availability of a treatment can convert a lifestyle wish into a health need, the pharmaceutical industry becomes a key player in the process of medicalisation, where normal conditions get pathologised.

It appears that when drug therapy is available, physicians are less willing to consider non drug treatments, even when there is no evidence that the former is superior (1). One reason is the pressure from the pharmaceutical industry. One example is the use of Orlistat for treating obesity. Although people taking Orlistat lose a little more weight than those controlling their dietary intake (about 8.9% with pharmaceutical aids vs. 5.6 % with placebo over 1 year), there is no evidence that the drug is any more effective than diet in reducing the morbidity and mortality due to obesity(2). Orlistat is available in India and the prices range from Rs 95 to 390 for 10 tablets. Its reported adverse drug reaction (ADR) varies from mild to severe like oily spotting, increased bowel movements, abdominal pain, headache, rashes and severe liver damage (3).

A number of anti-aging drugs are now available in the market. One of them is Botulinum toxin type A, used for ironing the wrinkles on the face and neck. It can produce paralysis of the small muscles of the face by blocking cholinergic transmission (4).

While there is doubt about the benefits of many modern "lifestyle drugs", there are also concerns about how the pharmaceutical market operates. Drug development is often driven by potential profitability rather than by public health needs. Once a drug is available, industry campaigns may seek to redefine the illness in the minds of doctors and potential patients, converting wishes into healthcare problems that require treatment.

In India where preventable and treatable diseases like malaria and tuberculosis thrive and kill millions of people and many new diseases emerge without any known treatment, the drug development is skewed towards unimportant "lifestyle drugs".

The increasing use of "lifestyle drugs" raises, among several others, one pertinent question: are we trying to homogenise society? There is a need to study the concept and impact of these drugs on society particularly in India. India needs to focus more on life saving and essential medicines rather than "lifestyle drugs". In a free market system, profits may not be the best indication of what drugs we need as a society.

References

1. Everitt DE, Avorn J, Baker MW. Clinical decision-making in the evaluation and treatment of insomnia. *Am J Med* 1990;89:357-62.
2. Therapeutic letter. New drugs V [Internet]. Therapeutics initiative. 2000 Apr 13 [cited 2011 Dec 30]. Available from: www.ti.ubc.ca/pages/letter34.htm
3. US National Library of Medicine. Orlistat: MedlinePlus drug information [cited 2010 Sep 10]. Available from: http://www.nlm.nih.gov/medlineplus/druginfo/meds/a601244.html
4. Jeeja MC. Botulinum toxin. Its cosmetic applications. Paper presented during CME on Cosmoceutical pharmacology at Medical College Thrissur. 2009 Oct 23.

Jeeja MC, *Department of Pharmacology,* ***Jayakrishnan T,*** *Department of Community Medicine, Government Medical College, Calicut 673 008 Kerala, INDIA e-mail: jayanjeeja@yahoo.co.in*

Ethics in animal experiments

Ethics is very important to any research. Authors are expected to report if the research was done in an ethical manner. Various studies have highlighted the fact that reports of research involving human participants do not always give adequate information on ethical aspects of the study, such as how informed consent was obtained, and details of the ethics review (1-3). This has been reiterated in studies on articles published in Indian medical journals (4-6).

While reporting of ethical parameters in clinical studies is discussed widely, the issue of ethical reporting in animal studies seems to have been ignored.

The present study was designed with the primary aim of analysing the reporting of ethical parameters in animal studies published in Indian journals. The secondary aim was to compare the reporting of ethical parameters between Indian and international journals. Most animal studies are published in pharmacology journals. Studies published in two leading indexed pharmacology journals, *Indian Journal of Pharmacology* (IJP) and *Indian Journal of Physiology and Pharmacology* (IJPP), were selected for the study. *The British Journal of Pharmacology* (BJP) was selected as a comparator international journal.

All the articles published in *IJP* and *IJPP* between 2002 and Jan – March issue of 2010 were downloaded from the journals' websites (www.ijp-online.com, www.ijpp.com). Animal studies published in *BJP* from 2002 to September 2009 were downloaded from the journal's website (http://onlinelibrary.wiley.com/journal/10.1111/%28ISSN%291476-5381). In the case of *BJP*, articles published after September 2009 were not available for open access. As for *IJPP*, articles published since 2002 were available on the website. So, to maintain uniformity, all articles published in or after 2002 were downloaded. Only original animal studies were considered for the study. Short communications, research letters and letters to the editor were not taken into account. Of the studies downloaded, 50 animal studies each from *IJP* and *IJPP* were selected randomly (by computer-generated random numbers) and 100 animal studies were selected randomly from *BJP* by the first author. For equal comparison, animal studies only related to pharmacology were downloaded from *IJPP*. Each author evaluated these animal studies on the basis of reporting of animal ethics committee approval and reporting of ethical guidelines. Discrepancies in evaluation were resolved by consensus.

Values were shown in the form of frequencies, and comparison between various ethical parameters between the Indian

journals (*IJP, IJPP*) and the international journal (*BJP*) was done with the help of Chi –Square test through excel sheet.

