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Indian Journal of Medical Ethics
Vol VII No 2, April-June 2010
(incorporating Issues in Medical Ethics, cumulative Vol XVIII No 2)

Cover: Hemant Morparia

EDITORIALS

Gifts to doctors, scientific information and the credibility gap in the Medical Council of India

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Gifts to doctors influence their prescribing patterns. Research has shown, quite unequivocally, that even a small gift, like a pen, can have an influence. The evidence on this is catalogued in detail on the website www.nofreelunch.org (1). The move of the Medical Council of India (MCI) to amend the code of ethics for doctors and incorporate a specific ban on gifts (2) must, therefore, be welcomed. It must be noted that the rule in India is far more stringent than that in other countries such as the United States. The new rule in India bans all gifts above Rs 1,000 in value. The recommended minimum punishment for accepting a gift up to a value of Rs 5,000 is censure, and above this value, suspension from the medical register for various periods is prescribed. Susan L Coyle, writing for the Ethics and Human Rights Committee of The American College of Physicians - American Society of Internal Medicine, considers as acceptable low cost gifts for office use like pens and calendars, low cost gifts of educational or patient care nature (like textbooks) and modest refreshment (3).

The laudable aim of such bans is to prevent the drug and medical device industry from influencing doctors to use inappropriate or expensive (or both) drugs and devices because of the benefits the doctor can receive for such use. As many commentators have pointed out, in medicine, the doctor decides and the patient pays; hence there is a special need to ensure that decisions are made solely in the interest of the patient.

Drug information in India

Good prescribing habits imply the availability of good information about drugs and medical devices. This means that the doctor must be aware, not only of the appropriate usage of drugs but also of the quality of the different suppliers and the prices. Unfortunately, in India such information is not easy to come by. In the United Kingdom, for example the Joint Formulary Committee publishes the British National Formulary (4) which lists all medicines available in Britain, the indications for their use and their side effects and prices. Similar publications exist in most of Europe. The European Union has established the European pharmacopoeia and is moving towards harmonisation.

In India, on the contrary, no official and reliable channel of information exists. Except for checking in the *Monthly Index of Medical Specialties* or the *Current Index of Medical Specialties,* there is no way for a doctor to know the relative prices of various brands of the same or similar drugs. Looking at hundreds of formulations from hundreds of companies is no easy task. The initiative of setting up drug information centres in several states has not taken off in a big way. One study (5) showed that in a period of three years from August 1997 to July 2000, only 132 of all queries (13.2%) made to these centres were from doctors.

Quality concerns

In a situation of poor regulation, the proportion of spurious to authentic drug formulations in India is estimated to range between 10% and 20%, the figure provided by the legitimate pharmaceutical industry in India and quoted by the World Health Organisation task force on spurious drugs (6). The Mashelkar Committee Report 2003 (7) put the percentage of spurious drugs in India at between 0.5% and 35%. The medical devices market is no different with a large number of small players many of whom are not compliant with good manufacturing practices. In 2005, 10 categories of medical devices were declared to be drugs and their manufacture needs approval from the Central License Approval Authority under the Central Drugs Standardisation and Control Organisation (8). In private conversations, manufacturers of these products allege that the licensing authority demands bribes of about Rs 15 lakh to certify the manufacturing unit as quality compliant. It therefore remains uncertain if the company makes quality goods. In critical areas like stents for the heart, and orthopaedic implants, it is unclear if these products have been put through the rigorous testing required. The Central Drugs Standardisation and Control Organisation is understaffed and poorly run and it is difficult to repose confidence in this institution. Almost all the problems listed in the Mashelkar Committee Report 2003 still exist. They are: poor enforcement of laws, understaffing, failure to establish a National Drug Authority, inadequate testing facilities, lack of drug inspectors, non-existence of a data bank, and non-availability of accurate information.

It is alleged that bribes are a way of life here. Certification by the CDSCO is therefore no guarantee of quality, and doctors must

seek other means to be assured of the quality of the drugs that they prescribe. One of the common tactics that doctors use is to prescribe only the products of multinational companies or large local companies in the belief that these companies need to protect their brand image and therefore will maintain quality. But the products of these companies are rarely the cheapest in the market.

Credibility gap in the Medical Council of India

There is also the problem of the huge credibility gap in the MCI. In recent years this statutory body of the government of India has been in the news for its poor regulation of medical education, its failure to play a leadership role in the governance of medical education and practice and several unsavoury allegations against its members. The situation has reached such a sorry pass that the government has expressed an intention to abolish it and replace it with another body. The way the Council is constituted lays it open to the shenanigans of people of little integrity. It is difficult to escape the conclusion that the present amendment to the ethical code is a feeble attempt to lay claim to ethical behaviour. The attempt is feeble because there is no way that this institution, which has never taken any action in spite of specific complaints and proof (9), is likely to take action now. And who is going to complain that the doctor has been given a gift? The drug or device company? The doctor?

If the Medical Council of India is really serious about setting right the numerous infractions of its ethical code, it needs to do much more than add another rule to a code which is seldom enforced. The present president, Ketan Desai, is seen to be so compromised that he should either resign or be removed. The method of composition of the council and the various state councils must be radically changed in order to allow people of integrity, instead of medical politicians, to come in. Today, membership of the council is sought after as an office of illegal profit and patronage. It needs to become what it is meant to be – a leader in developing, maintaining and enforcing the finest practices in medicine in the interests of the people of the country. Till that happens, all such cosmetic changes in rules will remain mere tokenism and achieve nothing.

References

1. No Free Lunch. Required reading [Internet]. NY (USA): [publisher unknown]; [cited 2010 Mar 8]. Available from: http://www.nofreelunch.org/reqreading.htm
2. Medical Council of India. Code of Ethics Regulations, 2002. Amendment notification [Internet]. New Delhi; 2009 Dec 10. [cited 2010 Mar 8]. Available from: http://www.mciindia.org/know/rules/ethics.htm.
3. Coyle SL; Ethics and Human Rights Committee, American College of Physicians-American Society of Internal Medicine. Physician-industry relations. Part 1: individual physicians. *Ann Intern Med*. 2002 Mar 5; 136(5): 396-402.
4. British National Formulary [Internet]. [place unknown]: BMJ group and RPS publishing; c2009 [cited 2010 Mar 8]. Available from: www.bnf.org
5. Lakshmi PK, Rao DA Gundu, Gore SB, Bhaskaran S. Drug information sources to doctors of Karnataka, India. *Ind J Pharmaco*. 2003; 35: 245-7.
6. IMPACT International Medical Products Anti-Counterfeiting Taskforce. Counterfeit medicines: an update on estimates [Internet]. Geneva: WHO;2006 Nov 15 [cited 2010 Mar 8] Available from: http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf
7. Ministry of health and family welfare, Government of India. Report of the expert committee on a comprehensive examination of drug regulatory issues, including the problem of spurious drugs [Internet]. New Delhi: Government of India;2003 Nov. [cited 2010 Mar 8]. Available from: http://cdsco.nic.in/html/Final%20Report%20mashelkar.pdf
8. Ministry of health and family welfare, Government of India. Office of the drugs controller general (India). Public notice [Internet]. New Delhi: DCGI; undated. [cited 2010 Mar 8]. Available from: http://www.cdsco.nic.in/Medical%20devices.pdf
9. Mani M K. Our watchdog sleeps, and will not be awakened. *Issues Med Ethics* [Internet]. 1996 Oct-Dec [cited 2010 Mar 8];4(4): 105-7. Available from: http://www.ijme.in/044ed105.htm

The new rural doctor: qualified quack or appropriate healthcare provider?

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The recent decision of the Medical Council of India (MCI) to initiate the training of an exclusive cadre for the healthcare needs of rural areas has provoked intense debate. Groups as well as individual experts have raised several points while arguing on either side of the debate (1-3). This short comment discusses here two such debates, one on the "level of skills" with which the new cadre would put its profession into practice and the other about the need for basic practitioners.

There have been several questions, some with ethical overtones (why should there be substandard care for the rural population?) and some on practical matters (will the cadre be able to handle the population's healthcare needs?). These are based on the notion that what we have today (the current medical graduation programme) is the gold standard, and what we are considering as a new cadre is nothing but a compromise and a short-term solution to the problem of non-availability of doctors. This position can be challenged because the issue of health human resources in rural areas is not limited to their non-availability. Another important question relates to their appropriateness to work in the rural context, especially for primary level care.

The need for social physicians

Many experts have pointed to the urban-centred training of the present cadre of doctors, and the focus on biomedicine without consideration of the socioeconomic context of healthcare, which makes them inappropriate to work in most rural areas and rural health institutions. For example, the recently submitted Government of India Task Force report has commented on the nature of the problems with medical graduates that are produced by the existing educational system (4).

By and large they carry the values of the urban middle class. Even those from a rural background are unwittingly co-opted into the urban milieu, discarding their social roots. As a result, fresh graduate doctors have no concept of broad community healthcare needs. Their professional world-view, regardless of whether they pursue a career in the public or in the private sector, is of providing curative services with considerable high-tech backup. Professionally they aspire to specialise in one or the other clinical disciplines, and their skills are organically linked to the back-up infrastructure of a tertiary care hospital. The Task Force sees the lack of an understanding of broad community health needs in the fresh medical graduates as a critical deficiency. This results in a misconceived approach to primary healthcare, whether in the public or in the private sectors.

This is not an isolated comment. Almost every such commission and committee that has studied various aspects of the Indian health system after the Bhore committee report has pointed to this aspect. In fact, the Bhore committee itself had envisaged a qualitatively different kind of medical cadre, which the report called "social physicians" (5). By calling them social physicians the report envisaged that the doctors of the future should be guiding people to a healthier life and recommended that students of medicine be brought into contact with the environmental and social conditions which largely influence the health and disease of people. Fifteen years later, the Mudaliar Committee (1961) reiterated the need for the "social physician" (6). Other important reports like the Srivastava Report of 1975 (on the family and community-oriented practitioner) and the Bajaj committee report (1989) on the community physician also described the ideal medical cadre in similar lines (7, 8).

The recent report of yet another high power committee, the subgroup on medical education set up by the National Knowledge Commission (2007), has pointed the finger at the Medical Council of India for the failures which led to the progressive decline of medical education in the country (9). The commission argues that the shortcomings of new medical graduates are principally the outcome of their urban orientation and the skewed pattern of their aspirations. "Most of them have only lived and trained in the urban setting. The few with a rural background acquire an urban mindset in the course of their training that is focused around a tertiary care hospital."

A historic opportunity

Of course this can lead to the argument that what we need is a revamping of medical education, and not a new cadre. This notion can be challenged because I believe that the present cadre survived because there was a market for it in the "powerful" curative services in the secondary and tertiary care sectors. Any attempt to reorient the training of medical graduates to primary level care, or to create "social physicians", would be politically unviable, no matter how desirable it is. It is here that the option of a new cadre offers us a historic opportunity. Surely this is neither a quality compromise nor a short term solution. It is in fact an opportunity for providing appropriate care at the primary level.

An alternate policy option that is being increasingly debated in this context is the compulsion – as a strategy – to deploy more doctors in rural institutions, even though the mechanism applied so far to deploy medical personnel in such underserved areas

has been a losing battle (3). Even if we succeed in forcing a certain percentage of medical personnel to work in rural areas, how would such a reluctant cadre serve the purpose? I quote again from the National Knowledge Commission report (9):

> Compulsion fills up vacancies – much more at the apparent level than at the real level. It also provides a poor quality person for these jobs, and with very short term commitments to working there. After all, one can force a horse to the water, but one cannot make it drink.

Another incorrect assumption in this entire debate is that the present curative care needs in the rural areas of the country can be addressed if all vacant positions of medical officers in primary health centres (PHCs) are filled. An epidemiological profile based on available morbidity data will throw more light on the inadequacy of present norms for human resources for curative services in rural India. The 60th round of the National Sample Survey Organisation morbidity survey identifies 53 morbid persons for every 1,000 population on the previous day of the survey (10). This amounts to about 1,590 morbid persons in a day for a PHC area population of 30,000. This, along with clinical examination related to maternity and family planning services and medical screening for certain public health programmes such as immunisation services and disease control programmes, forms a sizeable caseload for clinical management through inpatient and outpatient services which is difficult for one or two doctors at PHCs to handle. Today, this unfulfilled gap is dealt with by a range of less than qualified providers, or by self medication, or no treatment. With the increasing prevalence of non-communicable diseases, the requirement for such services is only going to increase in the future. Ideally, it is time for us to think of having medical practitioners placed at the level of sub-centres to attend to curative care needs.

Recognition of the new cadre

I have used the initial part of this article to defend the policy of a new health human resource cadre for primary level care. However, let me also state some of my concerns as the new policy is implemented. At the outset, the MCI has made it clear that practitioners in this new cadre should not be allowed to call themselves doctors. This is definitely a step backward and an attempt towards disempowering the cadre. It is important that people recognise these providers as their primary level physicians who have the mandate and capacity to diagnose and prescribe appropriate treatment for their ailments. Based on past experience, the MCI's capacity to govern the new cadre in terms of professional practice and education can be called into question. The regulatory concern should be more in terms of avoiding medical malpractice, especially the interference of commercial interests in their professional practice; for this the MCI has been a bad governor for the current cadre of medical practitioners. Similarly, the MCI's inability to revamp current medical education to meet the needs of the country has been repeatedly noted by several high powered committees and commissions. This calls for different institutional mechanisms outside the purview of the MCI for governance of this new cadre.

It is also important that we have a balanced approach to the new cadre when we consider their career path against the country's present health human resource requirement. Having the title "rural" attached to their degree will permanently tie them down to rural areas, which is not desirable. In fact, their services should be also made available for primary level care in the entire country (even though they can be deployed exclusively for rural areas, in the initial years). It is unfortunate that while considering the entry requirements for training of the new cadre, the potential of other health professionals like nurses and nurse auxiliaries to switch to the new cadre was not considered. The training of nurses has a strategic advantage as they are already trained in the allopathic stream and also have gained patient management skills at the end of their training.

A matter of equity

Those who raise ethical arguments based on notions of inequality – that the new cadre will result in sub-standard care for the rural population – should also understand that one of the principles of healthcare ethics is the principle of justice and an important expression of justice is equity (11). The provision of a primary level of care to all sections of society according to their need is crucial in achieving equity in healthcare provision. Nevertheless, there is a danger if we approach the present initiative in health human resources as a stopgap arrangement which can be reversed when enough of the present cadre of medical personnel are trained and made available for the rural areas. Our health system would only benefit if we approach them as an important type of healthcare provider and use their potential in providing universal primary level care.

