NGO research? (Of course, I do not hold that all institution-based research is relevant and I do believe that some NGOs are doing very useful research.) The intervention component is particularly characteristic of large projects. By now we also know that conditionalities (hidden or explicit) are attached to large-scale funding, whether for development projects or research.

A related question is: how is intervention designed? Do we ask the respondents what they need, or do we decide what to give? What if they really need something which we cannot give? What if there are conflicting demands? What if most respondents are not particularly concerned about the rewards? Such issues in sociological research on sexuality become difficult to resolve, while it may be easier to do in a more specific health research project.

After much discussion within the group we decided that we would try “to do something for the students,” based on our financial and other capacities as well as students’ demands. In order not to let it influence respondents’ decisions to participate, we decided not to announce any intervention but informed those who asked about it. The study’s returns may not benefit all respondents equally – or for that matter any of them. However, it may have more significant indirect effects. To illustrate, we were surprised when the principal of one of the colleges was quick to grant permission to conduct the study. Later, he mentioned that an unmarried student who became pregnant had been dismissed from the college at the management’s behest, an action he felt was unfair to the student. He felt sex education could help prevent unwanted pregnancies but needed concrete findings to convince the management of its need. Here, we saw some benefits accruing from our study, perhaps not to the participants specifically but to the students in general. After the study, our efforts have been to communicate the findings to parents at large, educators and other agencies, in the hope that it will benefit young people. One organisation finds the study useful in its programmes for youth in a rural setting. These issues of benefits and relevance need to be brought to the centre of social research, particularly because of the blurred boundaries between types of research – market research, action research, intervention research, theoretical research and so on. The agencies and players in these types of research have different agendas and objectives.

We tried to meet an obligation to give back to the community in different ways. Wherever possible, we tried to provide information on specific topics, and specific services to those respondents who asked for them. We also asked the students if they wanted a programme organised for them and, if so, what the content should be. Some wanted a meeting with an outside expert to answer their personal queries. This was arranged and the students seem to have found it useful.

Confidentiality

It was not difficult to convince the research staff of the importance of data confidentiality and protecting respondents’ identity, but I soon realised that this was not enough. Most research reports only

state that confidentiality of the data was assured but do not speak of how they did this. I realised that these young researchers were discussing “interesting details” with their peers and family members and disclosing the identity of the college. At the same time, college authorities were pressurising them to divulge the names of other colleges where the study was being conducted and the staff felt it was okay to share the information between colleges. ‘Leakages’ occurred despite many efforts, particularly in the initial stages of the study till the staff became habituated to “guard it as a secret.” It was also difficult to ensure that trained staff who leave the study for better jobs continue to maintain confidentiality.

Respondents’ identities were easier to maintain as we did not ask their names and their interviews were linked only to a code number. However, another problem arose here: after the transcriptions, I needed more information in some cases but could not go back to gather it. In an exploratory study, unanticipated responses come up which need to be followed up.

Informed consent

This seemingly straightforward ethical requirement turned out to be difficult to implement. One practice suggested for literate populations is to obtain respondents’ signatures on informed consent forms. Our research population consisted of highly literate college students (16-22 years), but getting their signatures on consent letters seemed to go against our assurance of protecting their identities. The most convincing way we could assure protection of their identities was by not recording their names anywhere. Instead, informed consent was operationalised as follows: In order to recruit students for focus group discussions, members of the research team addressed classes, informing them about the study’s objectives and our organisation. A meeting was announced for those willing to participate in the discussions. On the appointed day, many students did not turn up: the reasons given by those present were that some changed their minds, some were absent, and some were not free. We restated the purpose of research and who we were, and how we would maintain confidentiality. We said if they wished to discontinue, they could do so. We began the group discussions a few days later, by which time some more students had dropped

out. Once the group discussions began, the participants stayed on through the multiple sessions conducted with each group.

This two-layered recruiting procedure may have helped ensure the ethical requirement of informed consent. But from a sociological angle, I would have been equally interested in talking to those who wished to stay away from the discussions. Such a self-recruitment procedure is methodologically weak, as it tends to leave out important groups, compromising the validity of data. The objective of an exploratory study is to arrive at a general understanding of the issue, for which it is important to have as many diverse experiences and representations as possible.