Our study revealed that 79% of animal studies published in the two Indian journals reported permission from an ethics committee, which is more than the comparator international journal (62% in *BJP*). Information related to various guidelines was reported more often in *BJP* (58%) as compared to the Indian journals (38%). Regarding ethics committee approval and information related to ethical guidelines, there was no significant difference between the two journals.

Our findings show that reporting of ethical parameters such as institutional ethics committee approval is better in animal studies published in Indian journals as compared to clinical studies published in Indian journals. In a study by Chaturvedi et al of articles published in the *Indian Journal of Psychiatry,* it was observed that permission from an ethics committee was reported in 25% of the articles (5). In a similar study undertaken for articles published in two Indian paediatrics journals, permission from an ethics committee was reported in 29.5% of the articles (4).

In a new guideline ARRIVE (Animal Research: Reporting In Vivo Experiments) for reporting animal studies, authors of articles reporting research are instructed to report on: the nature of ethics review permission; the relevant licence, and the national and institutional guidelines related to the care and use of animals (7). This study shows that though reporting of ethical parameters is better in animal studies as compared to clinical studies, there is room for improvement and authors should be encouraged to report these ethical parameters in the articles.

Though efforts have been made by journal editors towards improving the reporting of ethical parameters (8), there is a need for more in animal as well as clinical studies. Young researchers and students working in the field of biomedical research involving animal studies should be trained in ethical aspects of research while conducting experiments and reporting the same in publications. Journal editors and peer reviewers should make sure that information regarding ethical parameters is incorporated in the manuscript.

References

1. Ruiz-Canela M, Gomez-Gracia E. Informed consent and approval by institutional review boards in published reports on clinical trials. *N Engl J Med*. 1999 Apr 8;340:1114-5.
2. Yank V, Rennie D. Reporting of informed consent and ethics committee approval in clinical trials. *JAMA*. 2002 Jun 5;287:2835-8.
3. Schroter S, Plowman R, Hutchings A, Gonzalez A. Reporting ethics committee approval and patient consent by study design in five general medical journals. *J Med Ethics*. 2006 Dec;32 (12):718-23.
4. Bavdekar SB, Gogtay NJ, Wagh S. Reporting ethical processes in two Indian journals. *Indian J Med Sci.* 2008 Apr;62 (4):134-40.
5. Chaturvedi SK and Somashekar BS. Reporting ethical aspects in published research articles in the Indian Journal of Psychiatry. *Indian J Psychiatry*. 2009 Jan - Mar;51(1):34.
6. Jaykaran, Gohiya S, Gohiya V, Sharma G, Saurabh MK, Yadav P. Reporting of the methodological quality and ethical aspects in clinical trials published in Indian journals: a survey. *J Pharm Research*.2010 Mar;3(2):307-9.
7. Kilkenny C, Browne WJ, Cuthill IC, Emerson M, Altman DG. Improving bioscience research reporting: The ARRIVE guidelines for reporting animal research. *PLoS Biol. 2010 Jun;*8(6):e1000412. doi:10.1371/journal.pbio.1000412.
8. Bavdekar SB, Gogtay NJ, Chavan R. Reporting ethical processes: survey of instructions to authors provided by Indian journals. *Indian J Med Sciences*. 2009 Jun;63(6): 260-2.

***Jaykaran**, Assistant Professor, Department of Pharmacology, Government. Medical College, Surat 395 001 INDIA e-mail: drjaykaran@yahoo.co.in **Preeti Yadav**, Associate Professor, Department of Pharmacology, Government Medical College, Surat 395 001 INDIA **N D Kantharia**, Professor and Head, Department of Pharmacology, Government Medical College, Surat 395 001 INDIA*

Bridging the ethics gaps

"Sir, I have already collected 15 cases in my research project, and have not taken consent from any of the participants. What should I do now?" asked a postgraduate student in an ethics committee meeting that I happened to be attending, several years ago. Promptly came the reply from the head of the institution, who also happened to be the chairperson of the ethics committee there: "No problem, just go to any patient who is admitted in the ward and take his thumb print on the consent form." This encounter rudely awakened me to the huge gap between knowledge and practice in medical ethics.

In keeping with the advances in medical technology, the world has moved forward in the area of bioethics, but in India we are still rooted in outdated concepts. In the four and a half year MBBS course, students cover a very limited ethics syllabus, inadequate in today's context. The course content in ethics at the undergraduate level stresses deontological theories and lacks in applications or skill development. The focus is on the doctor-patient relationship, issues of negligence and the Consumer Protection Act. In other words, medical ethics is taught on the premise that the law is breathing down a medical practitioner's neck and one should be careful not to cross the legal boundary.

The past decade has seen an astronomical rise in clinical research in India. The lure of money that has inevitably accompanied this has not only attracted human participants from vulnerable populations, as research participants, but also many graduates of medicine or related disciplines, who decide to engage in a career in clinical research. Many of them come from disciplines like homeopathy, and other Indian systems of medicine, besides allopathy. These youngsters lack the exposure to and competence in research ethics. Even principal investigators of clinical trials are not well grounded in the basic issues of research ethics. Often, ethics committees, which give ethical clearance to myriad clinical research protocols involving human subjects, lack qualified or even knowledgeable members.

The undergraduate curriculum should be covering areas