References

1. IMA Kerala Branch. Stop BRMS for quality medical education. About the BRMS issue [Internet]. Kerala (India): Indian Medical Association Kerala State branch; 2010 [cited 2010 Mar 8]. Available from: http://www.stopbrms.com/index.php
2. Mudur G. India decides to train non-medical rural healthcare providers. *BMJ* [Internet]. 2010 Feb 9[cited 2010 Mar 8];340:c817. Available from: http://www.bmj.com/cgi/content/full/340/feb09_3/c817
3. Ramdas A. The wrong way for rural doctors. *The Hindu* [Internet]. 2010 Feb 27 [cited 2010 Mar 8]; Opinion:[about 4 screens]. Available from: http://www.hindu.com/2010/02/27/stories/2010022762151400.htm
4. Government of India. Taskforce on medical education for National Rural Health Mission [Internet]. New Delhi: Ministry of Health and Family Welfare; 2005 [cited 2010 Mar 8]. 107p. Available from: http://www.mohfw.nic.in/NRHM/Documents/Task_Group_Medical_Education.pdf
5. Government of India. Report of the health survey and development committee [Internet]. Kolkata (India): Manager of publications, Government of India

Press;1946 [cited 2010 Mar 8]. 232 p. Available from: http://nihfw.org/NDC/DocumentationServices/Reports/bhore%20Committee%20Report%20VOL-1%20.pdf
6. Government of India, Ministry of Health. Report of the Health Survey and Planning Committee (August 1959- October 1961) [Internet]. New Delhi: Government of India; 1961[cited 2010 Mar 8]. 523p. Available from: http://nihfw.org/NDC/DocumentationServices/Reports/Mudalier%20%20Vol.pdf
7. Group on medical education and support manpower. Srivastava Committee Report. Health services and medical education. A programme for immediate action [Internet]. New Delhi: Ministry of Health and Family Planning, Government of India; 1975[cited 2010 Mar8].63p. Available from: http://nihfw.org/NDC/DocumentationServices/Reports/Srivastava%20Committee%20Report.pdf
8. Expert Review Committee for Health Manpower Planning and Development. Bajaj committee report [Internet]. New Delhi: Ministry of Health and Family Planning, Government of India; 1989 [cited 2010 Mar8].39p. Available from: http://nihfw.org/NDC/DocumentationServices/Reports/Bajaj%20Committee%20report.pdf
9. National Knowledge Commission. Report of the working group on medical education [Internet]. New Delhi: Government of India; 2007 [cited 2010 Mar8].69p. Available from: www.knowledgecommission.gov.in/downloads/documents/wg_med.pdf
10. National Sample Survey Organisation. Morbidity, health care and the condition of the aged, NSS 60th round (January -June 2004)[Internet]. Ministry of Statistics and Programme Implementation, Government of India; 2006 Mar [cited 2010 Mar 8].55p. Available from: http://mospi.gov.in/national_data_bank/pdf/NSS%2060th%20Round-507.pdf
11. Stark R, Nair NVK, Omi S. Nurse practitioners in developing countries: some ethical considerations. *Nurs Ethics*.1999 Jul; 6(4): 273-7.

Publisher's Note

Form IV (See Rule 8)

1. Place of publication: FORUM FOR MEDICAL ETHICS SOCIETY
   Address: 0-18 Nav Bhavna Premises Co-op Society
   2nd floor, Veer Savarkar Marg, Prabhadevi, Mumbai 400 025 Maharashtra
2. Periodicity: quarterly
3. Printer's name: Dr Sanjay Nagral
   Nationality: Indian
   Address: FORUM FOR MEDICAL ETHICS SOCIETY
   0-18 Nav Bhavna Premises Co-op Society
   2nd floor, Veer Savarkar Marg, Prabhadevi, Mumbai 400 025 Maharashtra
4. Publisher's name: Dr Sanjay Nagral
   Nationality: Indian
   Address: FORUM FOR MEDICAL ETHICS SOCIETY
   0-18 Nav Bhavna Premises Co-op Society
   2nd floor, Veer Savarkar Marg, Prabhadevi, Mumbai 400 025 Maharashtra
5. Editor's name: Dr George Thomas
   Nationality: Indian
   Address: FORUM FOR MEDICAL ETHICS SOCIETY
   0-18 Nav Bhavna Premises Co-op Society
   2nd floor, Veer Savarkar Marg, Prabhadevi, Mumbai 400 025 Maharashtra
6. Name of owner: FORUM FOR MEDICAL ETHICS SOCIETY
   Address: 0-18 Nav Bhavna Premises Co-op Society
   2nd floor, Veer Savarkar Marg, Prabhadevi, Mumbai 400 025 Maharashtra

I, Dr Sanjay Nagral, hereby declare that the particulars given above are true to the best of my knowledge and belief.
Sd/-
31 March 2010.

FROM THE PRESS

Hope for the HIV positive

The international health funding agency UNITAID has created a "patent pool" that will make HIV drugs affordable to patients in developing countries. Drug manufacturers will have access to patented processes and those bartering their patented knowledge will receive royalties for it.

The value of the patent pool is summed up by Mike Foster, the international development minister of the UK which was one of the founding countries of UNITAID: "Last year 2.7 million people were newly infected with HIV and 2 million people died from AIDS – the need to make effective HIV medicines affordable for developing countries has never been greater."

UNITAID is an international health financing agency that works to improve access to drugs related to HIV/AIDS, malaria and tuberculosis. It not only makes existing drugs accessible, but also encourages research in this area. This has major implications for those affected by these diseases in developing countries. For example, all patients on drugs for HIV will develop resistance to these drugs over a period of time. Second generation drugs are so expensive that they remain inaccessible to a majority of patients. Worldwide, only 42% of HIV infected people in need of treatment have access to it.

Peter Moszynski, HIV drug patent pool offers hope of cheap drugs to millions, *BMJ*, January 16, 2010.

Fighting the asbestos lobby

Civil rights and health groups are campaigning for a total ban on asbestos in India. They are calling on legislators to pass the White Asbestos (Ban on Use and Import) Bill that was introduced in the Rajya Sabha in 2009. In January 2009, the Kerala State Human Rights Commission issued a ban order against asbestos, declaring that exposing consumers to asbestos fibres of all kinds was a violation of human rights.

Though asbestos is banned in 50 countries, in India, consumption is actually increasing, from 125,000 metric tonnes in 2000 to about 300,000 metric tonnes in 2007. Asbestos is mixed with cement for roofing sheets and India's asbestos cement industry has grown by about 10% every year, and employs some 100,000 people. Experts express grave concerns about the consequences to workers' health. The mineral is indicted in a number of diseases including asbestosis and cancers of the lung, pleura and peritoneum, larynx and ovaries. An estimated 90,000 people die every year from diseases related to occupational exposure to asbestos; this number does not include the deaths of family members of asbestos workers, and of those living near asbestos factories and mines.

The industry runs a massive lobby that has blocked efforts to get chrysotile, or "white asbestos", listed in the UN registry of hazardous materials and has launched media campaigns to convince the public that asbestos is a safe material. 90% of India's asbestos comes from Canada and the Canadian government-funded Chrysotile Institute has run a global campaign in support of chrysotile.

Closer home, organisations working to get asbestos banned are coming up against a strong political lobby, according to Madhumita Dutta of the Ban Asbestos Network, Chennai. Several parliamentarians have major holdings in asbestos companies, the government owns asbestos companies, and industry funding has influenced government studies on asbestos.

Activists are also concerned about the poor quality of health data. While there is no doubt about the health hazards of asbestos, there is no systematic information collection to give a sense of how many people are getting affected. Hospitals have reported seeing many cases of the asbestos-caused mesothelioma.

Occupational health has not been a priority in Indian medical education. Only one medical school in the country has a training programme in occupational health. There are 55 million Indians under the Employees State Insurance Corporation but very few of the 6,500 physicians in this scheme have any training in occupational health. So asbestosis is frequently diagnosed as tuberculosis or bronchitis. According to V Murlidhar of the Occupational Health and Safety Centre in Mumbai, doctors do not have access to the particular radiological plate that is necessary to give a firm diagnosis of asbestosis. India's labour laws have made it difficult to punish negligent employers and few workers have received compensation for asbestos-related disease.

Talha Burki, Health experts concerned over India's asbestos industry, *The Lancet*, February 20, 2010. T Nandakumar, Fighting for a ban on asbestos, *The Hindu*, December 21, 2009.

NCW sees red over the morning after pill

The National Commission of Women (NCW) has written to the Medical Council of India and the Ministry of Health and Family Welfare expressing concern over the extensive advertisement campaigns for emergency contraceptive pills. The advertisements of the pills promote these as an alternative to safe sex; this not only conceals the numerous side effects of these pills but also increases the risk of HIV and other sexually transmitted diseases.

These pills are available over the counter and are increasingly being used by teenagers. They are designed for use by women above 25 years of age and can have serious side effects, such as hormonal imbalance, for teenagers and women who use them regularly.

The NCW statement aims to draw attention to the large scale publicity of emergency contraceptives undertaken by pharmaceutical companies. It states: "With concern, it is seen that the drug is being projected as an after saviour of unsafe sex. The advertisements of these pills are quite misleading and its side-effects as well as efficacy are not at all being disclosed."

PTI, NCW writes to health ministry on emergency contraceptive pills, *The Hindu*, February 22, 2010.

Illegal drug trial – but with government support

Illegal drug trials in Cambodia have human rights activists fuming. In December 2009, police picked up heroin users from an area notorious for heroin use. These addicts were given urine tests to confirm that they were using an opiate. Then, instead of being entered into a detoxification programme, they were forced to take a traditional herbal medicine, Bong Sen, for 10 days and then sent home. A total of 90 people were forced into two trials. The purpose was apparently to test the drug's efficacy and safety. The programme was run by Cambodia's National Authority for Combating Drugs.

Two non-governmental organisations were asked to provide participants for the trials. When they insisted on evidence that all legal and ethical requirements for research had been followed, they were threatened with closure notices and withdrawal of their license to run a needle exchange programme. Two days after they were enrolled in the "trial", the "participants" were made to put their thumbprints on "informed consent" forms.

Most of the "participants" had vomiting and diarrhoea after they took the herbal medicines.

The drug manufacturer, the Ben Tre Fataco General Import-Export and Trading Service Company, received support from the Vietnamese government to develop Bong Sen. The Vietnamese government also recommended the drug to the Cambodian government as a cheaper alternative to methadone, the drug currently used in de-addiction programmes.

The head of Cambodia's National Authority for Combating Drugs denied that a drug trial was conducted and insisted that the participants were volunteers who were convinced about the benefits of the drug.

The international community has been highly critical of the drug trial. "The illegal importation and coercive tactics used to put drug users on a wholly unknown and unproven cure for drug dependency is not merely unethical, but a violation of the most sacrosanct of principles of medical ethics," said Joe Amon of the health and human rights division of Human Rights Watch.

Margaret Harris Cheng, Cambodia criticised over unethical drug trial, *The Lancet*, January 16, 2010.

(Mis)use of international aid in Haiti

Health facilities in Haiti receiving aid in the form of medicines from international bodies have been found to be charging patients for these drugs. The earthquake in Haiti has led to a sudden flow of aid to the country of essentials, nutritional supplements, and life-saving medicines.

UN officials have warned that hospitals would be cut off from receiving supplies under the programme on essential medicines and supplies if they were found to be levying fees.

John Zarocostas, Officials look into possible misuse of medical aid in Haiti, *BMJ*, February 20, 2010.

H1N1, the vaccine industry and the World Health Organization

India's health secretary, K Sujatha Rao, has asked the World Health Organization (WHO) to respond to media reports accusing it of blowing the issue of H1N1 influenza out of proportion.

WHO has been accused of creating a false alarm about the seriousness of the H1N1 pandemic due to its vested interests in the pharmaceutical industry. WHO's director general, Margaret Chan, has replied to this allegation: "I believe we would all rather see a moderate pandemic with ample supplies of vaccine than a severe pandemic with inadequate supplies of vaccine."

The World Health Organization is also caught up in the controversy after allegations that some WHO experts have financial ties to the drug industry. A Danish newspaper obtained documents showing that Juhani Eskola, a Finnish vaccines adviser on the WHO board, received £5.6million for his research centre from GlaxoSmithKline for research on vaccines during 2009. Professor Eskola is a member of WHO's Strategic Advisory Group of Experts on Immunization, which advises member states on which vaccines to use and how much to buy. On his institute's advice, the Finnish government bought large quantities of GSK's H1N1 vaccine Pandemrix.

Express News Service, H1N1: India asks WHO to explain 'false pandemic' reports, *Indian Express*, January 22, 2010. Jo Carlowe, WHO expert had conflict of interest, Danish newspaper alleges, *BMJ*, January 16, 2010. Jason Gale,WHO to clarify H1N1 data after false pandemic claim, *Bloomberg*, January 22, 2010.

Paying for the sins of others

A study on carbon dioxide consumption at the global level revealed that carbon dioxide emissions in developing countries are caused by consumption in developed countries. 23% of carbon dioxide produced globally comes from products that are traded internationally. It comes as little surprise that the US is the largest importer of carbon.

"India is a net exporter of emissions, producing 100 million metric tonnes of carbon dioxide in 2004 that were consumed

elsewhere," says Steven Davis, one of the authors of the study that appeared in Proceedings of the National Academy of Sciences. The authors of the study hope to influence current trade and environment policies. They advocate increased accountability on the part of the developed countries. Carbon dioxide emissions should be understood in terms of consumption patterns and not on production patterns alone.

Anika Gupta, "Carbon intake should decide climate policy", *Hindustan Times*, March 9, 2010.

Bailing out the dying

On March 8, 2010, the Bombay High Court directed that regular inspections be carried out in jails in the state of Maharashtra, with special reference to issues of health. It has been found that the health problems of jail inmates are compounded by the lack of health facilities in prisons.

A division bench consisting of Justice P B Majumdar and Justice R G Ketkar pulled up the home department for not fulfilling its duties.

On January 12, 2010, the court had ordered the state home department to fill all vacant posts for nurses, laboratory assistants and medical officers and submit a compliance report. This report was not submitted.

The Bench asked for an explanation of why the government failed to provide a compliance report. "Either you comply or seek an extension – there is no third alternative," stated Justice Majumdar.

In 2008, Advocate Rajesh Bindra filed a bail plea on the behalf of his HIV positive client stating that he needed bail in order to obtain adequate treatment. The client died without treatment. Not only are health facilities poor, escorts are not provided to take ill inmates to hospitals. The amicus curiae, Advocate Yug Chaudhary, stated that many patients who were not even critically ill were dying in jails due to lack of medical treatment. The judges refused the request made by Advocate Anand Grover that prisoners be provided with condoms to prevent the transmission of HIV. They stated: "They can be educated for not indulging in such risky acts, but if still they want to do it and die, we cannot help it. They [prisoners] also need to maintain some discipline. They are not freedom fighters to get extra facilities."

HT Correspondent, HC raps state on HIV+ jail inmates' treatment, *Hindustan Times*, March 3, 2010. Rebecca Samervel, HIV-positive inmates can apply for bail, says HC, *Times of India*, March 9, 2010. Hetal Vyas, Give inmates gyan, not condoms. *DNA*, March 9, 2010.

Assam records the highest maternal mortality rates

According to the latest official data, Assam has the highest maternal mortality ratio (MMR), at 480/100,000 live births, compared to the national ratio of 254 per 100,000 live births. Though insurgency is being blamed for this, many other factors are involved. "There is a gamut of social issues, insurgency, no development, lack of infrastructure, lack of manpower in [the] healthcare system and other such things which contribute to such drastic results," said Aparajita Gogoi of the White Ribbon Alliance that works towards safe motherhood.