Similarly, in individual interviews and in the survey, students were informed of the survey's objectives and nature, the confidentiality of the data gathered and also about us. Their willingness to participate was taken as their consent. However, some of those interviewed did not wish to answer some of the questions and they were not probed. Then, in the self-administered questionnaire, students chose not to respond to some of the questions, and 'no response' was recorded in these cases. On the whole, once they opted to participate the 'no response' rate was low.

Looking back, I wonder if our over-enthusiasm to ensure that the students' participation was completely voluntary ('choice' is something which they are not used to in an institutional context) actually provoked some students' curiosity and generated peer pressure leading to their participation. Some students asked to be included in the study as their friends had been interviewed. Does this violate the rule of 'informed consent'? There could also have been herd behaviour: "Others are doing it, so I must do it too..." Our understanding is that these young people are not used to being given choices. Once college authorities permit an activity by an external agency, it is expected that students cooperate. Of course, students do subvert authority. Besides, any activity that is not compulsory is generally not seen as an important activity by students. Even before we talked about the study, many asked, "Is it compulsory?" Some lost interest when told it was voluntary. The value of 'voluntarism' was obviously in conflict with the culture of authoritarianism in our educational institutions.

Recently, someone asked me how consent was obtained from students under the age of 18. I had not thought about it in such strict legal terms. All were treated equally except that younger (high school) students were given a more detailed explanation.

Should we have intervened?

There were two instances when girl respondents refused to answer questions of sexual experience, in a manner which suggested that they had traumatic experiences. The interviewer respected their 'choice' and merely recorded her observations. Later, we wondered whether we should have probed further and at least offered to help them. As a researcher, I felt that we should have made efforts to collect more sensitive information. Perhaps neither an institutional setting like a college nor a family setting is a suitable location for such data gathering.

Conclusion

Looking back, I feel that important ethical and methodological issues are meshed together especially in areas such as sexuality research. Attempts to protect individual rights may compromise the quality of information, and vice versa. How do we deal with such issues? They cannot be dealt with separately, but should become part of methodological training and debates in social sciences.

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Role of ethics committees in medical research

D S Shrotri

Institutional review boards (IRBs) or ethics committees are a relatively new phenomenon in India. Their role is becoming crucial in the supervision of medical research. The author presents a concise summary of best practices that would enable IRBs to function effectively.

Having worked on the institutional review boards (IRBs, also known as ethics committees) of some institutes, I have a few comments to make on their role in research planning.

Every research institute should formulate a policy statement that should be made available to the IRB. It should mention the type of research it will undertake, such as: pre-clinical toxicology, animal studies in pharmacology or pathology, epidemiological surveys, clinical trials involving patients and studies using healthy volunteers, depending on its resources and infrastructure. This will help in deciding the types of studies to be avoided. The purpose of research – the benefits to be expected from the point of view of its staff, clients, students, society in general or the local community and the institute itself – should be revealed in this policy.

Every research protocol should be scrutinised and cleared by a scientific advisory committee before it is presented to the IRB. Proposals from abroad should have been scrutinised and cleared by an academic body in that country. The local committee may suggest modifications to suit local conditions.

The IRB is not expected to examine the technical details and statistical design in depth. It considers mainly the interests of research subjects. Participating research workers, clinical and para-clinical staff, administrative staff and the institute as a whole may also be objects of its review to some extent. Taking into consideration the source of funding, study objectives, and the welfare and rights of volunteers, patients or (in animal research)

animals, the IRB can suggest suitable modifications to the plan or reject it totally.

The IRB should approve the information and consent forms to be presented to the patients or volunteers recruited for the study. These documents should be in simple language and contain no inducements.

Approval of the IRB should be for a specific period of time, during which the researcher is expected to report to the IRB the occurrence of any unexpected adverse events, difficulties encountered in the work and the progress of the work in general. The IRB has the right to stop the study, modify the protocol or deny further extension of the initial approval if it thinks that the study is not proceeding satisfactorily. For an imported project, guidelines provided by agencies responsible for the protection of rights in the parent country will be useful in continuing the review.

