FROM OTHER JOURNALS

Submission guidelines of Indian medical journals

The authors read the "instructions to authors" for 100 Indian medical journals to see if they explicitly mentioned ethics committee approval, obtaining informed consent and assent, and the necessity to carry out research in accordance with the ICMR's guidelines or the Declaration of Helsinki.

They found that 38 journals did not provide explicit instructions to their contributors regarding the reporting of ethics committee approval; 56 journals did not ask for reporting of informed consent and only three journals mentioned instructions for providing assent. The authors argue that reporting on these crucial issues should be a minimum requirement. They suggest that editors should ask authors to include an "ethics section", under "materials and methods". Similarly, providing checklists for authors and reviewers to ensure ethical compliance could also be helpful.

Bavdekar SB, Gogtay N, Chavan R. Reporting ethical processes: survey of 'instructions to authors' provided by Indian journals. *Indian J Med Sci*. 2009; 63; 6: 260-2.

What do registered clinical trials report?

The authors reviewed clinical trials registries for information reported on 312 global randomised intervention trials of malaria, HIV/AIDS, and tuberculosis conducted between October 9, 2004 and April 10, 2007.

Of the 312 trials, 222 were related to HIV/AIDS, 67 to malaria and 23 to tuberculosis. Most trials were conducted in high income countries, and 75% of principal investigators were from high income countries.

Informed consent is reported in the majority of trials. Overall, 27% trials included child participants, but 90% of these trials did not report obtaining assent from the child. 37% trials employed placebo controls. The majority of trials (99%) made no mention of post-trial provisions in their protocols. The majority of trials (72%) were publicly funded. Trials that measured surrogate outcomes were most often conducted by pharmaceutical com0panies. Only 20% of trials measured clinical events as primary outcomes.

The authors found that reporting on standards relevant to the ethical conduct of research was suboptimal and state that this is so because such reporting is not required. Investigators from high income countries were more likely to measure clinical outcomes rather than surrogate outcomes. Yet clinical outcomes were five times more likely to occur in low to middle income countries than in high income countries. Also, most trials in developing country settings were funded by developed nations. Nonetheless, trials intended for developing country settings had consistently poor reporting of ethical considerations compared to those in more developed settings.

Cohen E, O'Neill J, Joffres M, Upshur R, Mills E. Reporting of informed consent, standard of care and post-trial obligations in global randomized intervention trials: A systematic survey of registered trials. *Dev World Bioeth*. 2009; 9; 2; 74-80.

The budding discipline of community medicine

This article comments on the discipline of community medicine, a discipline that is now challenged by a fresh set of problems caused by both demographic and epidemiological changes. Non communicable diseases and injuries are becoming more common even while the old problems posed by communicable diseases and hunger are yet to be overcome. The existing health system based on a biomedical model of disease prevention and control is inadequately geared to meet these challenges.

In the present era of globalisation, social policies at the national and international level also have a profound influence on the health of communities. This calls for integration of biomedical, ecological and sociological approaches with academic community medicine so as to have the desired impact on population health.

Indian public health standards have specified the requirement of a public health professional in each community development block. The Integrated Disease Surveillance Project is recruiting an epidemiologist in every district of India, and the National Rural Health Mission has also created the position of public health manager in most health institutions. Therefore, due priority should be given to institutional capacity for development of public health human resources. This can be by initiating certificate, diploma and degree courses of one to two years' duration for pre-service and in-service candidates from the medical, nursing, laboratory, nutrition, environment, biology and social science streams. A three-year bachelor of public health course can be a good addition for augmenting the already depleted supervisory cadre in the public health system.

Academic community medicine in 21st century: challenges and opportunities. *Indian J Community Med*. 2009; 34; 1; 1-2.

Public access to information on clinical trials

This report comments on the significance of transparency in clinical research, something that has been highlighted during the last decade. The first major initiative in this direction was launched by the International Committee of Medical Journal Editors in 2004 when it mandated registration of trials in public databases for the purpose of publication in its member journals. Another such major initiative in the European Union has been the regulation on better medicines for children.