AK Sivakumar, member of the erstwhile National Advisory Council, points out that insurgency need not lead to such high MMR. "Look at Sri Lanka. They had to battle a lot of insurgency, yet they managed to bring down their MMR to 43..." It is not simply in Assam; as a nation India as a whole has not done too well in this area. India should reduce its MMR to 109/100,000 if it intends to meet Millenium Development Goals.

IANS, Assam records highest maternal mortality rate in the country, *The Hindu*, March 5, 2010.

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ARTICLES

Is there an elephant in the room? Boundary violations in the doctor-patient relationship in India

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Abstract

An anonymous postal survey on the awareness of the occurrence of nonsexual and sexual boundary violations (NSBV and SBV) in the doctor-patient relationship in India was conducted with psychiatrists and psychologists working in the state of Karnataka in India (n=51). Though this was not designed to be a prevalence study on violations, the results suggest that both NSBV and SBV do occur and, more importantly, respondents felt that this is an area which needs urgent attention in India. There was disagreement on whether some behaviours in certain situations could be construed as NSBV in the Indian culture. Though several respondents agreed that there was a need to develop guidelines on this issue in India, there was a perception that the problem was not in the availability of guidelines but in their implementation. The ethical implications of the study are discussed.

Introduction

The doctor-patient relationship is central to the healing art of medicine (1). However, the dynamics of authority, power, control and trust in the relationship can make a patient vulnerable to abuse by the treating doctor. Boundaries exist in the doctor-patient relationship to protect the patient from abuse (2). Defining these professional boundaries and what constitutes boundary violations has been extensively discussed in the West (3). In India, boundary issues have been discussed in the context of psychotherapy (4). Nonsexual boundary violations (NSBV) can encompass a range of behaviours from dual relationships with patients and undue self disclosure to accepting gifts for personal use. Sexual boundary violations (SBV) can range from inappropriate touch and sexual talk to sexual intercourse with a patient.

In the West, doctor-patient sexual boundary violations have been described as a "public health problem". (5) Anecdotal experiences of doctors working in India suggest that sexual abuse and other forms of boundary violations do occur here. However, we could find little in the form of published literature from India on inappropriate behaviour by doctors towards their patients (6). Both NSBV and SBV can have devastating effects on patients; they can have devastating effects on doctors as well, if the allegations are false (7-9). There can even be negative consequences to the doctors or therapists to whom the BV is reported. We submit that there is an urgent need for discussion in this area in India. The first step would be to learn whether or not these boundary violations occur in India and, if they do, whether doctors are aware of the existence of this problem. "Consensual" acts of SBV with adults are considered unethical but not illegal (3). Nonconsensual acts which amount to sexual harassment and rape are outside the purview of this study.

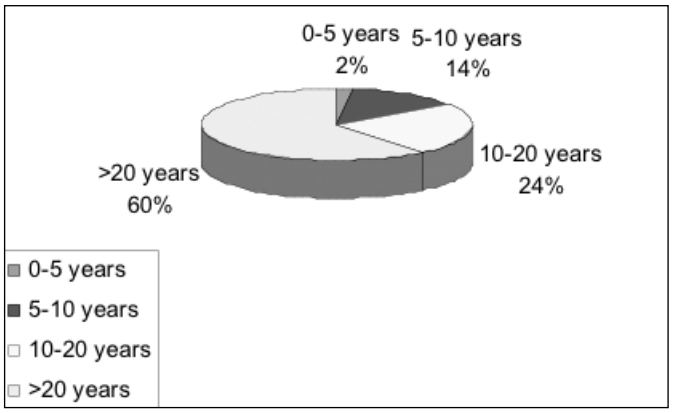
Methods

An anonymous postal survey on the awareness of the existence of boundary violations by doctors and therapists in India was conducted among psychiatrists and clinical psychologists practising in Karnataka. This study was not designed to specifically measure the prevalence of boundary violations. A questionnaire designed by the authors, a covering letter explaining the purpose of the questionnaire and a self-addressed stamped envelope was posted to 163 individuals. (The list of psychiatrists and clinical psychologists known to be practising in Karnataka was obtained from the mailing list of the Karnataka branch of the Indian Psychiatric Society and the Karnataka Association of Clinical Psychologists, respectively.) The questionnaire covered a range of NSBV like active socialisation with patients, becoming friends with patients, undue self disclosure, accepting gifts for personal use and accepting free services from patients. It also covered a range of SBV like inappropriate/ unnecessary physical examination, inappropriate touching, sexual talk/ jokes, sexual touching and sexual intercourse with patients. The questionnaire also covered some practice-related issues like physical examination without the use of a chaperone. At the beginning of the questionnaire, the respondents were told that the term "mental health professional" in this survey meant psychiatrist, doctor, psychologist, social worker, nurse or counsellor. The study was approved by the institutional ethical review board at St John's Medical College, Bangalore.

Results

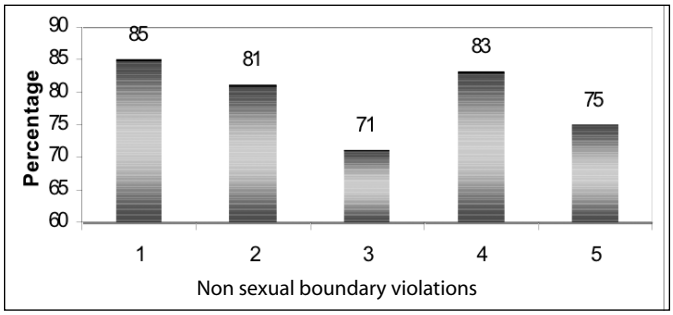
163 questionnaires were posted and 51 replies were obtained (9 female psychologists, 5 male psychologists, 5 female psychiatrists and 32 male psychiatrists). 6 were returned by the postal department as the addressee had moved. The profile of respondents in terms of the number of years after their postgraduate qualification is listed in Figure 1.

Figure 1 Respondent profile: number of years working after postgraduation qualification



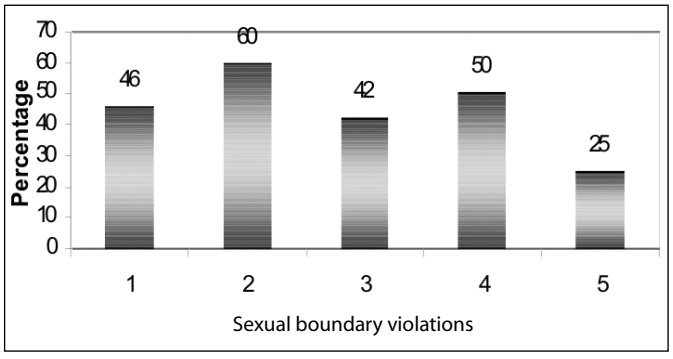
The percentage of respondents who were aware of the occurrence of various kinds of NSBV and SBV is shown in Figures 2 and 3.

Figure 2 Percentage of respondents who are aware of nonsexual boundary violations



1 Active socialising with patients
2 Becoming friends with patients
3 Undue self disclosure to patients
4 Accepting gifts for personal use
5 Accepting free services from patients

Figure 3 Percentage of respondents who are aware of sexual boundary violations



1 Inappropriate/ unnecessary physical examination
2 Inappropriate touching
3 Sexual talk/ jokes with patient
4 Sexual touching patient
5 Sexual intercourse with patient

Nearly 61% of the respondents had heard of boundary violations by psychiatrists, 45% by other medical doctors, 37% by psychologists, 18% by social workers, 10% by nurses, 22% by other counsellors and 2% by ward boys and OT (quoted exactly as this acronym) personnel. Several had heard of violations by more than one group of health professionals. More than half of the respondents (60%) had heard about a boundary violation by a particular health professional more than once. The source of information regarding BV is listed in Table 1 and the timing of occurrence of BV in Table 2. Many respondents (78%) had heard of physical examination of patients – and 59% had heard of physical examination of children – being done without an attendant, chaperone or guardian being present.

Table 1
Source of information regarding BV

* Source of information	Number of respondents (percentage)
Patients	23 (45)
Carers	17 (33)
Colleagues	30 (59)
Case records/ case files	4 (8)

** Some respondents cited more than one source*

Table 2
Timing of boundary violation

* Number of years ago	Number of respondents (percentage)
<1	6 (12)
1-5	13 (25)
5-10	17 (33)
10-20	14 (27)
>20	9 (18)

*Some respondents marked more than one option

Several respondents stated that in certain circumstances in our culture, certain actions by doctors/ therapists (such as accepting gifts) cannot be construed as boundary violations (Table 3). Some suggested that if a patient insists on the doctor taking a gift, it is not a BV. One said that if the socialisation is initiated by the patient, it is not a BV. One respondent felt that a "long handshake/ hugging in a consoling manner [of patients] with panic disorder is not a BV". This respondent felt that these actions were actually helpful. The same respondent also felt that "pentothal abreaction would work only if [the] patient and [the] doctor are alone," and that, in sexually abused patients, "physical examination helps." On the issue of physical examination without chaperones, some respondents felt that it was often not feasible to arrange a chaperone in India.

About half the respondents (53%) had heard of at least one incident of sexual boundary violation in which it was likely that the allegation was a false allegation and 49% of respondents had heard of at least one incident where it was unlikely that the allegation was false. A third (33%) of respondents had heard of at least one allegation of SBV that was investigated but a larger number (51%) had heard of at least one allegation of SBV that was not investigated. Table 4 lists some details about the investigations.

Table 3	
Number of respondents who felt the some behaviours by doctors/ therapists in certain circumstances DO NOT constitute a BV	
Action of doctor/ therapist	**Number of respondents (Percentage)**
Taking gifts for personal use from patients	15 (29)
Becoming friends with patients	10 (20)
Accepting free services from patients	9 (18)
Actively socialising with patients	7 (14)
Undue disclosing about self to patient	7 (14)
Inappropriate/ unnecessary physical examination	1 (2)
Inappropriately touching patient	1 (2)
Sexual talk/ jokes with patient	0
Sexual touching patient	0
Sexual intercourse with patient	0

Table 4	
Awareness of investigations into allegations of SBV	
Circumstance	**Number of respondents (percentage)**
Number of respondents who were aware of at least 1 likely false allegation that was investigated	11 (22)
Number of respondents who were aware of at least 1 likely false allegation that was NOT investigated	15 (29)
Number of respondents who were aware of at least 1 likely true allegation that was investigated	7 (14)
Number of respondents who were aware of at least 1 likely true allegation that was NOT investigated	12 (24)

A substantial number of respondents (41%) felt NSBV were a concern, while about half (49%) felt that SBV were a concern in India. Most respondents felt that the issue was not discussed adequately with various groups. Only 10% felt that the topic was taught to or discussed adequately with students, 22% with colleagues, 8% with patients and with 18% with carers. A large number (88%) felt that there was a need to develop guidelines on the topic of professional-patient boundary issues in India.

Discussion

The study design was aimed at assessing awareness among respondents while retaining their anonymity. It has been reported that studying the area of boundary violations is methodologically difficult and, generally, anonymous surveys have generated useful data (3, 10, 11). We felt an anonymous survey would allow respondents to feel comfortable enough to discuss their experience and opinion on this topic. As our results show, boundary violations are not limited to any one group of health professionals and this is in agreement with evidence from other countries (11,12). Our data only show the percentage of doctors who are aware of BV by particular groups of health professionals. It should not be assumed that just because more respondents in our survey had heard of BV by psychiatrists, other medical doctors and psychologists, that BV is more common in these groups. It could be that as our respondents were psychiatrists and clinical psychologists, they are more aware of boundary violations within their own group. The finding could also be due to the possibility of several doctors referring to the same incidents. We have used the term "doctor-patient relationship" in a broad sense rather than "mental health professional-patient relationship" in this article.

Though there is a degree of awareness about NSBV and SBV, it is clear that not everyone is aware of its existence in the doctor-patient relationship in India. If treating therapists do not know that this issue exists here, they are unlikely to be adequately equipped to handle it.

The issue of a possible "cultural sanction" with NSBV needs further reflection. Even if it is the patient who insists on presenting gifts for personal use (and even if most doctors have occasionally accepted gifts), it may still be a boundary violation with its attendant problems. The skill to be gently assertive while refusing such gifts without hurting the sentiments of patients and carers usually comes with experience but can be easily taught to junior doctors. Common sense would dictate that accepting a box of sweets by a patient who can afford it, on behalf of the entire treating team and on an occasion, would be acceptable. Self disclosure can be a useful technique to be used by an experienced therapist to help the patient feel better, but undue disclosure about oneself to make the therapist feel better is unacceptable (13). Becoming friends with patients is inadvisable (14).

No single culture defines India. However, if one accepts that a boundary violation is anything that violates the dynamic of the doctor-patient relationship, it would not be difficult to introspect and differentiate between a boundary crossing and a violation (15). Of course, situations may arise in which an occasional gift taking or having a social or business contact becomes inevitable for some reason. A simple "self test" for doctors could be, "Never do something you would not like other colleagues to know about." The major concern is that NSBV are the well known "slippery slope" to SBV (16). Not all NSBV lead to SBV, but nearly all SBV have started with NSBV (17). Setting limits protects not only patients but also doctors. It is known that behaviourally disturbed patients can also harass doctors (18).

In sexual abuse literature the world over, it is known that false allegations are rare but do occur (9). Unfortunately, by the time the inquiry "clears" the doctor the damage to that doctor's reputation is already done. Physical examination of patients without a chaperone is an area in which some doctors put themselves at risk. It is inadvisable to lower standards of good and safe practice citing logistic reasons in India. A "comfort touch" can be risky in some situations as it is the meaning of the doctor's behaviour to the patient and not his/her intention that determines harm (19).

Our questionnaire was designed only to ascertain whether respondents were aware of investigations into allegations of SBV; it did not seek to ascertain why some cases were investigated and some were not. Our data show that awareness of the occurrence of SBV allegations that were not investigated was higher than those which were investigated (especially in

the cases where an allegation was likely to be true). However, we cannot presume that allegations that are investigated are more likely to turn out to be false, as it has been noted earlier that false allegations are likely to be over-reported (10).

Is there an elephant in the room?

Our data suggest that both SBV and NSBV do occur in the doctor-patient relationship in India and that it is not a new phenomenon. As there is no published scientific literature in peer reviewed journals on this topic in India, it suggests to us that the idiom about the elephant in the room is an appropriate one (implying that there is an obvious problem that is being ignored).

This elephant is not a cultural or an Indian phenomenon. There is a parallel in the western literature in the natural history of disclosure of sexual abuse. Usually incidents come to light after several years (20). Patients are usually reluctant to report these issues due to concerns about confidentiality, shame, not being believed or even because they are emotionally attached to the doctor. Others may have been victims of past sexual abuse ("the sitting duck syndrome") and therefore find it even more difficult to disclose the problem (21). Family members might not want to make complaints due to confidentiality and stigma issues. Offending doctors can be reluctant to seek help for behavioural difficulties as they fear adverse publicity. "Third party" doctors (doctors to whom the patients subsequently disclose the history of abuse) might not report the abuse due to concern about causing "further harm" or the perceived suicidal risk to the patient (especially if the patient and their family are unwilling for an inquiry process to take place). Others might not believe the patient, they may not understand the seriousness of the BV if it did not amount to sexual intercourse or they may be unaware of the risk of serial offences by the offending doctor. Their additional concerns may be the consequences to the errant doctor and even to themselves if they are perceived to be "whistleblowers". Whistleblowing can have serious career consequences (22, 23). Mandatory reporting laws regarding sexual abuse of patients by doctors have received mixed reviews across the world (24). Doctors have felt they would rather consult a senior colleague or counsel the offending colleague themselves when they come of know of professional misconduct (25).