Data obtained during the course of the study, the results of data analysis and conclusions drawn from these results are important concerns from the points of access, custody, ownership, secrecy and publicity. These must be clarified in the research proposal. The IRB must insist that the funding agency or the sponsor will have no access to raw data and individual records. They will be submitted a report in a format similar to that of a paper sent for publication. Interim reports of progress of work may be given for release of instalments of grants. The final analysis should always be made by an academic institute.

The identities of the patients or volunteers must be guarded in most studies. If leftover biological material is to be preserved and used in another study, informed consent forms must mention this possibility. The protocol should also clarify whether the individuals will receive the results of investigations performed on them either immediately or after a period.

The institute and the IRB should insist that the study results are quoted only in scientific literature or technical reports submitted to regulatory authorities and not used for media publicity aimed at the lay public.

The working of the IRB involves extensive documentation. A properly designed research project is educative from the point of

view of record keeping, which proves useful to the researcher in the long run.

To conclude, one must understand that the IRB is an important tool that can be used to put into practice the concern expressed by the medical profession about medical research nearly 40 years ago in 1964 in Helsinki, and which continues to be expressed to cover a wider field.

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Fraud in medical research

Stephen Lock

Researchers don't talk about scientific fraud, but there is no doubt that it is widely prevalent, with serious consequences for medical practice. The writer gives a short history of scientific fraud and then discusses why it happens and what needs to be done to prevent it.

Introduction

With fraud and sleaze so visible all over the world in politics, finance and public life, finding that these also exist in medical research should come as no surprise. Yet it does, and medical scientists still react as if a case were unique. And they manage it so badly, with the whistle-blower often more penalised than the miscreant (1). Seemingly, fraud has a brief history. I argue that scientists should be aware of the problem, try to deal fairly with any suspected case on well-recognised lines and, crucially, aim at preventing it by following good standards of research practice.

A brief historical account

Most accounts of fraud start in 1974, when William Summerlin purported to show that skin taken from a black mouse could be transplanted into a white one. In fact, Summerlin had used a black-tip felt pen to colour in an ordinary graft of white skin (2).

Nevertheless, fraud has probably always been a feature of scientific work. Some commentators have even accused workers as distinguished as Newton, Mendel and Pasteur of fudging their results (3), while the fact that fraud has featured in at least four novels (from Dorothy L Sayers' *Gaudy Night* [1936] to Carl Djerassi's *Cantor's Dilemma* [1989]), suggests that at the very least it has always been part of the tittle-tattle of senior common rooms.

Should the term be confined to the acknowledged major categories – forgery (the invention of data), plagiarism (stealing the data of others), and piracy (stealing ideas) – or should it include other

abuses such as gift authorship, undeclared conflicts of interest and multiple publication? Some – especially the Nordic countries – see the topic as a spectrum (or a slippery slope) of practices and prefer to talk about “scientific dishonesty” rather than fraud or misconduct, given that there is still no internationally agreed term for the abuse.

In the USA, the central body – first the Office of Scientific Integrity (OSI), and now the Office of Research Integrity (ORI) – wrestled with the problem of definition. Its original statement was unexceptionable until its latter part, which clever defence lawyers could (and did) drive a coach and horses through. This spoke of “other practices that seriously deviate from those that are commonly accepted within the scientific community.” What, in particular, were those practices? Did they include, for example, sexual harassment of the supervised by the supervisor? For this reason the ORI set up a special commission to produce a special definition. To many of us the result was a great improvement on the old one, defining misconduct as “significant misbehaviour that improperly appropriates the intellectual property or contribution of others, that intentionally impedes the progress of research, or that risks corrupting the scientific record or compromising the integrity of scientific practices.” But the US government rejected this new proposal and hence currently we are stuck with the old one or variations on the theme.

