FROM OTHER JOURNALS

Missing data in clinical trials

Suppressing negative results or selectively publishing results from a clinical trial, thus skewing the results in favour of a drug or a device, is common. This editorial cites the example of the antidepressant reboxetine, reviews of which were published in reputable journals based on the analysis of a small amount of data. A re-analysis after integrating 74% of the data, that had not been included earlier, proved that claims about the drug were false and that the drug was both ineffective and dangerous.

The problem is that researchers are often not allowed complete access to the raw data of a clinical trial, and enquiries about missing data usually do not yield results. Data may also be misinterpreted while publishing the trial results. It has been suggested that journal editors be allowed to inspect trial data. However, this may be difficult even for journal editors.

Making unpublished or missing data available later may not always change the evidence base of an existing treatment option. The editors express the hope that the Food and Drug Administration Amendment Act of 2007 in the US, and changing laws in Europe, will make complete clinical trials data available in the public domain; at present there are lacunae in the existing information due to missing and incomplete data. They urge researchers, drug companies and device manufacturers to make all data available so as to strengthen the clinical decision making process.

Lother E, Godlee F. Missing clinical trial data: setting the record straight. *BMJ*. 2010 Oct 16;341:c5641

Consent for blood transfusion

The consensus is that general consent before a medical treatment also covers consent for blood transfusion. In this analysis in the *BMJ*, the authors advocate for a separate informed consent process for blood transfusion. The issue has come to the fore in the UK after a consultation was held by the Independent Advisory Committee on the Safety of Blood, Tissue and Organs.

Though no additional consent is required for giving a patient a blood transfusion, concerns have been raised about patients' awareness of the risks and benefits of transfusion, alternatives to it, and, above all, their right to refuse. The UK National Health Services gave hospitals and healthcare providers leaflets for patients, with information about transfusion. But it was found that the leaflet did not reach many patients who underwent blood transfusion.

The authors argue that disclosure of all information related to a therapy is necessary to uphold the autonomy and dignity of the patient undergoing treatment. They explain that blood transfusion is also a procedure which involves risks and side effects. Taking informed consent for blood transfusion well in advance of an operative procedure; explaining later, in the case of emergency procedures if consent could not be obtained in advance; informing patients about the possible future negative outcomes of transfusion and the ways to tackle them, are some best practices that the authors suggest for hospitals and healthcare providers. In a country like India, where truly informed consent is often not obtained, and where transfusion-related complications are common, it is high time that we adopt a policy that addresses these issues.

Farell AM, Brazier M. Patients should consent to blood transfusion. *BMJ*. 2010 Sep 11;341:539-41.

Antibiotic resistance and medical tourism

The Indian medical tourism sector reacted with caution to the reports regarding the global spread of NDM-1 (New Delhi Metallo _ Beta _ Lactamase 1) enzyme carrying bacteria. Interest was sparked by the fact that the NDM-1 enzyme renders the bacteria resistant to all antibiotic regimes except colistin and tigecycline. Naming the bacteria after the city where it is supposed to have originated affected the Indian medical tourism sector; the harm caused by treatment for antibiotic resistant bacteria acquired in India will far outweigh the advantages of undergoing cheaper treatment here. India has responded by taking initiative for a policy for the rational use of antibiotics.

The authors argue that medical tourism and hospitals in middle and low income country settings cannot take all the blame for the development of antibiotic-resistant strains of bacteria. They give the example of MRSA- Meticillin resistant *Staphylococcus* aureus which had its origin in the UK and which subsequently spread across the world. They also explain that restricting medical tourism will not necessarily effectively prevent the spread of antibiotic-resistant strains of bacteria. They state that combating drug-resistant strains is central to the advancement of healthcare provision and is all the more significant due to the dearth of newer antibiotics. The two ways to combat this are infection control and the rational use of antibiotics. The medical tourism sector which is often based in the best hospitals in the country should take the initiative to reduce infections in hospital settings. Quality control measures like infection control are given priority while giving accreditation with Joint Commission International. What is viewed as a crisis can be converted into an opportunity by the medical tourism sector.

So A, Furlong M, Heddini A. Globalisation and antibiotic resistance. *BMJ*. 2010;341:c5116.

Drug companies and a "duty of care"

The *Hastings Center Report* invited people new to bioethics to identify issues on which bioethicists should be concentrating.

Not surprisingly one of these is the need for assigning a more responsible role for pharmaceutical companies.