In India additional factors are also relevant. When faced with (nonsexual) medical malpractice, patients and carers are generally disinclined to give formal complaints to local medical councils and courts, as there is an impression that anyway justice will not be served (26). Media reports suggest that in the few cases of sexual abuse which find their way to court, the inquiry process is perceived to be as abusive as the original abuse (27). So, the reason why no one openly talks about doctor-patient abuse is not because it does not occur. Rather, talking about it can lead to adverse consequences to everyone who knows about it. This can lead to a false sense of security in which we feel that doctor-patient abuse is not an issue in India because we do not often hear of it.

Limitations

Our study was an anonymous postal survey, designed to be simple and non time consuming to maximise response rates from busy doctors. This meant we did not go into detail about the actual incidents of NSBV and SBV that the doctors had heard about. However, the comments section gave doctors the opportunity to discuss any point further (Table 5). Our study focused on asking respondents about their awareness of boundary violations being an issue in India, not whether or not they had violated boundaries. If one is studying prevalence of this issue in respondents, then surveys would tend to underreport the phenomenon as some offenders would not wish to report their own behaviour, even anonymously. As our study was not a prevalence survey, the low response rate would not dilute, but arguably add to, the central finding of this study – that both NSBV and SBV occur in the doctor-patient relationship in India, but not everyone is aware of it and this is not often openly discussed from an academic viewpoint. Surveys do have the intrinsic bias of eliciting a higher response from respondents who feel more strongly on an issue, but some respondents in our survey did participate despite stating that they felt it was not an issue in India. Even a single case report on an important clinical issue is a valid method to draw the attention of the medical fraternity to a medical problem. In the case of sexual boundary violations, one is unlikely to be able to get informed consent from the patient to write up the case report. Therefore, an anonymous survey is an important method to study this issue. One can only guess the reasons for non-response – either the non-responders did not receive the questionnaire, or they were too busy, or they did not think BV was an issue, or the topic made them uncomfortable in some way.

Implications

Acknowledging a problem is the first step towards dealing with it. This preliminary study suggests that not only do both NSBV and SBV occur in the doctor-patient relationship in India but not all doctors are aware of it. As the fundamental ethical principle in medicine is *primum no nocere* (first, do no harm), there can be no doubt that we need to deal with this issue. However, attempting to do so can pose certain ethical dilemmas. First, awareness about BV has to be made universal among doctors, therapists and all health professionals, as our data show that BV is not restricted to psychiatrists and psychologists. Incorporating the topic into the undergraduate and postgraduate medical ethics curriculum would be a good start (8). However, it has to be done without making students wary about the doctor-patient relationship, which remains central to the practice of medicine (1). Second, there is a need to develop clear, culturally acceptable guidelines on boundary issues in India as that can reduce unethical behaviour among doctors and therapists (28, 29). Given the cultural diversity in India, developing acceptable, nuanced guidelines might be a challenge (30, 31). Third, third party doctors should have clear guidelines on what needs to be done when a BV is alleged, without risking the costs of whistle blowing. Fourth, we need to

Table 5: Some comments by individual respondents

- Appreciate taking up the issue as awareness on this topic is important and necessary. Need to sensitise other medical personnel too. This is a neglected topic. Worth developing guidelines. Sometimes naïve therapists are exploited by patients!
- Maybe less here than in other professions. Personality of offending mental health professional needs to be evaluated. Need to refer for treatment on a case by case basis (if needed). Closing door when patient is alone with doctor should be strictly avoided.
- Non service staff to be included and guidelines given to them too. For example, receptionists, OT attendants after ECT or narco analysis after the psychiatrist leaves (the room).
- Make literate and illiterate patients aware of boundary issues in the context of physical examination. Display 'Dos and don'ts' in all major hospitals. Then similar notices can be put in psychiatric hospitals. In case of BVs in the context of therapy, first carer and then patient to be adequately informed. All hospitals should have suggestion box/ complaint box.
- Having guidelines and training are necessary but BV will continue to occur as with (violation of) other ethical guidelines.
- This is an important area. Needs urgent attention. (The issue of boundaries)... is very tough unless therapist has trained himself to be vigilant about his own internal and psychic state. I have not heard of any such reports.
- Therapist should respect the sanctity of the therapist patient relationship. They should not fall prey to momentary pleasures.
- Existing guidelines in any standard textbook is fine if implemented. How to implement them should be the focus rather than reinvent the wheel. Every professional is aware of the risk of crossing boundaries. In spite of knowing, if he crosses boundaries, he will have to face consequences. Boundary violation issue is surely a disgrace to the profession and the fraternity giving enough room for 'generalizations' in the minds of the public.
- (In case of an allegation) there should be an investigation by a body comprising a senior psychiatrist and three others. Incident 1- warn if found guilty, incident 2- punish.
- Gift taking and self disclosure an issue. SBV can be a concern in smaller centres. BV usually discussed as gossip and not as a professional issue. There are no clear guidelines as to what one has to do when one notices it (BV).
- From an academic viewpoint it (the study) is appropriate.
- Whilst I think what you are doing is necessary and important the crying need of the hour is public health awareness/ education.
- Thank you for the sensitisation regarding this topic.
- Guidelines are already there. Ethics classes needed. (BV can be due to) mood disorders or manifestations of 'general loose behaviour'.
- This is an important area. Definitely need guidelines, teaching, monitoring and where needed deterrent action

have a confidential, workable and credible investigating system headed by specially trained individuals so that the inquiry process is not abusive to patients or to errant doctors. On the one hand, patients and carers should not feel intimidated about making complaints but on the other hand, false allegations must be dealt with strictly if made with malicious intent. The "predating" boundary violator has to be handled differently from the "unwell" violator. Last, as it is unrealistic to expect SBV to never occur, future patients have to be protected. Patient and carer education on this topic can be in the context of protecting oneself from sexual abuse in general. It would be crucial to ensure that the information given is not sensationalised and does not lead to further reluctance to gain access to much-needed psychiatric and medical care in India.

We suggest that, at this stage, one does not need a prevalence study on BV (even if it were feasible in India). We now have more than anecdotal evidence that NSBV and SBV do occur in this country. It really does not change things very much whether it is one doctor or 10 who engage in SBV, as sexual abusers can turn out to be serial offenders. The Kerr Haslam Inquiry in the UK details how a single doctor ended up abusing at least 67 patients and another at least 10 patients spanning a period of two decades (20).

There can be little debate that we need to address this issue now. How we should go about doing it, with minimum collateral damage and keeping sensitivity to cultural issues in mind, should be the subject of future research using qualitative research methodology. Till those data become available, it might be wise not to ignore lessons from the West in terms of managing patient victims of SBV and the alleged offenders (5, 21). This article should not imply that abuse is a phenomenon only in the professional-patient relationship. This is only one facet of the problem of sexual abuse in a society. This study implies that psychiatrists and psychologists want to shake themselves out of their collective learned helplessness on this issue. Having clear, nuanced ethical guidelines and the ability to practise them effectively can only strengthen the doctor-patient relationship, which is the fundamental rock on which the healing art and science of medicine is based.

References

1. Osler W. *Aequanimitas, with other addresses to medical students, nurses and practitioners of medicine*. London: H K Lewis; 1904.
2. Frick D. Non sexual boundary violations in psychiatric treatment. In: Oldham JM, Riba MB, editors. *Review of Psychiatry*. Washington DC: American Psychiatric Press;1994: 415-32.
3. Nadelson C, Notman M T. Boundaries in the doctor patient relationship. *Theor Med Bioeth*. 2002; 23(3): 191-201.
4. Avasthi A, Grover S. Clinical practice guidelines Ethical and legal issues in psychotherapy. *Indian J Psychiatry*. 2009; 148-63.
5. Spickard WA, Swiggart W, Manley G, Samenow CP, Dodd D. A continuing medical education approach to improving sexual boundaries of physicians. *Bulletin of the Menninger Clinic*. 2008;72(1): 38-53.
6. Mundakel TT. *Blessed Alphonsa*. Bombay: The Bombay Saint Paul Society: 2005:25-6.
7. Feldman-Summers S, Jones G. Psychological impacts of sexual contact between therapists or other health care practitioners and their clients. *J Consult Clin Psychol*.1984 Dec;52(6):1054-61.
8. Fahy T, Fisher N. Sexual contact between doctors and patients. Almost always harmful. *BMJ*. 1992 Jun 13; 304 (6841):1519-20.
9. Hall RC, Hall RC. False allegations: the role of the forensic psychiatrist. *J Psychiatr Pract*.2001 Sep;7(5): 343-6.
10. Sarkar S P. Boundary violation and sexual exploitation in psychiatry and psychotherapy: a review. *Advan Psychiatr Treat*. 2004;10:312-20.
11. Wilbers D, Veenstra G, van de Wiel HB, Weijmar Schultz WC. Sexual contact in the doctor-patient relationship in The Netherlands. *BMJ*. 1992 Jun 13; 304(6841):1531-4.
12. Dehlendorf CE, Wolfe SM. Physicians disciplined for sex-related offenses. *JAMA*. 1998 Jun 17;279(23):1883-8.
13. Nisselle P. Is self disclosure a boundary violation? *J Gen Intern Med*.2004 Sep; 19(9):984.
14. Cole-Kelly K. Can friends become patients? *Am Fam Physician*. 2002 Jun 1;65 (11):2390,2392,2395.
15. Gutheil TG, Simon RI. Non-sexual boundary crossings and boundary violations: the ethical dimension. *Psychiatr Clin North Am*. 2002 Sep;25(3):585-92.
16. Galletly CA. Crossing professional boundaries in medicine: the slippery slope to patient sexual exploitation. *Med J Aust*.2004 Oct 4;181(7):380-3.
17. Simon R. The natural history of therapist sexual misconduct: identification and prevention. *Psychiatric Annals*.1995;25(2):90-4.
18. Bird S. Harassment of GPs. *Aust Fam Physician*. 2009 Jul;38(7):533-4.
19. Lindsey C, Jones D, Holmes J, Shooter M. Vulnerable patients, vulnerable doctors: good practice in our clinical relationships (Council Report CR101). London: Royal College of Psychiatrists; 2002.
20. Kennedy P. Kerr/ Haslam Inquiry into sexual abuse of patients by psychiatrists. *Psychiatr Bull R Coll Psychiatr*. 2006 Jun; 30 (6):204-6.
21. Kluft RP. Treating the patient who has been sexually exploited by a previous therapist. *Psychiatr Clin North Am*. 1989 Jun;12(2):483-500.
22. Faunce T, Bolsin S, Chan W-P. Supporting whistle blowers in academic medicine: training and respecting the courage of professional conscience. *J Med Ethics*.2004;30:40-3.
23. Thomas G. Practising medicine in India: some ethical dilemmas. *Indian J Med Ethics*.2005 Jul-Sep;2(3):88.
24. White GE, Coverdale J. General practitioner attitudes toward mandatory reporting of doctor-patient sexual abuse. *N Z Med J*. 1998 Feb 27;111(1060):53-5.
25. Raniga S, Hider P, Spriggs D, Ardagh M. Attitudes of hospital medical practitioners to the mandatory reporting of professional misconduct. *N Z Med J*. 2005 Dec 16; 118(1227):U1781.
26. Pandya S.K. Doctor-patient relationship: the importance of the patient's perceptions. *J Postgrad Med*.2001;47(1):3-7.
27. Sharon M. Molested at home, humiliated in court, she fights on [Internet]. IBN Live;2009 Sep 17[cited 2010 Mar 9]. Available from http://ibnlive.in.com/news/molested-at-home-humiliated-in-court-she-fights-on/101542-3.html
28. Tubbs P, Pomerantz AM. Ethical behaviors of psychologists: changes since 1987. *J Clin Psychol*. 2001;57(3):395-9.
29. Isaac R. Ethics in the practice of clinical psychology. *Indian J Med Ethics*.2009 Apr-Jun;7(2):69-74.
30. Bloch S, Green SA. An ethical framework for psychiatry. *Br J Psychiatry*. 2006 Jan;188:7-12.
31. Medical Council of India [Internet]. New Delhi: Medical Council of India; c2002. Rules and regulations, Code of ethics regulations 2002 ; 2002 Mar 11[cited 2010 Mar 9]; [about 8 screens]. Available from: http://www.mciindia.org/know/rules/ethics.htm

Acknowledgements: *The authors would like to acknowledge the contribution of the following: Elizabeth Kurian, Postgraduate Student, Department of Psychiatry, St John's Medical College Hospital, Bangalore, whose clinical skills in a busy outpatient clinic resulted in the preliminary impetus for this study; G D Ravindran, Head of the Department of Medical Ethics, St John's Medical College Hospital, Bangalore, for his encouragement and support, and Mathew Varghese, Professor, Department of Psychiatry, NIMHANS, Bangalore, for his intellectual inputs into the methodology and design of the questionnaire.*

Patenting of human genetic material v. bioethics: revisiting the case of John Moore v. Regents of the University of California

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Abstract

Moore v. Regents of the University of California was one of the first cases internationally that dealt with the patenting of human genetic material. The case is closely related to the development of medicine and of biotechnology applied to medicine. These developments require the utilisation of human body parts, both for experiments and for transplant, and present certain major medico-legal problems. However, the case did not produce conclusive decisions on the various key legal issues that it raised involved in biomedical research and the patenting of human genetic material. This article re-examines the case from an Indian and an international perspective.

After a brief introduction in Part I, Part II of the article describes existing laws in various countries with respect to the patenting of human genetic material. Part III discusses legal regimes applicable in the context of biological materials. Part IV elaborates on the importance of the doctrine of informed consent in the context of biomedical research on human subjects. Part V discusses the significance of bioethics in research and the patenting of biotechnology, according to international law. Part VI concludes the article with an assertion of the urgent need for legislation in this area.

I. Introduction

In Moore v. Regents of the University of California (1) (hereinafter referred as the Moore case), John Moore, a resident of Seattle, USA, was treated for hairy-cell leukaemia by David W Golde at the University of California-Los Angeles (UCLA) Medical Center. Moore was advised to undergo surgery to remove his spleen. At that point in time, apart from regular consent forms for the surgery and other related procedures, he was also asked for permission to contribute to medical research, which he explicitly refused. Following the surgery, despite his refusal, portions of Moore's excised spleen were used by Golde and his research colleagues to develop a cell line from his T-lymphocytes. UCLA applied for, and was granted, a patent on the cell line, which listed Golde and a colleague, Shirley Quan, as inventors. Neither Golde nor anyone else at UCLA informed Moore before surgery, after surgery, or during the three follow-up visits suggested by Golde, during which additional blood and other biological specimens were obtained, that UCLA intended to use Moore's biological material for research or commercial purposes. When Moore learned of the use of his cell lines without his permission, he sued the defendants under various causes of action. Two of these were: breach of fiduciary duty and "conversion" – the use of property of another for commercial benefit, without the owner's authority (2). His case was decided in 1990.