Extent of fraud

The next question – and one that is inevitably raised – is how prevalent is fraud in research? Almost certainly, the cases in the public domain are the tip of an iceberg, but any higher estimates are also likely to be inaccurate. These are derived from two sources: first, surveys of academics for their private knowledge of possible, probable or definite cases and, second, audits of research projects. The first show that anything between a quarter and a half of medical research workers have come across one or more cases, and the second that around 0.25 per cent of research projects are tainted. Furthermore, the list of cases published each quarter by the ORI for one aspect of research alone – that funded by the US National Institutes of Health (NIH) – shows that in each period a consistent

five or six scientists are being found guilty of malpractice. The background to such cases has usually been prestigious. Few of these are lowly workers doing research in minor institutions on mundane topics; instead, the last have comprised the usual range of disciplines and particularly ‘hot’ fast-moving subjects such as molecular biology, immunology and cancer research. Thus, despite all the publicity, clearly some scientists think that they can get away with fraud. (And perhaps many of them do; we just don’t know.)

Causes of fraud

Of the six causes of fraud usually quoted, the first is the pressure on scientists for large-scale publication of positive results to obtain research grants, tenure and promotion. Second comes greed: in some drug trials, particularly, pharmaceutical firms have paid £ 750 or even more for every patient enrolled into a study, and the temptation to invent data for non-existent patients has overwhelmed some less-than-honest doctors. The third cause is vanity – the desire to keep in the swim – and the fourth, though rare, frank mental illness. The fifth is deviancy. As Nobel Laureate Sir Peter Medawar pointed out, every section of the community has a small proportion of crooks and there is no reason why research should be any different (4).

Nevertheless, the most important is what Medawar called the “Messianic complex.” In this, the scientist’s own conviction that he knows the cause of schizophrenia or cancer overwhelms the normal imperative to do research and obtain the data – which he (and it has usually been a he) then proceeds to invent. This seems to be the reason for the prominent Australian obstetrician William McBride falsifying data showing that emetics given to pregnant animals were teratogenic: one of the first to describe the harm thalidomide did to the human foetus, McBride became convinced that most, if not all, drugs had a similar effect under similar circumstances (3).

Corrective steps

The official approach to misconduct has varied according to the country. The phase of shock/ horror/ denial was succeeded, initially in the USA, by a flurry of reports and recommendations from the

professional bodies, and eventually, after a series of Congressional hearings, by the formation of the OSI. Despite some success, however, this was perceived as ineffectual and liable to frequent legal challenge, and only two years after its creation, it was superseded in May 1992 by the ORI. This reports to a different government department, has a different method of working, and, crucially, sees prevention as equally important as dealing with established cases reported to it (as required for any institution funded by the NIH). Thus it holds regular courses on the ethics of good scientific research, such as the recording and storage of data, the need for regular presentation and audit of data, and good publication practices (including a policy on who is and who is not an author in any individual case).

Such preventive measures are also a feature of the special organisations in the four Nordic countries. Each of these has a central committee on scientific dishonesty, which sees its role as much as for maintaining a high profile for good research practice as for advising on sanctions and instigating investigations with “due process” – the American term covering speed, confidentiality and respect for the rights of the accused and particularly of the whistle-blower.

The USA, the Nordic countries and Austria are unique in having permanent committees devoted to the problem. Other countries – including Australia, Canada and Britain – have produced official reports but have done little to implement them in the way of establishing tangible and long-lasting procedures. Britain, in particular, has relied on its General Medical Council (GMC) to discipline its doctors found guilty of research fraud. The Council has considered the cases of over a dozen general practitioners (though only two consultants), mostly involved in forging data on multi-centre drug trials. They have been admonished, suspended from practice or had their names removed from the medical register altogether. Though such sanctions are severe, the procedure for bringing a case before the GMC is elaborate, while the fact that the case is heard in public on the adversarial basis of English law is enough to deter all but the most committed whistle-blower.