A large proportion of drugs are used for children outside the approved conditions of their product licence. To address this problem, in 2007, the EU passed legislation requiring companies to formulate a paediatric investigation plan. The law also made it a requirement that information about clinical trials of investigational medicinal products being conducted in Europe with children should be made publicly available on the EudraCT database.

However, this meant that the EudraCT database provided public access to information about clinical trials with children, but not those conducted on adults. In February 2009, the European Commission therefore published the list of data fields to be made public from the EudraCT database for all trials, including the ones for children. The commission hopes that data about the protocols of ongoing trials will be available later this year, and the results of trials will be included about a year after this.

Smyth RL. Making information about clinical trials publicly available. *BMJ*. 2009; 338:b2473.

Computer screening for family violence

Intimate partner violence and control (IPVC) poses a serious health risk to women. Direct inquiry by physicians facilitates disclosure, but physicians often fail to inquire about a patient's risk of IPVC because there is no time to ask; there are pressing acute medical problems to deal with; they are uncomfortable asking such questions; they fear offending the patient, or they are not familiar with the resources to which the person can be referred for help.

A randomised trial was designed to assess the effect of computer assisted screening to detect the risk of IPVC in a family practice setting in Toronto, Canada.

It was found that when a computer-generated report detailing patients' responses to questions about IPVC was attached to medical charts, family practitioners asked about it and detected it more often. The overall prevalence of any type of violence or control was 22%. The intervention increased opportunities to discuss IPVC and increased detection of IPVC. Among detected cases, physicians assessed patient safety, offered referrals, and advised a follow-up visit more often in the screened group than in the usual care group. Participants recognised the benefits of computer screening but had some concerns about privacy and interference with physician interactions. It is recommended that physician training programmes should continue to emphasise the importance of privacy, confidentiality, and communication skills for addressing this sensitive issue.

Ahmad F, Hogg-Johnson S, Stewart DE, Skinner HA, Glazier RH, Levinson W. Computer assisted screening for intimate partner violence and control. *Ann Intern Med*. 2009; 151; 1; 93-102.

On editing a medical journal

The outgoing editor of *Annals of Internal Medicine* has put down the lessons he learned and the concerns he has about editing a medical journal. Harold Sox notes that he has learned three things over the years: spotless research is a rare exception; editors and statisticians who constantly strive to improve reports of clinical research are a national treasure; and clinical journals can provide a unique public service if they ensure that research methods are correct, reporting is accurate and complete, and conclusions are appropriately cautious.

Journals occupy a prominent place in the chain that links research to improving medical practice. However, good journal editing is expensive, and the shrinking resources might even turn journals into a weak link in the chain. Internet-only publication and free access to publications are exciting, although threatening for the print copy. Web publication and other factors are likely to turn commercial advertising into a declining source of support for the editorial expenses of journals. Neither will sales of reprints and classified ads make up for the difference. Who shall pay for good editorial practices? What should be the measure of editorial excellence? And what are the consequences if those who should pay simply cease to do so? These are some of the questions that the experienced editor raises for readers to ponder.

Sox HC. Medical journal editing: who shall pay? *Ann Intern Med*. 2009; 151; 1; 68-9.

Ethics of NGO research

This editorial comments on the need for nongovernmental organisations (NGOs) to conduct ethics review. NGOs provide medical care and humanitarian assistance to vulnerable populations. Such organisations are also important producers of health research, ranging from simple health surveys or interviews to complex clinical trials. Data collection at NGOs, however, does not have research as its primary aim. It is usually aimed at improvement of delivery of care to populations that normally lack access to services; and often provides evidence for advocacy on behalf of these populations.

This tension between research and delivery of care is not easy for NGOs to reconcile, taking organisations whose primary role is to provide care into a whole different sphere – that of scientific investigation involving human participants. This raises the question of how such research is reviewed and monitored. To lose important research evidence from NGOs due to lack of appropriate oversight constitutes a waste of the resources involved in conducting the research, introduces a potential source of bias in the literature, and betrays the trust of participants. The authors therefore argue for the need for ethical oversight in these circumstances.