The case, from the legal perspective, has two important aspects. The first one refers to the authorisation that should have been obtained from Moore, and the second one is the susceptibility of patenting body parts. The California Supreme Court of Justice which rendered a decision partly in favour of Moore based its decision on three basic principles (3):

- An adult in full use of his faculties has the right to decide whether or not to submit to a medical treatment, based on his "right to have control over his own body".
- The patient's consent shall be informed.
- The physician has the obligation to give all the necessary information for the patient's decision.

The California Supreme Court ruled that Moore's consent was not obtained, and the doctors were in breach of their fiduciary duty. However, the court rejected Moore's argument that his cells were unique and therefore he had a right over them. They stated that the lymphokines used by the defendants were of the same basic molecular structure in all human beings. It is difficult to accept such an argument, in science or in fact, because it was precisely the uniqueness of the cell line derived from John Moore that purportedly made it so valuable. It is evident that the case is closely related to the development of medicine and biotechnology applied to medicine, which requires human body parts both for research and for transplant, resulting in certain major medico-legal problems (4). The Moore decision reflects an unwillingness to recognise the infringement of human dignity that results from intentional fraud. No judgement was made on the consequences of, or the problems caused by, the absence of informed consent. The decisions given by the court did not concern the legal regime that governs informed consent in biomedical research. These decisions will become increasingly important as biomedical research advances in the 21st century. This is a judgement by a United States court and is not binding in other jurisdictions like India. However, the case has serious implications regarding the patenting of human genetic material. Such patenting is beginning to be accepted in the US and is a matter which could arise in any other country. Thus, it is essential to revisit the Moore case in order to analyse those issues which were not sufficiently dealt with by the California Supreme Court and also to explore the case from the point of view of Indian law.

II. Legal overview: patenting human genetic material

Patents are said to serve the goal of fostering the development of innovation (5), promoting the growth of knowledge by providing innovators an incentive to risk their time and the costs of research and development (6). However, this view is a matter of controversy; some scholars question the notion that patents necessarily lead to innovation and that they are an incentive to research.

A. Human genetic material is patentable

The fact, however, is that human genetic material has been granted a patent in numerous cases. In Diamond v. Chakrabarty (7), the United States Supreme Court held that a genetically engineered bacterium was patentable as a "new and useful ... manufacture, or composition of matter", thereby opening the floodgates for gene patenting in the US. A patent claim on human genetic material, DNA, was made for the first time in Amgen v. Chugai in 1991 (8). Similar claims were made in Re Bell (9), and in Re Deuel (10). These reiterated the stand that human genetic material was patentable.

In the Relaxin case, for the first time in Europe (11) the European Patent Office issued a decision on whether or not a gene coding was patentable. This was for a hormone, Relaxin. The patent was granted. The Patent Office held that patenting of human genes did not go against ethics, as patenting genes was not tantamount to patenting a human being. Following the Relaxin suit, in Biogen v. Medeva (12) a patent application was made for human genetic material and subsequently granted. It is now a settled matter of law in the US and recently in the European Union (EU) that human genetic material is patentable. Many other countries support this but have not incorporated express provisions in their domestic statutes. However, there are also countries which staunchly oppose the patenting of human genetic material.

In the Moore case, for the first time in the history of patent law, a patent was claimed on a human cell line (1). A cell line, in tissue culture, is defined as the cells growing in the first or later subculture from a primary culture, or a clone of cultured cells derived from an identified parental cell type (13). The distinction between primary cells (cells taken directly from the body) and cell lines is that while primary cells typically reproduce a few times and then die, one can sometimes continue to use cells for an extended period of time by developing them into a cell line, a culture capable of reproducing indefinitely (13). In the case of Moore, a patent was obtained for a cell line using cells taken from Moore's body.

The court in this case held that the patented cell line and the products derived from it could not be Moore's property. The court stated that this was so because the patented cell line is both factually and legally distinct from the cells taken from Moore's body. Since then, there have been numerous instances where cell lines have been patented across the world (14, 15).

B. Product of nature v. product of man

It is this inventive effort that patent law rewards, and not the discovery of naturally occurring raw materials. Intangible intellectual property in the body, such as a gene patent or a cell line, receives much more protection than do physical body parts. The "inventor" or "discoverer" of intellectual property in the body is granted broad protection, unlike the individuals who are seen as supplying the "raw materials" such as the blood, tissue, and other body parts necessary to conduct such research.

In the case of Diamond v. Chakrabarty (8), the court held that Chakrabarty's invention, a genetically engineered bacterium, was not a product of nature but a product of man; the human role involved in the invention differentiated it from a product of nature. The court stated that the starting point of the invention was a product of nature, but the inventor had added his ingenuity in engineering the bacterium to possess the capacity to eat up oil spills. Therefore, the court held, the invention was a non-natural, human-made product, a result of human ingenuity and labour. The court explicitly held that "anything under the sun that is made by man" is patentable.

Even the EU directive on legal protection of biotechnical inventions, 1998 (16), and Article 3 of the European Patent Convention, 1973 (17), declare that biological material produced or isolated and purified by means of some technical process is patentable. As biological materials are not available in isolated and purified form in nature, it is argued that the isolation and purification involved is an inventive step (18).

Similarly, the decision of the court in Moore's case clearly indicates that under US law a cell line is an invention and therefore a non-natural, human-made product, different from John Moore's cells, which are a product of nature. The cells were a product of nature until human intervention, whereupon they turned into a product of man and developed new abilities to grow in different media. This is the direction in which US and EU laws have been developing, though it is not explicitly accepted in other parts of the world.

It is essential to note that the court in the Moore case did not acknowledge the fact that the cells used for making the cell line were Moore's property, and Moore alone had the right to determine and direct the use of his cells. Using his cells for research without his consent raises issues relating to property and privacy, which are addressed in the next section.

III. The right to property v. the right to privacy

It has always been a moot question whether the law applicable in the context of biological materials is the "Law of Property" or "The Law of Privacy". Conversion is a common law tort related to the law of property. As defined in the case of Fouldes v. Willoughby (19), conversion is a voluntary act of taking with the intent of exercising over the chattel (in legal terms a moveable possession including intangible and transferable possessions such as a lease) an ownership that is inconsistent with the real owner's right of possession.

In the Moore case, the majority opinion decided that Golde's use of Moore's cells did not amount to "conversion". This decision was based largely on the proposition that a patient generally possesses no right to a body part that has already been removed from his body. The most challenging aspect of this case was the decision on whether or not Moore's cells and tissues could be considered "property", or "chattel" thereby allowing them to be converted. The court in this case addressed only the question of proprietary rights over the cell line developed by the doctors at the medical institute. It failed to deal with the infringement of the patient's right to privacy. In this section, I will discuss these rights in detail with reference to biological materials. I will also examine these rights from the perspective of Indian law.

A. The right to property

The definition of property is sufficiently broad to include "every species of real estate, real and personal, and everything which one person can own and transfer to another." Under existing law, a quasi-property right is recognised with regard to dead bodies and embryos (20-23). Even cell lines have been recognised as property (24). Therefore, by drawing an analogy from these cases, even extracted dead cells of John Moore can be considered to be his property.

Under existing law in the United States, John Moore has the right to control his body, exclude others from it, and dispose of it in any legal way. This right to dispose of property includes the right to direct the use of excised cells and tissue, while the right to exclude includes the right to refuse medical treatment (25, 26). A person of "sound mind and adult years" has the right to determine, in exercising control over his body, whether or not to submit to lawful medical treatment.

Further, in the United States, though the Uniform Anatomical Gift Act (27) applies only to anatomical gifts that take effect on or after the death of the donor, the general principle of "donor control" which the Act embodies is clearly not limited to that setting. In the transplantation context, for example, it is possible for a living donor to designate his organ to the specific donee. If a hospital, after removing an organ from such a donor, decided on its own to give the organ to a different donee, no one would deny that the hospital had violated the legal right of the donor by its unauthorised use of the donated organ.

The principle of "donor control" has also been recognised in India in the Transplantation of Human Organs Act, 1994 (28), which clearly states that "Any donor may, in such manner and subject to such conditions as may be prescribed, authorize the removal before his death of any human organ of his body for therapeutic purposes."

These particular laws, in the US and in India, clearly spell out some of the rights associated with property, one of them being the right to dispose of a tangible thing in every legal way. Other relevant privileges are the right to possess the thing, to use it and to exclude everyone else from it.

While these issues concerning human genetic material have not been interpreted in India, if such a matter comes up before an Indian court, the court may refer to the US case. The present state of the law in India and the US provides sufficient justification to establish that John Moore has a property interest in his blood cells, and the right to direct the use of excised cells and tissue before they were extracted.

B. The right to privacy

As stated above, the California Supreme Court did not deal with the law of privacy before delivering its judgement. The following paragraphs will exemplify how the law of privacy has been recognised in US and Indian jurisprudence, and how it can play a key role in matters concerning the patenting of human genetic material.

The conceptual framework of life is connected to natural law which stands for inherent values of life such as dignity, integrity, sustenance, survival and self-preservation. The Supreme Court of India has in Francis Coralie v. Union Territory of Delhi (29) held that the right to life enshrined under Article 21 of the Constitution of India means something more than survival or an animal existence. It includes the right to live with human dignity (30).

Patenting of biotechnology inventions is an incentive to the manipulation of living beings. The Constitution of India gives every living being a right to self dignity and integrity, and every living being has the right to preserve the intrinsic values of life which should not be disturbed or altered. Such alterations or manipulations strike not only at the dignity and integrity of the living beings concerned but also at the integrity and balance of nature (18). A patent is private property which can be owned, transferred or sold just as goods can be. It is suggested that patenting genetic materials of a person amounts to owning private property rights over life, making life a market commodity. Hence it is argued that patenting of genetic materials is nothing but commodification and marketing of life, which is a gross violation of the dignity of life.

The right to live with dignity includes the right to privacy. Genetic research may cause intrusion into three forms of individual privacy: bodily privacy in cases where the sample is taken from a person's body; genetic privacy, where predictive health and other information about the person is obtained from the sample; and behavioural privacy where genetic information is used to determine where a person has been and what he has done. Also, the right to publicity, or the right to control and profit from the commercial use of one's name, likeness and persona, is an intrinsic part of the fundamental right to privacy.

B 1. Infringement of the right to bodily privacy

In the background of the Indian law, if the issue of privacy is raised in a case similar to that of Moore, an infringement of Article 21 of the Constitution of India can be argued. Article 21 of the Constitution of India states that "No person shall

be deprived of his life or liberty except according to the procedure established by law." The Griswold v. Connecticut (31) pronouncement of the United States Supreme Court, wherein the right to privacy was recognised as an extension of substantive fundamental rights embedded in the First, Third, Fourth and Fifth Amendments of the United States Constitution, was one of the judgements used to interpret Article 21 of the Indian Constitution in the privacy case of Gobind v. State of MP (32).

In India, the right to privacy flows from the right to life, and is therefore considered a fundamental right, as also held in People's Union of Civil Liberties (PUCL) v. Union of India (33), by the Supreme Court. Thus, the right to control one's body which is implicit in the right to privacy also includes the right to be free from unwarranted intrusion of body and mind.

In the US, this has been stated in Schloendorff v. Society of New York Hospital (34). The court in Bouvia v. Superior Court (35) also affirmed the proposition that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body..." Thus, it is the patient who must have the ultimate power to control what becomes of his or her tissues and to hold otherwise would open the door to a massive invasion of human privacy in the name of medical progress. In R v. Legere (36), plucking a person's hair without his consent constituted a breach of his privacy and a violation of Sections 7 and 8 of the Canadian Charter of Rights and Freedoms. The courts have further extended the doctrine of privacy in Venner v. State (37) by holding that "[i]t is not unknown for a person to assert a continuing right of ownership, dominion or control, for good reason or for no reason, over such things as excrement, fluid waste, secretions, hair, fingernails, toenails, blood, and organs or other parts of the body...." Also, La Forest J observed in R v. Dyment (38) that "[t]he use of a person's body without his consent invades an area of personal privacy essential to the maintenance of his human dignity...." Lamer J places the right to bodily privacy on a higher pedestal by observing in R. v. Pohoretsky (39) that "a violation of the sanctity of a person's body is much more serious than that of his office or even of his home."

The aforementioned Indian and US cases enumerate the development of privacy law in both India and the US, and its importance and influence on the issue of patenting of genetic material. Thus, if such a case is addressed in the Indian courts, the fraudulent taking of cell lines from the patient's body without adherence to the procedure established by law would amount to infringement upon his right to have control over his body and thereby would trample on his fundamental right to bodily privacy and dignity guaranteed under Article 21 of the Constitution of India.

B 2. Grave and imminent danger of infringement of genetic privacy

Another form of individual privacy which is important but which was not addressed in the Moore case is the concept of "genetic privacy", which has two dimensions: protection from the intrusion of others and protection of one's own, hitherto unknown, secrets (40). The power and potential of genetics rest in the knowledge that it provides, thereby raising concerns about privacy and confidentiality in various situations.

In a similar case, the issue of genetic privacy comes up if the doctors or people involved in medical research, in the course of their practice, come across genetic materials of patients upon which they conduct tests or research without the patient's knowledge. The genetic material could expose the patient's medical history or bring out some confidential facts of his life, which the patient would not have wanted to be brought to light or made known, thereby violating his privacy.

B 3. Infringement of the right to publicity

The right to privacy is an evolving right (41) and also includes the right to publicity. The right to publicity finds its genesis in the right to privacy and is referred to as a "subset" of privacy rights. Roughly defined, it is the right to charge for (or bar entirely) the commercial exploitation of one's name, likeness, voice or "personality". By the broadest definition, the right to publicity is the right of every individual to control any commercial use of his or her name, image, likeness, or some other identifying aspect of his or her identity (42). Protecting the individual from the loss of commercial value resulting from the unauthorised appropriation of an individual's identity for commercial purposes is the principal purpose of the right to publicity.

It was precisely the unique properties of his genetic "programs" – the fact that his virus-infected cells overproduced lymphokines – that made John Moore's tissue and bodily fluids valuable for medical research. Therefore, although a patient may not retain any legal interest in a body part after its removal when he has properly consented to its removal and use for scientific purposes, it is clear from the above arguments that before a body part is removed, it is the patient, rather than his doctor or hospital, who possesses the right to determine the use to which the body part will be put after removal.

However, if the case was such that Dr Golde and his research assistant, Dr Shirley Quan, had informed John Moore, prior to removal of his spleen, of the possible uses to which his body part could be put, and if Moore had authorised one particular use, then, in my opinion it is possible that the defendants would be held liable for conversion if they had disregarded Moore's decision and used the body part in an unauthorised manner for their own economic benefit, or if they intentionally withheld material information that they were under an obligation to disclose to him.

IV. The doctrine of informed consent

A violation of the fundamental right to privacy usually occurs when the procedure of informed consent has not been observed. The doctrine of informed consent is that the donor of any genetic material used for genetic or genomic research, or for any therapeutic purpose, must give consent to

the procedure after being fully apprised of all relevant facts regarding the method of collection of the information and the end use of such data. The doctrine of informed consent was developed in research settings in express response to revelations of abuses of human subjects by researchers. The deliberations that followed these revelations led to the construction of the informed consent doctrine and to the institutionalisation of bioethics as an area of practice (43).