Nevertheless, it would be unfortunate if whistle-blowers were discouraged from carrying out their moral duty in bringing any

legitimate suspicions to official notice. After all, most cases have come to light in this way (with a very few also being disclosed by editorial peer review – though we know that this cannot be relied upon to detect fraudulent work). The ORI commission, which reported on the definition of fraud, also recommended that the whistle-blower's bill of rights should be introduced, similar to that already in operation for civil services disclosures.

Lesson for research workers

They should practise research ethics, not only for their intrinsic goodness but also as an example to others. They should report suspicious conduct to the appropriate authority, insisting that any suspicions be followed to a satisfactory closure. They should ensure that whistle-blowers who raise any questions in good faith are not penalised in any way. They should believe that however rare, misconduct may occur in their own laboratories and that rather than brushing allegations under the carpet, a full and fair inquiry must eventuate.

Those countries that do not have a central committee on research misconduct are, in my view, considerably disadvantaged. Apart from disclosing a cowardice that is usually alien to science, such countries lack several important features of the scientific life: the high profile which a committee gives to good scientific practice (including holding regular courses for trainee researchers); a method for giving the advice and support that both whistle-blowers and local investigating committees need; and a mechanism for collating all the cases in any years, monitoring the action taken and enshrining the details in an annual published report.

Finally, of course, by no means is all medical fraud committed by doctors, in which case other disciplinary mechanisms will have to be devised. At present this is largely limited to dismissal of a non-medical researcher by an employer, but with a code of sanctions laid down by a central body, this would become easier and fairer.

Difficulties there are bound to be, to be sure, in creating some sort of statutory authority which yet has a sure but light-handed touch. But in failing to do so – and, worse, in pretending that either the problem does not exist or can be dealt with on the old-boy network – any establishment is not only selling short its scientific

community but also its population in general, who, through their taxes and contributions to charity, are the true paymasters.

Thus, India, which has a notable tradition of scientific research, should consider what mechanism(s) would best suit its own circumstances. A preliminary attempt might be, as has recently happened in Britain, for funding bodies to give research grants only if they are assured that the institution has in place a mechanism for handling whistle-blowers' complaints with due process.

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Ethics of authorship of scientific papers

R D Ganatra

Researchers writing up their results for publication find that credit must be given to those who do not do any work. The person who did all the work often gets last priority. Technicians are usually excluded from authorship when they are the ones who need it most for career advancement. The author notes that the Vancouver guidelines provide clear norms for authorship: the person should have participated in the conception, design, data collection, analysis, and interpretation, writing and revision of the research and the resulting paper.

Rules governing authorship

My nephew, who works as a research scientist in a reputable medical organisation, asked me: “What were the rules governing authorship of a scientific paper in your time?”

“What do you mean?”

“How did you decide who should be the authors of a scientific paper?”

“There are no rules. You decide by way of convention followed in your institution.”

The interval between when I started my research career and when my nephew started his scientific career is about 40 years. It appears to me that the situation regarding authorship of a scientific paper has remained the same over all these years. There are no set guidelines. Each institution has its own traditions. It is still not possible from the list of authors to guess who the real scientific worker is, and who are the supernumeraries.

The Indian experience

It is common experience that if the paper is to be presented in a local conference, the person who has done most of the work would

be the first author and present the paper. If it is a national conference, the head of the division presents the paper and takes credit as first author of the paper. If it is an international conference, the director of the institution presents the paper and hogs the limelight.

The names of the authors on an Indian paper are very often in south Indian style. The name of a south Indian would show his community first and then, in descending order, the names of the village, the grandfather and the father. At the end would be the person's name. The list of authors in an Indian paper follows the same pattern, starting with the director of the institution and going all the way down, the humble scientific worker ending up as the last author of the paper.

Ethical considerations

Are there any ethical considerations involved in deciding the authors of a paper? Are all the authors rightful contributors or is authorship gifted to some? Are all those who have contributed to a scientific project recognised as authors at the time of publication?

All medical research is the collaborative work of a group and multiple authors for a scientific paper is a rule rather than an exception. Who are the persons whose contribution to a project should be recognised by authorship and who are those whose help can be recognised by a mere mention under 'Acknowledgment'? Is the chief of the institution always to be included as an author in all the papers published from an institution?