The author quotes Marcia Angell who likens the pharmaceutical industry to an 800 pound gorilla -- difficult to control. She describes how pharmaceutical companies violate the basic principles of bioethics -- justice, beneficence and non-maleficence, and autonomy. Drug companies donate inappropriate, outdated and mislabelled drugs, and also drugs which near their date of expiry, to resource-poor settings and gain tax exemptions in the name of those donations. Drugs with side effects are marketed intentionally for profit. Research for newer drugs is limited to those drugs which are guaranteed to bring in profits.

The author of this essay argues for the need to establish a code of conduct, a "duty of care" for pharmaceutical companies, just as is expected in the doctor-patient relationship. The duty of care, in addition to providing guidelines for behaviour, will also provide a sense of responsibility to pharmaceutical companies.

Miller R. Establishing a "duty of care" for pharmaceutical companies. *Hastings Cent Rep*. 2010 Nov- Dec;40(6):18-20.

Controlling genetic testing firms

Direct-to-consumer genetic testing firms offering home test kits have come under the US Food and Drug Administration scanner after the release of a report by the US General Accounting Office (GAO). The GAO ran an undercover operation with operatives posing as consumers for the tests.

Websites of these firms are suppoed to advocate genetic counselling before testing, provide information on the scientific validity and require informed consent from those who are utilising these services. The GAO investigation found that consumers received misleading and insufficient clarifications over the phone when they contacted the firms for guidance regarding the tests.

The writer discusses various ethical issues associated with such testing. One is of privacy related to a person's genetic material when it is handled by a private firm. There is also the concern that tests for deciding simple traits are often offered together with tests for detecting more serious and life threatening traits. The author reiterates the need for genetic counselling and for such genetic tests to be available only under the supervision of experts.

The German government now requires that such tests be carried out only after authorisation by a qualified physician. The Nuffield Council of Bioethics has published a report criticising the practice of converting genetic testing into a commodity. "Surreptitious testing" is another danger, and the GAO report cites examples of companies encouraging consumers to send samples taken from their fiancées to surprise them with the results. The author quotes Gail Javitt, a research scholar at the Johns Hopkins Berman Institute of Biomedical Ethics, who advocates "risk based" regulations -- the higher the risk, the tighter the regulations. Javitt states that tests should be made available only when they are backed by science, are accurate, and will be conducted properly. Consumers should be able to interpret the tests. The Nuffield report calls for steps to be taken to ensure the security of genetic samples. It also maintains that consumers should be equally responsible and supply only their own samples for genetic testing. As the author points out, the first step will be to check whether the science has matured enough to be marketed.

Udesky L. The ethics of direct-to-consumer genetic testing. *Lancet*. 2010 Oct 23;376:1377-8.

Social networks and drug promotion

The Internet is fast emerging as a powerful medium for mass communication, and social networking sites have millions of followers across the globe. A computer-literate person with access to the Internet can use search engines to get information on all health-related issues. The writers of this essay discuss the dangers of using the Internet for health information. They also discuss the precautionary measures that should be in place if pharmaceutical companies decide to use social networking sites as a medium for product promotion. They state that the Pure Drug and Food Act of 1906 in the US has enabled the Food and Drug Administration to control drug promotion practices and ensure balanced information about the risks, side effects and benefits. Manufacturers have also waited for well defined codes of conduct from the authorities before investing in promotion through a particular medium. The authors cite the example of an FDA 1985 document which provided the format for issuing a summary of risks. Enabled with the guidelines, producers increased their investment in direct to consumer advertisements from $579 million in 1996 to $4 billion in 2008.

Anticipating a powerful use of the social marketing sites, in February 2009, the FDA convened a public hearing . Some major areas of concern regarding the promotion of drugs and devices emerged. There is a need for a balanced picture of risks and benefits in a dynamic medium, and manufacturers must retain control over the content posted on social networks. There is also a need to have information about the impact of such communications on public and clinical health. The authors also call for full disclosure of financial interests when internet-based social networks are used as a promotional medium. The FDA and manufacturers should be responsible for maintaining the credibility of information provided through websites. The authors point out that since the FDA may lack the resources to monitor all promotional content uploaded on the Internet, manufacturers should take responsibility for maintaining credibility with support from the authorities.

Greene JA, Kasselheim AS. Pharmaceutical marketing and the new social media. *N Engl J Med*. 2010 Nov 25;363(22):2087-8.

