LETTERS

Universal Immunisation Programme

This refers to a very thought-provoking article by Jayakrishnan (1). I fully agree with the statement, "Immunisation matters are left to manufacturers and international organisations, to "guide" and decide what is to be introduced in our market."(1).

There is an acute need to protect adolescents and young adults from the economically poor sections against pertussis and diphtheria. In 2008, the Indian Academy of Pediatrics Committee on Immunisation (IAPCOI), in the consensus recommendations on immunisation, stated: "There is no reason to believe that the disease burden of pertussis is low in adolescents in India. A safe and efficacious vaccine is available. The IAPCOI , therefore, recommends offering Tdap vaccine instead of Td/TT vaccine in all children/adolescents who can afford to use the vaccine" (2). Tdap contains acellular pertussis antigen, and is very expensive (MRP Rs 699) while Td costs Rs 10.08 only. In 2006, the author and a colleague had suggested the use of a reduced quantity of the whole cell pertussis component" (3).

Adolescents and young adults belonging to the weaker economic groups are more prone to infections, but they would not be able to afford such a costly vaccine. On November 5, 2008, this author had written to the Serum Institute of India, a leading vaccine manufacturer, with copies to the convener, IAPCOI and other functionaries of the IAP, "to take the initiative and come out with a combination vaccine of tetanus with reduced quantity of diphtheria and whole cell pertussis components. This is needed for the masses that also need protection against pertussis but cannot afford the current Tdap vaccine." There was no response from any one.

However, the drug manufacturers alone are not at fault. Under the existing system, tetanus toxoid with reduced quantities of diphtheria antigen and whole cell pertussis antigen is considered as a new molecule, and needs to be studied afresh for safety and efficacy before even applying for a licence. All this would require heavy investment, while the permitted price cannot exceed that of the DTP vaccine. This "will discourage any manufacturer to go for a vaccine which may be the need of the hour but is bound to act as a loss incurring venture. The solution to bail out industry should come from the authorities and the medical profession."(4) Regarding the administration of hepatitis B vaccine, I quote from a 2007 publication of Jan Swasthya Abhiyan which maintains "Considering the low prevalence of hepatitis B, and the resource constraints, this vaccine should be limited to babies born to hepatitis B+ mothers. For this purpose, all pregnant women should undergo testing for Hepatitis B as part of other tests for anaemia and blood grouping. This does not require any additional effort or equipment and the test kit can be bought in bulk by the government for, say Rs 15-20." (5).

In 2000, I had stated, "Checking of HBs Ag status is not a very expensive or difficult procedure. If it is checked for the prospective marriage partners, the problem of horizontal and later vertical transmission of the virus to the new born can be eradicated" (6).

I had emphasised the importance of blood testing by stating: "If a person is already infected, administration of the vaccine (by routine schedule) will not alter the course of the disease. The infected person may act as a source of infection, while having the false assurance that he or she has been immunised against hepatitis B disease"(6). This point was raised since, sometimes, hepatitis B vaccination is carried out as a campaign, providing vaccine free or at subsidised cost.

I fully agree with Dr Jayakrishnan's views that the national vaccination policy should be disease-oriented. In addition, it needs to be stressed that tuberculosis, measles, polio, diphtheria, tetanus, pertussis, and typhoid should be given priority before including hepatitis B, haemophilus b influenzae, pneumucoccal and varicella diseases in the National Immunisation Programme.

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Saving lives, or styling them?

The past few years have witnessed the rise of highly publicised "lifestyle" drugs. They are used to alter our appearance, physical and mental capabilities, the effects of aging, and so on. As the

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.

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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.

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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

of skill-building in ethics such as identifying ethical issues and violations, and focusing on remedies and ethical case resolutions. Currently, this is not being done. At the postgraduate level, ethical deliberations, end-of-life decisions, ethical conflicts resolution and clinical ethics consultation are not touched upon.

To bridge this gap, the Centre for Ethics was established by Yenepoya University, in Mangalore, Karnataka. The first programme launched by the Centre was the Postgraduate Diploma in Bioethics and Medical Ethics, a year-long course with six contact programmes, supplemented by projects, online assignments and group discussions, culminating in a summative written exam. The course exposes the student to the basics of ethics, morality, theology and philosophy and their inter-relatedness in healthcare, technology and research involving human subjects. The main objective is to train enough people in the basics of healthcare and research ethics issues so as to do justice to their positions on institutional ethics committees or as members of clinical research teams.

In 2011, the Centre signed a memorandum of understanding with the Department of History, Philosophy and Ethics in Medicine at the Johannes Gutenberg Medical University, Mainz, Germany, and another with the Duquesne University, Pittsburgh, USA. These collaborations promote staff and student exchange and take up joint research ventures in the field of trans-cultural clinical ethics. The six-month certificate course in clinical ethics consultation conducted by our centre utilises the services of the faculty members of both these universities. Two one-week long intensive contact programmes in each trimester are supplemented with online assignments and group discussions. This is designed to train participants in the basics of ethics, its applications in healthcare and how to conduct a clinical ethics consultation. The objective is to bring into India the concept of clinical ethics consultation that will have an impact on the ethics of healthcare practices in our country.

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Through a nurse's eyes

I sincerely appreciate the editorial "Life and Death after Aruna Shanbaug" written by Dr Roop Gursahani in the *Indian Journal of Medical Ethics (IJME)* dated April-Jun 2011. The editorial is very well written and articulated and the author has very aptly discussed every part of the judgment delivered by Justices Markandey Katju and Gyan Sudha Misra of the Supreme Court of India. I would like to add that had the euthanasia plea been granted it would have led not only to intense resentment among all the doctors and nurses of KEM hospital, but would have opened a new avenue for unscrupulous people in our society, who for the sake of property and money, could go to the extent of getting their parents and relatives killed by bribing and conspiring with unethical, and greedy doctors. Hence, there are strong chances of euthanasia being prone to misuse. Moreover, there may be a cure in future for a medical state perceived as incurable today. I strongly oppose the plea by Ms.Pinki Virani. One must understand that in all these years, the nurses caring for her have not tired, but in fact, feel greatly privileged to care for her. Why, then, should the views of a third party, who has not even cared her for a single day, be considered? .Hence, there is no point in worrying unnecessarily about Aruna, writing a book on her life story, or even paying visits to her, as all these things cannot be a substitute for the high quality, holistic nursing care being rendered to her by our fellow nurses working ceaselessly day and night. I must agree with Dr Sanjay Oak, Dean, KEM Hospital, when he said , in his testimony, "I must put on record that in the world history of medicine there would not be another single case where such a person is cared and nurtured in bed for 33 long years and has not developed a single bed sore. This speaks volumes of the excellence of nursing care that KEM nursing staff has given to her" (1). Once again I salute the spirit of all the nurses of KEM Hospital, Mumbai.

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