These questions are important from the ethical viewpoint because the authorship of a paper confers several benefits on the author, the most important being enhancement of the merit for a job or for a promotion. While evaluating candidates, the list of their scientific papers is always taken into account. This list seldom shows the order of names of authors. Few candidates present a list of only those papers where they are the first authors.

International convention prescribes that the principal scientific worker, the person who has done most of the work, should be the first author of a paper. The order of names after the first name depends on the extent of the contribution of each worker to the research project. If at all the director's name is on the paper, it is as the last author.

Gifting authorship

The one who has done the scientific work usually makes a gift of co-authorship with some ulterior motive – continuation of the job, promotion in the job, sponsorship for a fellowship or travel abroad. A gift of authorship is a bribe paid by the real scientific worker because he expects something in return. Acceptance of this gift is an obligation to do something in return.

The practice of putting the name of the head of the institution as co-author is justified by the argument that he was responsible for providing facilities for carrying out research. To promote research is the normal task of any director of a research unit. This justification is also applied for including names as co-authors of heads of clinical units from which patients are drawn for research.

Years ago, I had the following argument with a renowned consultant from whose unit I had obtained patients for liver scan.

“I find that you have published a paper on liver scanning where patients were drawn from my ward.”

“Sir, I have put the name of your registrar as co-author of the paper.”

“But they were my patients.” I was brash and bold then. Moreover, I did not expect anything from that consultant, as I was not an employee of the referring hospital.

“Sir, you have not bothered to look at the reports of the liver scans that I have been sending periodically. You have not even seen the scanner. You have not talked about this procedure to me or to your registrar. All of us know that they become your patients by the fortuitous circumstance of their reporting to the hospital on Monday.”

“You will not get any of my patients for your nuclear medicine procedures. I do not wish to see you in my ward in the future.”

He was so piqued by this incident that he talked to my chief who castigated me for my insouciant behaviour.

That consultant was so well-known and well-to-do from his private practice that having his name on a paper published in an Indian journal did not make an iota of difference as far as his reputation was concerned but such is the lure of authorship that he craved to see his name on the paper.

As a rebound from this incident, I started putting as my co-authors all those who had really or even remotely helped me in that project, including my technicians and laboratory assistants.

The same chief who had shouted at me in the previous incident called me again. He said, "In this paper where you describe experiments on five rabbits, you have nine authors."

"Yes, Sir. This is because each of them helped me in the conduct of my experiments."

"What is the animal house attendant doing on your scientific paper? The fellow cannot even read English."

"Sir, he got the rabbits for me and helped me in the animal experiments."

"But that is his job. And why did you put my name as a co-author with the animal house attendant?"

"You allowed me to carry out this research project."

Arbitrarily, he removed some names and reduced the list to five – a number identical to the number of experimental animals reported in the paper. The attendant lost his name but my chief did not remove his name.

Authorship of a scientific paper enhances reputations

All heads of institutions have to their credit papers by the hundreds. This is only possible if they allow or force subordinates to put their names as co-authors on all papers published from their institutions. The lure of authorship is so great that many senior scientists accept the "gift" of authorship on papers to which they have contributed nothing. As with all presents, givers often derive some benefit too. If the expectations are higher, the name of the chief is put as a first author. Once one staff member sets this trend, others have to follow.

Vancouver guidelines

The International Committee of Medical Journal Editors (the Vancouver group) drew up criteria for authorship based on the idea that "each author should have participated sufficiently in the work to take public responsibility for the content." (1) In view of this recommendation, many journals go through the ritual of obtaining signatures on the consent form from all the authors. This does not

eliminate the ‘gifted’ authorship but does ensure that all authors are aware of the names included in the paper.

The Vancouver guidelines suggest that authorship should be based only on substantial contributions to (a) conception and design analysis and interpretation of data (b) drafting the article or revising it critically for important intellectual content and (c) final approval of the version to be published (2).

The guidelines emphasise intellectual contributions and do not include fund raising and supervision of the research group as legitimate justifications for authorship. The guidelines do, however, make it clear that between them the authors must take responsibility for all aspects of the work.