Village workers reduce infant mortality

Basic healthcare has remained abysmally low in India and other developing countries, more so in the rural areas. Increasing

privatisation in the health sector may further reduce access to healthcare in remote areas. Primary healthcare provided by skilled, community-based health workers can improve child survival rates in areas with high child mortality. This article reports on an evaluation of the Comprehensive Rural Health Project (CRHP) on childhood mortality in Jamkhed, rural Maharashtra.

The base of the three-tier health system consists of village women who have received intensive training in primary healthcare from the Comprehensive Rural Health Project. The second level is of mobile health teams of doctors and nurses who visit the village monthly. At the third level is the secondary care hospital at Jamkhed. From September 1992 to December 2007 there was a 30% decline in the risk of child death after the neonatal period for CRHP villages in comparison with villages in the control area. The effect of the intervention lasted long after the intervention was over.

Mann V, Eble A, Frost C, Premkumar R, Boone P. Retrospective comparative evaluation of the lasting impact of a community-based primary health care programme on under-5 mortality in villages around Jamkhed, India. *Bull World Health Organ*. 2010;88:727-36.

Controlling cancer in developing countries

The authors of this paper state that cancer which was once a dreaded disease in the West is now the leading cause of death in developing countries. Survival rates for cancer are directly linked to the country's income. Developed countries have reduced cancer mortality through awareness programmes, early screening and vaccination against cancer-causing infections like HPV and the hepatitis B virus, and access to new drugs. Regrettably, interventions for early detection and treatment remain inaccessible for most in developing countries.

To bring down the incidence of cancer, these countries will need to cut down on major risk factors such as smoking, focus on prevention such vaccination, and bring cancer screening under the primary health care programme. Limiting the incidence of the disease or even detecting it early is much better and less expensive than treating advanced cases. International funding for cancer care is almost non-existent compared to funding for diseases like AIDS. The Global Task Force on Expanded Access to Cancer Care and Control in Developing Countries was formed to look into these issues. It focused on reducing prices of drugs, having oncologists train local doctors, and generating funds for treatment and palliation.

Farmer P, Frenk J, Knaul F M, Shulman L N, Alleyne G, Armstrong L, Atun R, Blayney D, Chen L, Feachem R, Gospodarowicz M, Gralow J, Gupta S, Langer A, Lob-Levyt J, Neal C, Mbewu A, Mired D, Piot P, Reddy K S, D Sachs J, Sarhan M, Seff rin J R. Expansion of cancer care and control in countries of low and middle income: a call to action. *Lancet*. 2010;376:1186-93.

The disease tailored to fit the drug

The term "female sexual dysfunction" is a good example of "corporate-sponsored creation of diseases" -the drug industry's practice of coming up with new diseases in order to promote the drugs that they manufacture.

There is no doubt that some women do suffer from sexual difficulties, and their condition may even need medical attention. Drug companies extend the definition of this condition to cover a very large population. They also focus on a biomedical response, and sexual dysfunctions arising out of relationship issues or religious, cultural and personal beliefs are not taken into account. Further, companies identify the causes of sexual dysfunction according to the drugs that they have developed.

The writer also comments on the conduct of corporate-sponsored research into "sexual dysfunction". Lead researchers are often company employees and the research design and questionnaire may be tailored to produce results beneficial to the company. Research done without industry funding has asked, instead, whether there was such a thing as "lack of libido" and whether lack of interest in sex could be termed a medical condition. Companies also create awareness about the "syndrome" through websites, and through workshops in hospitals to educate the general public and doctors, using these as ways to promote their brand of drugs.

Moynihan R. Merging of marketing and medical science. *BMJ*. 2010 Oct 2;341:698 -9.

Facing death gracefully

The deathbed ritual has lost its meaning in modern times. Rapid advances in technology mean that a person's life can be prolonged through support systems and medications, and we no longer accept the inevitability of death. The role of religion in preparing individuals for death has lost its importance in a secular society. With better medical care and increased life expectancy, society is more focused on the "art of living", ignoring the "art of dying".

In the mid 14th century, the bubonic plague killed hundreds of thousands of people, creating panic in society. Religious leaders responded to the crisis with advice to laypersons on the procedure, protocol and prayers for dying. "Ars Moriendi" helped prepare the dying as well as those left behind. As modern societies age, we can expect a time when large numbers of people will die of old age over a short period. We should be prepared for this loss. Bioethicists must teach our aging population how to face death and support each other in the process of dying.

Dugdale L. The art of dying well. *Hasting Cent Rep.* 2010;40(6):22-4.

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