The ethical principles laid down in the Nuremberg Code (44) were developed following the trial of Nazi doctors and researchers who had conducted horrific experiments on human subjects during the Second World War. These principles articulated concepts such as consent to participate in medical research and the avoidance of harm to human research subjects.

The Nuremberg Code was followed by a number of guidelines, codes and regulations to ensure the protection of human volunteers in medical research; among these the most important documents are the Declaration of Helsinki, 1964 (45), Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 1979 (the Belmont Report) (46), the Council for International Organisations of Medical Science (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects (47) and the International Declaration on Human Genetic Data (48).

In India the concept of informed consent was recognised in The Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council for Medical Research (ICMR) in 2000 and revised in 2006(49), followed by the Good Clinical Practices Guidelines prepared by the Central Drugs Standard Control Organisation (50). In 2005, Schedule Y of the Drugs and Cosmetics Rules, 1945 (51), was amended to include, inter alia informed consent of volunteers.

According to the principles set out in the ICMR guidelines and the GCP guidelines, "respect for persons" implies that the person should recruited into research voluntarily only if he comprehends the (adequate) information provided to him by the investigator.

An important principle concerning informed consent for research that is expressed in international as well as Indian guidelines is that volunteers should be allowed to withdraw from the study at any stage, even if it means terminating the study.

A. Judicial decisions explaining the informed consent doctrine

A plethora of judicial material supports the rigorous application of the principle of informed consent, particularly to cases where blood and tissue samples are collected for the purpose of conduction of genetic research upon them, irrespective of the element of risk (52-54). In this section, I discuss Indian and US case laws which have analysed this doctrine.

The binding nature of the doctrine of informed consent entails more than a formal acquiescence; it requires that consent is granted pursuant to complete knowledge of the purpose for which consent has been undertaken. Thus, the use of a patient's genetic material for a purpose wholly unconceived of by the patient, without availing of his fresh consent for this use, is a reprehensible violation of the principle of informed consent (48). More particularly, the principle of informed consent is antithetical to the use of any coercion in the collection of blood and tissue samples; the term coercion includes within its ambit the provision of any incentives to the donor of blood and tissue samples, particularly when the donor belongs to a marginalised, economically, socially, geographically or otherwise backward community, and particularly indigenous communities in developing nations (55).

The Supreme Court of India has recently, in Samira Kohli v. Dr Prabha Manchanda and Anr (56), formulated the law on informed consent in the following words:

> We therefore hold that in Medical Law, where a surgeon is consulted by a patient, and consent of the patient is taken for diagnostic procedure/surgery, such consent cannot be considered as authorisation or permission to perform therapeutic surgery either conservative or radical (except in life threatening or emergent situations). Similarly where the consent by the patient is for a particular operative surgery, it cannot be treated as consent for an unauthorized additional procedure involving removal of an organ, only on the ground that such removal is beneficial to the patient or is likely to prevent some danger developing in future, where there is no imminent danger to the life or health of the patient.

In the US, in Kaimowitz v. Department of Mental Health (57), on the issue of consent, the Michigan Court discussed the Nuremburg Code and declared: "To be legally adequate, a subject's informed consent must be competent, knowing and voluntary." The court based its pronouncements on the need to protect the "inviolability of the individual" which, it said, was "one of society's most fundamental values." The court therefore concluded: "Consent is not an idle or symbolic act; it is a fundamental requirement for the protection of the individual's integrity."

Some individuals object on religious, ethical, or other personal grounds to particular medical procedures, even when those procedures carry an appreciable possibility for improving their own health (58, 59). Hence, the mere fact that collection of blood and tissue samples is a standard medical procedure, or can be necessary in a procedure that has medical benefits, is no ground for evading the doctrine of informed consent.

In light of the aforesaid judicial decisions, it can be concluded that, if the issue were brought to Indian courts, under Indian law, the fraudulent taking of cell lines from the body of a patient without adherence to the procedure of informed consent established by law would infringe upon his right to have control over his body, and would thereby violate his fundamental right to privacy that is guaranteed under Article 21 of the Constitution of India.

B. Informed consent and international law

Having examined judicial decisions recognising the doctrine of informed consent in the previous section, it is necessary to look at how international bodies have incorporated this doctrine in international treaties and conventions. The doctrine of informed consent is firmly ingrained in the corpus of customary international law. Article 7 of the International Covenant on Civil and Political Rights (ICCPR) (60), to which India is a signatory, prohibits medical and scientific experimentation on persons without their free consent. Further, free consent refers to consent obtained without the intervention of any element of coercion, undue influence, fraud, misrepresentation, or mistake (61, 62). Keeping in mind the doctrine of informed consent emphasised in the Nuremberg trials, and its significance in international customary law, Golde and Quan were under a duty to inform Moore, from whom genetic data were collected, that his genetic data were liable to be used for different purposes.

A number of international legal documents which came into effect after the inception of the ICCPR also state that consent must be not only free, but it must also be informed, expressed and given prior to the action for which it is sought (48, 63).

Article 16 of the International Declaration on Human Genetic Data (48) refers to a change of purpose, and states that if the original consent is incompatible with the different purpose for which genetic data are to be used, then prior, free, expressed and informed consent must once again be obtained from the person before the use of the genetic data for a different purpose.

Further, Article 17 of the ICCPR (60) states that no person shall be subjected to an arbitrary or unlawful interference with his privacy.

In the John Moore case, not only did the doctors disregard a specific directive from the patient with regard to the future use of his body part, before the spleen was removed, but they also intentionally withheld material information that they were under an obligation to disclose to him and that was necessary for his exercise of control over that body part. Therefore, the act of using the genetic material of the patient for a purpose incompatible with the original consent, as in the Moore's case, should be considered an arbitrary and unlawful interference with his privacy and confidentiality. Although a patient may not retain any legal interest in a body part after its removal when he has properly consented to its removal and use for scientific purposes, it is clear that when a body part is being removed, it is the patient, rather than his doctor or hospital, who possesses the right to determine the use to which the body part will be put after removal.

V. Bioethics and international law

The case of Moore and many decisions which followed it have recognised and acknowledged that patenting of human genetic material raises several ethical concerns. This has had serious ramifications leading to the development and growth of international law in this field.

In 1993, a patent on human cell lines was claimed before the patent office of the United States (64). The cell line was developed from the blood of a woman from the Guarani Indian tribe of Panama, South America. The cell line was expected to be useful in research on AIDS and cancer. The patent was claimed by the US government However, several non-governmental organisations and the tribal communities in Panama objected and questioned the ethics of patenting a cell line. They argued that it amounted to commodifying life. Yielding to vehement opposition and international criticism, the US government withdrew the patent application.

In 1991, the National Institutes of Health in the US sought patent protection for a cell line developed from the DNA of a person belonging to the Hagahai indigenous group in Papua New Guinea (65). The application was later withdrawn following public criticism as no consent was obtained from the Hagahai donor.

It can be argued that patenting and owning human beings and genetic materials of human beings without their consent amounts to holding them in slavery. Slavery infringes upon the dignity of the human beings, which is guaranteed under different international covenants and declarations (60,66,67). Research in biotechnology should always be in consonance with the ethical standards of society. Research in the fields of biology and medicine should not prevail over the respect for human rights and human dignity.

With the coming into being of the Agreement on Trade-Related Aspects Of Intellectual Property Rights (68), it is universally accepted that ethics, morality, and public order form restrictions to the patentability of inventions. The United Nations Universal Convention on Human Genome and Human Rights, 1997 (63), says that research on the human genome shall respect the ethical standards of society. No research in the fields of biology and medicine should prevail over respect for human rights and human dignity.

The European Patents Convention (17) states that inventions which are against public order and morality shall not be patented.

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine (69) intends to protect human dignity in respect of human beings being made the subject of research in biomedical sciences. According to the convention, research on human beings, tissues, organs or the human genome shall be undertaken only after the person concerned has been informed of the possible risks associated and has given informed consent. Using the human body and its parts for financial gain is prohibited under the convention.

The Indian Council on Medical Research has issued ethical guidelines in human genetics (49). The guidelines are intended to guarantee human rights and dignity with regard to genetic research in which human beings, human tissues, cells and genetic materials are used. They state that research on human

subjects shall be done only after voluntary and informed consent is taken in which the subject has been explained all the possible risks associated with participation in the research.

VI. Conclusion

Life form patenting is allowed in the United States and the European Union and many other countries support the notion that human genetic material is patentable. However, there are also countries which oppose the patenting of human genetic material. There are discrepancies and ambiguities as regards the legal principles to be applied when disputes concerning this issue come before the Indian courts, and changes in the law may be necessary to effectively address these issues.

Further, the need for uniform and universally recognised ethical guidelines for research on human subjects has acquired a new urgency with the emergence of critical issues in the areas of biogenetic research involving human subjects.

In order to fulfil its obligations under the Declaration on Human Genome and Human Rights, 1997 (63), the US government set up the National Bioethics Advisory Commission, whose primary job is to report on the ethics involved in research in biology and medicine, especially research on the human genome and on human cloning. Similarly, the European Union has streamlined ethical standards and incorporated these into the patent law.

In India, existing legislation does not sufficiently address the ethical implications of different biotechnology inventions. There is no specific legislation regulating biomedical research on human subjects. The guidelines issued by the ICMR (49), which are in consonance with international ethical guidelines for biomedical research involving human subjects, issued by CIOMS in 1993(47) and the principles of the World Medical Association's Declaration of Helsinki, first issued in 1964 (45) and revised a number of times since then, hold good in the absence of any definite legislation.

The Biomedical Research Human Subjects Promotion and Regulation Bill, drafted by the ICMR, was cleared by the Union Law Ministry in January 2006 but has not been placed before Parliament. The Bill is better equipped to deal with the complexities emerging out of the field of biomedical research. Once the bill gets the cabinet nod, it will become mandatory for all medical institutions conducting human research, and the ethics committees in these institutions, to be registered with a central agency.

John Moore v. Regents of the University of California (1) and subsequent cases illustrate the manner in which patenting of human genetic material and bioethics are inextricably intertwined in medical law. This overview of the existing laws pertaining to patenting of human genetic material in different countries has dealt with various legal approaches that could be taken in such matters and important doctrines such as informed consent which plays a crucial role in conducting research involving human beings. Detailed legislation in this respect is called for.

References

1. Moore v. Regents of the University of California, 793 P.2d 479, 481 (Cal. 1990).
2. Rothstein MA. Genetic stalking and voyeurism: a new challenge to privacy. *Univ Kans Law Rev.* 2009 Mar;57:539.
3. Becerra RM. Patents and commercial transactions of human tissues. *Mex Law Rev*. 2007;1:7.
4. Andrew LJ. Replacing our current system of organ procurement with a future market: will organ supply be maximized? *Jurimetrics Journal of Law, Science and Technology.* 2007 Jan-Jun;37(2):167-86.
5. Ho CM. Biopiracy and beyond: a consideration of socio-cultural conflicts with global patent policies. *Univ Mich J Law Reform*. 2006 Spring;39:532-40.
6. Bonito Boats, Inc v. Thunder Craft Boats, Inc 489 US 141, 150 (1989)
7. Diamond v. Chakrabarty, 447 US 303 (1980).
8. Amgen v. Chugai, 18 USPQ2d 1016 (Fed Cir 1991).
9. Re Bell, 991 F2d 781 (Fed Cir 1993).
10. Re Deuel, 51 F 3d 1552 (Fed Cir1995).
11. Relaxin, (1995) EPO R541.
12. Biogen v. Medeva, (1997) RPC 1 HL.
13. US Congress, Office of Technology Assessment. Biomedical ethics in US public policy -background paper, OTA-BP-BBS-1O5.Washington, DC: US Government Printing Office;1993 Jun.
14. Re Lundak, 773 F.2d 1216, 227 USPQ 90 (Fed Cir 1985).
15. US Patent No 6,780,641 (filed 2001 Jun 22) (issued 2004 Aug 24).
16. European Parliament and the Council of the European Union. Directive 98/44/EC of the European Parliament and of the council of 6 July 1998 on the legal protection of biotechnological inventions [Internet].1998 Jul [cited 2010 Mar 11]. Available from: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:213:0013:0021:EN:PDF
17. European patent office. European Patent Convention [Internet]. 13th ed. 2007 Jul [cited 2010 Mar 11]. Available from http://documents.epo.org/projects/babylon/eponet.nsf/0E4F8409B2A99862FC125736B00374CEC/$File/EPC_13th_edition.pdf
18. Sreenivasulu N S, Raju C B. Biotechnology and patent law.1st ed. Noida (India): Manupatra Information Solutions Pvt Ltd; 2008.79p.
19. Fouldes v. Willoughby, (1841) 8 M & W 540, 550.
20. Deborah S Brotherton v. Frank P Cleveland, 923 F 2d 477, 59 USLW 2457.
21. York v. Jones, 717 F Supp 421, 58 USLW 2083, 55 Ed. Law Rep. 529.
22. Cohen v. Groman Mortuary, Inc., 41 Cal Rptr 481 (1964).
23. Hecht v. Superior Court, 16 Cal App 4th 836 (1993).
24. Pasteur v. United States, 814 F 2d 624 (Fed Cir 1987).
25. Cobbs v. Grant, 502 P 2d 1 (Cal 1972).
26. Bouvia v. Superior Court (1986) 179 Cal App.3d 1127, 225 Cal Rptr 297).
27. National Conference of Commissioners on Uniform State Laws. Revised Uniform Anatomical Gift Act, 2006 (last revised or amended in 2009). 2006 [cited 2010 Mar 11]. Available from: http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=1&tabid=63
28. Commonwealth legal information institute, free access to commonwealth and common law [Internet]. [place unknown]: Common LII. The Transplantation Of Human Organs Act, 1994. Act No. 42 of 1994; 1994 Jul 8[cited 2010 Mar 15]; [about 7 screens]. Available from: http://www.commonlii.org/in/legis/num_act/tohoa1994339/
29. Francis Coralie v. Union Territory of Delhi, AIR 1981 SC 746.
30. Olga Tellis v Bombay Corpn, AIR 1986 SC 180.
31. Griswold v. Connecticut, 381 US 479 (1965).
32. Gobind v. State of MP (1975) 2 SCC 148, 157.
33. People's Union of Civil Liberties (PUCL) v. Union of India, (1997) 1 SCC 301.
34. Schloendorff v. Society of New York Hospital, 105 NE 92 (NY 1914).
35. Bouvia v. Superior Court (1986) 179 Cal. App.3d 1127, 225 Cal Rptr 297.
36. R v. Legere (1988), 89 N B R (2d) 361 (CA).
37. Venner v. State (1976) 30 Md App 599, 354 A 2d 483.
38. R v. Dyment [1988] 2 SCR 417.
39. R. v. Pohoretsky [1987] 1 SCR 945.
40. Derek M. Issues in medical law and ethics. 1st ed. United Kingdom: Cavendish Publishing Limited;2001.103p.
41. Gary BL. A taxonomy of privacy: repose, sanctuary and intimate decision. California Law Review.1976 Dec;64:1447-83.
42. Haelan Laboratories, Inc v. Topps Chewing Gum, Inc, 202 F2d 866 (2d Cir).