Deficiencies in these guidelines

These guidelines were established to safeguard the position of the editors of journals and are concerned primarily with the written version of a scientific paper. They do not consider how the research project was conducted and who collected experimental data. They ignore technicians who slog to collect the data reported.

The guidelines say nothing about researchers who have contributed to the work but whose names are left out of the paper. It is not easy to build safeguards against this, unless the head of the institution defines responsibilities for the conduct of research projects in advance and closely monitors their progress.

Shapiro et al, in their survey of papers in one American journal, found that 62 of the 1, 176 authors had made no substantial contributions to six major tasks (conception, design, analysis and interpretation, and writing and revision plus collecting data and providing resources), while a further 206 contributed only by providing resources or collecting data (3).

The director of a research institution usually reserves the right to approve what is being published from his institution. It is easy to convert this right of approval into that of participation. Even the guidelines referred to above include “approval right” as a reason for authorship. No staff member grudges the name of the director as a last author if the director at least takes the trouble of going through the paper. Having the name of the director as a first author is carrying things too far.

There are several situations that are peculiar to the Indian scientific scene. There may be a string of intermediate bosses. Are they to be included as authors?

Technicians

Technicians are almost always deprived of authorship. In India, unlike in the West, most technicians are science graduates. It is beneficial for their careers to have their names on as many papers as possible. They work hard to get data from the experiments devised by someone else. They would also like to enhance their merit for a job or for promotion particularly as such opportunities are limited in research institutions. It is an unfortunate fact that this very limitation forces staff members to whom injustice has been done in deciding authorship to remain mute as they cannot leave their jobs.

In research, the most important aspect is conception of an idea and its intellectual nourishment. How are we to decide upon the origin of an idea? Was the idea suggested by your senior or your colleague or by your technician or was it generated during discussions?

Among the technical staff there are two categories: those who participate intelligently and those who carry out assigned tasks in a mediocre manner. Classifying them in this manner is a challenging decision. Usually the primary author does not make such a distinction and includes all his technical staff as co-authors. When you start rewarding mediocrity, you do not know where to stop. Should the laboratory assistants and attendants be included as co-authors?

Electronic media

The problem of electronic media does not affect us, but it will soon. Anybody can put a paper on the internet without any peer review to save the time taken for publication in print. What criteria on authorship will apply here?

Conclusion

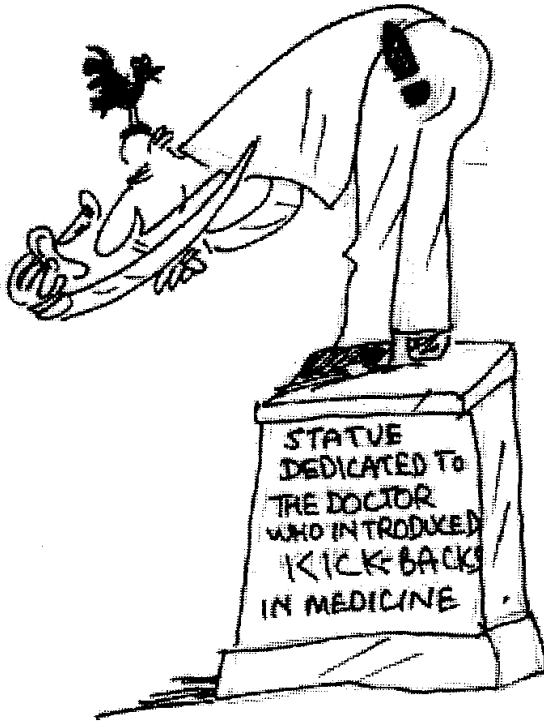
There are many ethical questions involved in the simple task of putting the names of the authors on a scientific paper. Are you

putting only those names as co-authors who have genuinely helped in the conduct of your research? Have any names that rightfully belong there been omitted? Answers to these questions are sometimes difficult. No rules or criteria can help. As in all ethical questions, it is more often a matter between your conscience and your common sense, two commodities rather scarce in the medical world.

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