The *PLoS Medicine* Editors. Ethics without borders. *PLoS Med*; 2009; 6(7): e1000119.

Editors' views on publication ethics

A questionnaire was sent to 524 editors-in-chief of Wiley-Blackwell science journals pertaining to different facets of publication ethics like plagiarism, data fabrication, redundant publication; their confidence in handling such issues, and their awareness and use of guidelines.

Responses were obtained from 231 editors (44%). The general level of concern about the outlined issues was low. The issue of greatest concern was redundant publication. Most editors felt confident in handling the issues related to publication ethics. They also believed that problems related to publication ethics occurred less than once a year, and less than 20% of the editors stated that 12 of the 16 items mentioned in the survey never occurred at their journal. However, 13%-47% were unaware of the frequency of the problems. Awareness of publication guidelines was generally low, as was the use of these guidelines. Most editors were unaware of guidelines other than the instructions to authors publicised by other journals.

The authors conclude that most editors of science journals seem unconcerned about publication ethics and believe that misconduct occurs only rarely in their journals. Many editors are unfamiliar with available publication guidelines, but would welcome more guidance or training.

Wager E, Fiack S, Graf C, Robinson A, Rowlands I. Science journal editors' views on publication ethics: results of an international survey. *J Med Ethics*; 2009; 35:348-53.

Impact of rising food prices

The writers analyse the impact of rising food prices on people's health. They note that global food prices rose by an average of 75% between January 2006 and July 2008. These high prices are expected to remain in effect for several years. Changing diets in emerging markets have resulted in a projected demand in future supply of meat and dairy products. This has directly led to the increase in demand for grain feed in these industries. Extreme weather incidents have caused the world cereal production to fall. Rapid increases in oil prices in 2007-08 have led to an increase in agricultural production costs. This has resulted in a cultivation of non-food crops for biofuel.

According to the World Bank's estimates, these prices have already pushed an estimated 100 million people into poverty worldwide. The Food and Agricultural Organization estimates that price rises have increased the number of undernourished people by 75 million in 2007. In middle and high income countries, the price rise has increased the cost of nutrient-rich food, thereby forcing consumers to buy low quality foodstuff. The rising cost of basic food has led to the erosion of purchasing power of poor people. This will definitely affect the quality of diets, exacerbating health inequalities.

Lock K, Stuckler D, Charlesworth K, Mckee M. Potential causes and health effects of rising global food prices. *BMJ*; 2009; 339:b2403.

Information in drug package inserts

The authors report the findings of a study to evaluate the presentation and adequacy of clinically relevant information published in drug package inserts in India.

The study concluded that the presentation of information in the drug package inserts studied was not uniform. As all inserts did not follow a standard layout and heading format, it was difficult to locate and retrieve information. Indications for use and contraindications were mentioned most consistently in the package inserts studied. Warnings and precautions frequently lacked information on paediatric and geriatric use. Information on adverse drug reactions (ADRs) was only summarily described in most leaflets. None of the leaflets highlighted the serious ADRs associated with the products. In the leaflets studied, the mention of drug interactions was brief and in most instances it was limited to drug-drug interactions. The date on which the information in the leaflet was last updated was mentioned in only six labels, raising doubts about the validity of the information.

The authors compare their findings to those from a 1996 study, also in India. They note that when compared to the findings from the earlier study, there has been an overall improvement in the percentage of inserts containing relevant information. However, there is still a need to refine the contents of circulated package inserts to make them complete, reliable, and up-to-date. Updating Indian guidelines for package inserts in line with those from the United States Food and Drugs Administration and the European Medicines Agency would be a step in the right direction.

Shivkar YM. Clinical information in drug package inserts in India. *J Postgrad Med* 2009; 55:104-7

Compiled by Sachin Nikarge
email: sachinikarge@yahoo.com