43. Dolgin Janet L. The evolution of the "patient": shifts in attitude about consent, genetic information, and commercialisation in health care. *Hofstra Law Rev*.2005;34:137.
44. The United States Holocaust Memorial Museum. The Nuremberg Code [Internet]. Washington, DC: US Government Printing Office;1949 [cited 2010 Mar 11]. Available from: http://www.ushmm.org/research/doctors/Nuremberg_Code.htm
45. World Medical Association. Declaration of Helsinki. Ethical principles for medical research involving human subjects [Internet]. October 2008. [cited 2010 Mar 11]. Available from: http://www.wma.net/e/policy/pdf/17c.pdf
46. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research [Internet]. Washington, DC: United States Department of Health, Education and Welfare; 1979 Apr 18 [cited 2010 Mar 10]. Available from: http://ohsr.od.nih.gov/guidelines/belmont.html
47. Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). International Ethical Guidelines for Biomedical Research Involving Human Subjects [Internet]. Geneva: WHO; 2002[cited 2010 Mar 10]. Available from: http://www.cioms.ch/frame_guidelines_nov_2002.htm
48. United Nations Educational, Scientific and Cultural Organization. International Declaration on Human Genetic Data [Internet]. Paris: UNESCO; 2003 Oct 16 [cited 2010 Mar 10]. Available from: http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html
49. Indian Council of Medical Research. Ethical Guidelines For Biomedical Research On Human Participants [Internet]. New Delhi: ICMR; 2006 [cited 2010 Mar 16]. Available from: http://www.icmr.nic.in/ethical_guidelines.pdf
50. Central Drugs Standard Control Organisation (CDSCO) in consultation with clinical expert. Good clinical practices guidelines [Internet]. New Delhi: CDSCO; undated [cited 2010 Mar 10]. Available from: http://www.cdsco.nic.in/html/gcp.htm
51. Government of India. Ministry of health and family welfare. The Drugs and Cosmetics Act and Rules [Internet]. 2005 Jun 30 [cited 2010 Mar 10]. Available from: http://cdsco.nic.in/html/Drugs&CosmeticAct.pdf
52. Palmer Larry I. Disease management and liability in the human genome era. *Vill Law Review*. 2002;47:24-28.
53. Jay Katz. Human experimentation and human rights. *St Louis Univ Law J*. 1993;38 (1):7-54.
54. Greenberg v. Miami Children's Hospital Research Institute Inc. Complainant 264 F Supp 2d1064.
55. Kevin KM. A proposal for the effective international regulation of biomedical research involving human subjects. *Stanford J Int Law*. 1998 Winter; 34(1):163-206.
56. Samira Kohli v. Dr Prabha Manchanda and Anr, 2008(1) SCALE 442.
57. Kaimowitz v. Department of Mental Health, Civil no.73-19, 434-AW (Cir Ct Wayne Co, Mich, July 10, 1973).
58. Re Osborne, 294 A.2d 372, 375 (DC 1972).
59. Lane v. Candura, 6 Mass App Ct 377, 385, 376 N E 2d 1232, 1236 (1978).
60. Office of the United Nations High Commissioner for Human Rights. International Covenant on Civil and Political Rights [Internet]. Geneva: OHCHR;c1996-2007 [cited 2010 Mar 11]. Available from: http://www2.ohchr.org/english/law/ccpr.htm
61. Indian Contract Act, 1872. Act no. 9 of 1872. Section 14 [Internet]. 1872 Apr 25[cited 2010 Mar 11]. Available from: http://chddistrictcourts.gov.in/THE%20INDIAN%20CONTRACT%20ACT.pdf
62. Louisiana Civil Code, Article 93 and Article 1948.
63. United Nations Educational, Scientific and Cultural Organization. Universal Declaration on the Human Genome and Human Rights [Internet]. Paris: UNESCO; 1997 Nov 11[cited 2010 Mar 10]. Available from: http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html
64. Patent application No. 9208784 A 1, 1993.
65. US Patent 5397696.
66. General Assembly of the United Nations. The Universal Declaration of Human Rights [Internet]. Geneva: United Nations; 1948 Dec 10 [cited 2010 Mar 10]. Available from: http://www.un.org/en/documents/udhr/
67. Council of Europe. Convention for the Protection of Human Rights and Fundamental Freedoms as amended by Protocol No. 11 [Internet]. Rome: Registry of the European Courts of Human Rights; 2003 Sep [cited 2010 Mar 10]. Available from: http://www.echr.coe.int/nr/rdonlyres/d5cc24a7-dc13-4318-b457-5c9014916d7a/0/englishanglais.pdf
68. World Trade Organisation. Agreement on Trade-Related Aspects Of Intellectual Property Rights [Internet]. Marrakesh (Morocco): WTO; 1994 Apr 15[cited 2010 Mar 10]. Available from: http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm
69. The Council of Europe. Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine [Internet]. Oviedo (Asturias): Council of Europe; 1997 Apr 4 [cited 2010 Mar 10]. Available from: http://conventions.coe.int/Treaty/EN/Treaties/html/164.htm

Acknowledgement: *The author would like to thank Mr Karan Singh Tyagi for his guidance and invaluable suggestions on the paper.*

Informed consent: a survey of general dental practitioners in Belgaum city

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Abstract

The informed consent process allows the patient or legal guardian to participate in and retain autonomy over the medical service received. Obtaining informed consent may also decrease the practitioner's liability from claims associated with miscommunication. The aim of this study was to assess knowledge and practices of general dental practitioners (GDPs) regarding informed consent. 118 GDPs in Belgaum city, Karnataka, India, were given questionnaires asking for information on their knowledge and practices related to informed consent. The questions covered general information, treatment-specific issues and the consent process. 80 responses were received out of which 44 were complete. 63.6% of GDPs reported that they obtained written consent. All of them reported that they obtained only general consent. 4 of them obtained written consent in the local language. 37 said they gave a detailed explanation of the procedure. 3 said they did not inform their patients on radiation exposure. Dentists should upgrade their knowledge regarding legal jurisprudence and legal medicine to avoid any litigation.

Introduction

The treatment of a patient without his or her consent has been viewed as battery and can invoke legal action. Litigation involving consent issues has often concerned the nature and extent of information that is provided to a patient in the course of obtaining authorisation for treatment (1).

Much has been written in the medical literature on why informed consent is so important and what it is in theory and in practice (2-4). However, there is a limited discussion on this issue in the dental literature within India, despite the importance of this subject to dental providers. In dentistry, as in other branches of medicine, patients have trusted their providers to do what is clinically best for them. Discussions between dentists and their patients on treatment are more in the nature of a few notes for the dentist's records than a written account of a negotiated clinical plan with the options explained for the patient. This situation may not concern patients unduly, as they may feel that the potential hazards of dental treatment are few. At present, the level of information given to obtain informed consent can vary widely between individual dentists.

This situation is changing. Patients are demanding better and more information about their healthcare. Some have taken legal action when they have concluded that their clinicians have failed to provide sufficient information about the outcomes of selected treatments.

Dentists' obligation to obtain the patient's consent to treatment is based on ethical principles, legal requirements and professional policies. Any treatment or investigation performed without consent can result in legal action for damages and even criminal proceedings. The dentist may be found guilty of serious professional misconduct by the professional registration body (5-7).

In India, the Dental Council of India is concerned with maintaining ethics among dental professionals. The code of ethics for dentists specifies certain duties and rights of a dental practitioner, including those that concern the welfare of patients (8), Some steps have been taken to educate dentists on ethics. A notification of the Dental Council of India published in the Indian Gazette contains a separate section on forensic odontology which includes jurisprudence and ethics in dentistry. Reference is made to a 30-hour curriculum with didactic lectures and practical exams (9).

However, such steps are no assurance that dental practitioners will practise dentistry in an ethical manner (10).

The present study was conducted to assess the knowledge and practice of general dental practitioners (GDPs) in Belgaum city regarding informed consent. Belgaum city is situated in the south Indian state of Karnataka with a population of about 42,00,000 according to the 2001 census.

Material and methods

A cross sectional survey was conducted using a self designed questionnaire. Institutional ethical clearance was obtained from the KLE VK Institute of Dental Sciences. The questionnaire covered general information, treatment specific issues and consent.

The list of 128 registered practising dentists in the city was obtained from the Belgaum branch of the Indian Dental Association. The questionnaire was pre-tested on 10 GDPs. Those interviewed in the pre-test were excluded from the final study. The remaining 118 practitioners were approached to participate in the study. The researchers approached the GDPs in person with the questionnaire. The GDPs were also given a written consent form to sign before they were enrolled into the study. 80 agreed to participate in this study and returned the signed questionnaires along with a signed consent form. The researchers personally collected the completed questionnaires from the GDPs. Of the 80 questionnaires that were returned, 44 questionnaires were completed; these 44 were included in the study. The results were tabulated and percentages were calculated.

Results

General information: 42 of 44 GDPs were male. 23 GDPs had a bachelor's degree and 21 had a master's degree in dentistry. The duration of the dentist's practice ranged from six months to 29 years. All the GDPs offered all general dental treatments including consultation and treatment for oral and maxillofacial surgery and orthodontics. 2 GDPs said they also offered implants at their clinics. The Karnataka State Dental Council (the statutory body) registration certificate was displayed by 20 GDPs (45.5%).

General clinical practices followed by GDPs: 41 GDPs (93.2%) stated that they discussed the various treatment modalities available at their clinic with their patients before starting treatment. 3 GDPs (6.8%) reported that they did not explain the various treatment modalities available.

39 said they noted all findings and treatment on the patient's case paper. Of these 39 GDPs, 28 reported that they took the signature of patients on the case papers. 11 said they did not take the patient's signature.

6 GDPs (13.6%) stated that they took the final decision on the treatment to be carried out on the patient. 30 GDPs (68.1%) stated that they left this to the patient to decide. 5 GDPs (11.3%) said that they decided on the best treatment option along with their patient. 3 GDPs (6.7%) said that this depended on the type of cases that they received.

Information given on risks and discomforts of procedures: 37 (84.1%) said they gave a detailed explanation of any procedure to be carried out and the complications associated with local anaesthesia. 36 (81.8%) said they gave the success and failure rate of root canal therapy before treatment. 37 (84.1%) said they explained the success and failure rate of periodontal surgery and its associated complications. 30 GDPs (68.2%) said that they did not find it necessary to discuss the gag reflex and how to overcome it.34 GDPs (77.3%) said that they did not advise their patients about the various treatment facilities available during replacement of teeth. 34 GDPs (77.3%) stated that that they did not inform their patients on the amount of radiation exposure while taking radiographs. 35 GDPs (79.5%) said they explained in detail the procedures, duration and costs associated with orthodontic treatment.

Taking consent: all 44 GDPs stated that they took consent before starting any procedure. 28 GDPs (63.6%) took written consent from the patient. 16 GDPs (36.4%) stated that they took only oral consent. All 28 of those who took written consent took general consent, not treatment-specific consent. 4 of them obtained written consent in the local language; the remaining obtained consent in English.

When taking consent from illiterate patients, 21 GDPs (47.7%) reported taking verbal consent. Of the remaining, 7 took the patient's thumbprint, 9 GDPs stated that they took the relative's signature, and 7 GDPs stated that they obtained verbal consent, as well as the patient's thumbprint on the consent form.

16 GDPs (36.4%) said that they provided a copy of the consent form to the patient if asked. 20 (45.5%) said they asked for a reason before giving the form, 8 GDPs (18.2%) said they refused to give a copy of the consent form to the patient.

GDPs' awareness of informed consent				
Question	**Number**	**%**	**Number**	**%**
Are you aware that one copy of the informed consent form should be given to the patient if asked for?	11	25%	33	75%
Do you find taking written consent time consuming?	18	40.9%	26	59.1
Do you believe that a consent form is necessary for every treatment provided at your clinic?	23	52.3%	21	47.7%
What are consent forms for?				
(i) To protect the doctor	31	70.4%		
(ii) To protect the patient	1	2.3%		
(iii) Both	12	27.3%		
Are you aware of the Consumer Protection Act?	44	100%		

11 GDPs were aware that a copy of the informed consent form should be given to the patient if asked. 18 GDPs (40.9%) stated that they found obtaining written consent time consuming. 23 GDPs (52.3%) said written consent should be obtained for every treatment.

31 GDPs stated that consent forms are to protect the doctor. 1 said it was to protect the patient. 12 said it was for both.

All 44 GDPs were aware of the Consumer Protection Act.

Discussion

An important medico-legal concern is improper consent and withholding complete information from the patient. This has been the subject matter of judicial scrutiny in various cases under the Consumer Protection Act (CPA) as it pertains to patients' rights.

The consumer movement in the 1980s led the government of India to enact the CPA in 1986, paving the way for the establishment of consumer courts. The CPA is meant to protect the rights and interests of consumers, those who hire or avail of services from others. Compensation is judged and decided upon the doctrine of deficient service, unfair trade practice. The Supreme Court of India, in a landmark judgment on November 13, 1995, included the healthcare profession under section 2 (1) (0) of the CPA, 1986 (11). This includes a) all medical and dental practitioners doing independent medical or dental practice unless rendering only free service; b) private hospitals charging all patients; c) all hospitals having free as well as paying patients and all paying and free category patients receiving treatment in such hospitals, and d) medical or dental practitioners and hospitals paid by an insurance firm for the treatment of a client, or by an employer for the treatment of an employee. The CPA exempts only those hospitals, and medical or dental practitioners in such hospitals, offering free services to all patients.

The Supreme Court of India has also given the following guidelines on informed consent: A doctor must seek and secure the consent of the patient before starting treatment. The consent so obtained should be real and valid. The information should include the nature and procedure of the treatment and its purpose, benefits and effect, alternative treatment if any available, an outline of the substantial risks and the adverse consequences of refusing treatment. The Supreme Court judgment emphasised the need for specificity of consent. Consent given only for a diagnostic procedure cannot be considered as consent for a therapeutic procedure. Consent given for a specific procedure will not be valid for conducting another procedure. However, there can be a common consent for diagnostic and operative procedures where they are contemplated. Consent can also be sought for a particular surgical procedure that also explicitly covers additional or further procedures that may become necessary during the course of surgery. The nature and extent of information to be furnished by the doctor to the patient to secure the consent should be acceptable as normal and proper by a body of medical men skilled and experienced in the particular field (12).

Record keeping: Only 20 GDPs (45.4%) had displayed the Karnataka State Dental Council registration certificate. In India, the Dentists Act of 1948 (13) regulates the profession of dentistry by constituting a Dental Council of India (DCI) under section 3 and state dental councils under section 21. The DCI maintains the Indian Dentists Register which contains information on all the dentists registered in the state. State dental councils are empowered to punish persons who claim to be registered and/or practise dentistry without registration with a fine or imprisonment or both (9). Display of the registration certificate lets the patient know that the person who is treating them is authorised to render treatment.

Clinical practices followed by GDPs		
Question	**Yes**	**No**
Before starting the treatment do you inform the patient of all the treatment options available?	41(93.2%)	3(6.8%)
Do you note down all the findings and treatment to be followed on the case paper?	39(88.6%)	5(11.4%)
If yes, do you take the patient's signature on the records?	28/39(71.7%)	11/39(28.2%)

All 44 GDPs stated that they maintained patients' records. This could be seen as an indication of their professional conduct and their awareness of the need to maintain records for further treatment. However, 5 GDPs (11.4%) said that they did not write down their findings on the case paper, so it is not clear what these dentists' records included. 11 GDPs (25%) said that they did not take the patient's signature on the case papers. 5 GDPs (11.4%) said that they neither recorded their findings nor took the patient's signature. If these dentists are accused of negligence they will not have documentation to support their case.

Discussing treatment options: 41 GDPs (93.1%) stated that they discussed the various treatment modalities available at their clinic with their patients. 3 GDPs (6.8%) reported that they did not explain the various treatment modalities available. The present study did not take into account the reasons for not informing patients about the various treatment modalities.

Discussing risks: The questionnaire contained questions on procedures routinely performed at the dentists' clinics. It is important for a dentist to convey that all treatments can have risks as well as side effects. This is especially so in aesthetic dentistry. The dentist should explain every aspect of the treatment to a patient who wants the implant or orthodontic surgical procedure, especially when it is cosmetic in nature. It should be emphasised to the patient that there are risks and side effects. Some of them are mildly inconvenient, others can cause inconvenience in routine life and others are serious. The recovery time and the extent of benefits can vary. Certain diagnostic investigations such as taking impressions can trigger a gag reflex. Patients need to be prepared for this discomfort. Dentists also need to convey information prudently; sensible dentists will use their discretion in deciding what to reveal and how to discuss the risks and benefits of the treatment.

Information given before initiation of treatment		
Question	**Yes**	**No**
Do you give a detailed explanation of the procedure and explain the complications associated with local anaesthesia?	37 (84.1%)	7(15.9%)
Do you give the success and failure rate of root canal therapy before treatment?	36 (81.8%)	8(18.2%)
Do you explain the success and failure rate of periodontal surgery and its associated complications?	37(84.1%)	7(15.9%)
Do you ask patients about the degree of gag reflex that they have before taking an impression?	14 (31.8%)	30(68.2%)
Are your patients advised about the various treatment modalities available during replacement of teeth?	10 (22.7%)	34(77.3%)
Before taking a radiograph, do you tell the patient about the amount of exposure to radiation	10(22.7%)	34(77.3%)
Do you explain in detail the procedures, duration and costs associated with orthodontic treatment?	35(79.5%)	9(20.5%)

Patients need to be informed about these outcomes before starting with the procedure. 30 GDPs (68.1%) said that they did not find it necessary to warn the patient about the gag reflex or to educate the patient on how to overcome the gag reflex. 34 GDPs (77.3%) stated that it was not necessary to inform their patients of the amount of radiation exposure while taking radiographs. The reason they gave was that the hazard associated with it is minimal. The minimum exposure time for an intra oral radiograph using a standard X-ray machine with 60-70kvp is 3.6-4.8mAs (miliampere seconds). The dose of exposure should not exceed 50mSv (mili Sievert) in persons who are not exposed to radiation in the workplace. In cases of frequent exposure these limits may be exceeded (14). L Doyal and H Cannell in their article on informed consent and the practice of good dentistry have discussed a case of negligence

against a dentist, in which the plaintiff stated that the doctor did not tell her about the hazards of radiation exposure. Her radiographs were taken shortly after she became pregnant. At that time, she knew nothing of the risks of radiation. Once she learned of the risks, her anxiety about the safety of her baby sent her into serious depression for which she needed treatment. This effectively ruined the experience of pregnancy for her and her partner. The authors concluded that a written note of treatment options explained to patients and countersigned by them should become a part of normal treatment practice (2).

GDPs' practices regarding obtaining informed consent				
	Yes		No	
Question	Number	%	Number	%
Do you take consent before starting any procedures?	44	100%		
If yes (44) *				
(i) Written	28	63.6%		
(ii) Oral	16	36.4%		
If written (28) *				
(i) General consent	28			
(ii) Treatment-specific consent	Nil			
Is the written consent obtained in the local language?	4		24	
Type of consent obtained from an illiterate patient				
(i) Verbal consent	21	47.7%		
(ii) Patient's thumbprint	7	15.9%		
(iii) Signature of relative	9	20.5%		
(iv) Verbal consent and thumbprint	7	15.9%		
If patient asks to take a copy of the consent form do you provide a copy?				
(i) Provide the form willingly	16	36.4%		
(ii) Ask for a reason before giving form	20	45.5%		
(iii) Refuse to give the form	8	18.2%		

Consent: In general, the consent process provides an opportunity for the dentist to create a good patient-clinician relationship by communicating with the patient regarding the details of the treatment, tailoring the information to the specific needs and understanding of the patient. It also allows for the patient to express his/her opinion and concerns. This can build patients' trust and confidence in the dentist as they feel that they are in control of the decisions in their treatment.

28 GDPs (63.6%) took written consent from the patient. 16 GDPs (36.4%) stated that they felt the need to take only oral consent. Most dental treatments involve "implied consent". For example, the patient opens his mouth for examination and allows a procedure to be done. However, implied consent may not provide sufficient protection for the dentist against legal action. Expressed consent is obtained from a patient for a specific procedure and should be obtained for all procedures that are not routine and carry a material risk (5). Oral consent is one form of expressed consent and is normally adequate for routine treatment such as fillings and prophylaxis (15). But it should be witnessed and properly documented in the patient's record. Apart from this oral discussion, written consent should be obtained for any proposed therapy, and the information provided should include the risks and benefits of the treatment and also possible alternative therapies. Written consent is advisable as it may decrease liability from miscommunication (16).

28 GDPs (63.6%) who stated that they took written consent took only general consent, though they had specialty consultants visiting their clinics to treat their patients. This could be because of lack of awareness. Consent forms should be procedure-specific, and multiple forms may need to be used. For example, the risks associated with restorative procedures will differ from those associated with an extraction. Separate forms or separate sections for each procedure within one form are necessary to accurately advise patients regarding each procedure. Consent for sedation or behaviour guidance techniques such as protective stabilisation (immobilisation) should be obtained separately from consent for other procedures. Consent may need to be updated or changed as changes in the treatment plan occur. For example, a primary tooth originally planned for pulp therapy is found to be non-restorable at the time of treatment. In such cases consent should be updated to reflect the change in treatment (17).

Out of 28 GDPs who took written consent, only 4 (9%) were aware of the need to obtain written consent in the local language (Kannada and Marathi). 24 GDPs (91%) obtained written consent in the English language. India is a multi-lingual country where every state has its own language. So people of one area cannot communicate with others in the local languages. English is a universal language for Indians. Even then, most patients from rural India will know only the local language. Urban patients may know both English and local languages and schools in these areas teach both the languages. This study was conducted in an urban area where most patients would be aware of English. However, their familiarity with English would depend partly on their socioeconomic backgrounds. If consent is not taken according to the language with which the patient is familiar it becomes difficult to communicate with the patient. The dentist may require reliable interpreters to explain the procedure to the patient. It is important for the clinician to be aware of the interpreter's ability to accurately communicate information to the patients or their guardians (5).

In the case of illiterate patients, 21 GDPs (47.7%) reported taking verbal consent, 7 said they obtained the patient's thumbprint, 9 GDPs (20.5%) stated that they took the relative's signature and 7 GDPs (15.9%) stated that they obtained verbal consent and also took the patient's thumbprint on the consent form.

Although consent is generally sought from the patients themselves, there are occasions in which others may be involved. In situations where a patient cannot give consent, the patient's relative can give consent (1). Even verbal consent, if obtained properly, is valid. But later the patient may deny having been given information either because they have genuinely forgotten or because they have a grievance and wish

to strengthen a legal case against the dentist (2). Hence when the patient cannot give consent it is always advisable to take the signature of the family member along with a third party witness signature.

8 GDPs (18.1%) said they refused to give a copy of the consent form to the patient. This suggests that GDPs do not see the need to respect a patient's rights or they are not aware of changing trends in obtaining consent from patients.

33 GDPs (75%) said that they were not aware that if a patient asks for a copy of the consent form, it should be handed over.21 GDPs (47.7%) felt that there is no requirement of consent for every treatment provided at their clinic. The reason given was that routine dental treatments do not require written consent and oral consent is sufficient.

The Hippocratic Oath that granted doctors the right to decide in the patients best interest has been in conflict with the 21st century trend in the West of patient autonomy. However, the doctor-patient relationship in India is somewhat different from that in the West; here it is predominantly governed by trust, the doctor is an authority figure and considered the right person to decide treatment modalities. Patients' ability to provide informed consent is also influenced by factors like the overburdened health services, low literacy levels (18) and poor awareness about consumer rights (19). However in recent years, patients' increasing awareness of their rights has resulted in more formal complaints being filed against dentists for treatment without consent (2).

Limitations

The conclusions of this study cannot be generalised due to the small sample size and the low response rate.

Conclusion

The importance of consent to treatment cannot be over emphasised. It is believed that the best arguments in favour of fully informed consent are moral rather than legal. In the present study it was noticed that GDPs were less aware of the concept of written consent and its importance. They knew about the CPA but lacked knowledge regarding obtaining written consent. Emphasis should be given in undergraduate and postgraduate training on legal jurisprudence and legal medicine as this is essential for dentists to protect themselves from civil litigation (trespass, assault or battery) and even criminal proceedings for common aggravated or indecent assault. The effective procurement of informed consent promotes patient autonomy, engenders trust and confidence in medical professionals and reduces the risk of unnecessary legal claims premised on incorrect assumptions regarding appropriate medical care.

References

1. Le Blang T R, Rosoff A J, White C. Informed consent to medical and surgical treatment. In: *Legal Medicine*. 6th edition. Philadelphia Pa: Mosby Inc; 2004.343p.
2. Doyal L, Cannell H. Informed consent and the practice of good dentistry. *Br Dent J*. 1995 Jun 24; 178(12):454-60.
3. Rule J T, Veatch RM. *Ethical questions in dentistry*. Chicago: Quintessence Publishing; 1993.
4. Odom J, Bowers D. Informed consent and refusal. In: Weinstein B, editor. *Dental ethics*. Philadelphia: Lea and Febiger;1993. p 65-80.
5. Mohamed Tahir M A, Mason C, Hind V. Informed consent: optimism versus reality. *Br Dent J*. 2002 Aug 24;193:221-4.
6. Bailey B L. Informed consent in dentistry. *J Am Dent Assoc*. 1985 May;110(5):709-13.
7. Grace M. Law and Ethics. *Br Dent J*. 1994 Mar 5;176(5):159.
8. Dental Council of India. Bachelor of Dental Surgery Course Regulation 2007. New Delhi: Dental Council of India; 2007 Jul 25.
9. Ministry of Health and Family Planning. Dentists (Code of Ethics) Regulations, 1976 [Internet]. New Delhi: Department of Health, Government of India; 1976 Aug 2 [cited 2010 Mar 10]. Available from:http://www.dciindia.org/annoncment_pdf_files/pdf_files/CODEOFETHICSREGULATIONS1976.pdf
10. Schwartz B, Bhan A. Professionalism and challenges in dental education in India. *Indian J Med Ethics*. 2005 Oct-Dec;2(4):119-21.
11. Supreme Court of India. Judgments, the judgment information system of India. Civil appeal no: 688 of 1993. Supreme Court of India [Internet]. 1995 Nov 13 [cited 2010 Mar 16]. Available from: http://judis.nic.in/supremecourt/imgs.aspx
12. Supreme Court of India. Judgments, the judgment information system of India. Civil appeal no: 1949 of 2004. Supreme Court of India [Internet]. 2008 Jan 16 [cited 2010 Mar 16]. Available from: http://judis.nic.in/supremecourt/imgs.aspx
13. Ministry of law and justice, Government of India. The Dentists Act, 1948 (16 of 1948) [Internet]. New Delhi: Government of India; 1948 Mar 29 [cited 2010 Mar 16]. Available from: http://www.dciindia.org/dentistact_1948_pages/pdf_file/DENTISTSACT1948.pdf
14. White SC, Pharach MJ. Radiation protection, oral radiology, principles and interpretation. In: Richards AG, editor. *Radiation physics*. Mosby;2000. p. 32
15. British Dental Association. Advice sheet B1. Ethics in Dentistry. London: Br Dental Assoc;1995;49:53.
16. Originating Council, Council on clinical affairs. Guideline on informed consent , Clinical guidelines [Internet]. American Academy of Pediatric Dentistry; 2005 [revised 2009, cited 2010 Mar 16]. Available from: http://www.aapd.org/media/Policies_Guidelines/G_Informed%20Consent.pdf
17. Adewumi A, Hector MP, King JM. Children and informed consent: A study of Children's perceptions and involvement in consent to dental treatment. *Br Dent J*. 2001;191(5):256-9
18. Bansal Y S, Singh D. Medico-legal aspects of informed consent. *Ind J Forensic Med Toxicology*. 2007;1:19-23.
19. Bal A. Informed consent legal and ethical aspects. *Issues Med Ethics*[Internet].1999 Apr-Jun [cited 2010 Mar 10];7(2):56-7. Available from: http://www.ijme.in/072mi056.html

COMMENTS

Medical negligence: need for balanced approach

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A well researched and authoritative judgment of the Supreme Court delivered on February 10, 2010 (1) attempted to circumscribe the scope of criminal liability for negligence by doctors and hospitals. The law of professional negligence, especially in the case of doctors, has been formulated in such a way as to eliminate fear and anxiety about legal consequences while making professional judgements during diagnosis and treatment. The decision reiterated the principles laid down in an earlier judgment (2) and restrained the tendency to criminally prosecute doctors for a simple lack of care or an error of judgment or an accident which, the Court declared, is not proof of negligence on the part of a medical professional. So long as a doctor follows a practice acceptable to the medical profession of that day, he or she cannot be held liable for negligence merely because a better alternative course or method of treatment was also available or simply because a more skilled doctor would not have chosen to follow or resort to that practice or procedure which the accused doctor followed. A highly skilled professional may be possessed of better qualities, but that cannot be made the basis or the yardstick for judging the performance of a professional proceeded against on indictment of negligence, said the Court.

The standard of care in criminal negligence was formulated in the following terms:

> To prosecute a medical professional for negligence under criminal law it must be shown that the accused did something or failed to do something which, in the given facts and circumstances, no medical professional in his ordinary senses and prudence would have done or failed to do. The hazard taken by the accused doctor should be of such a nature that the injury which resulted was most likely imminent.

There is reason for the medical world to be happy with this judgment as they sometimes feel threatened by police and prosecution in the course of discharging their professional functions.

The case under review involved an operation done in a private hospital in Delhi on a man diagnosed as having a malignant abdominal tumour. During the surgery, his pancreas was injured and a second surgery was done to control the flow of fluids. He was discharged carrying two bags on his body, with advice to change the dressing periodically. The patient suffered severe pain and agony and was treated at the All India Institute of Medical Sciences for a pancreatic fistula. He was readmitted, to another hospital, where he was diagnosed as having post operative complications of adrenoloctomy and gluteal abscess. The patient vomited while convalescing and was taken to hospital where he died on account of pyogenic meningitis.

When the complaint in the National Consumer Commission failed, the wife of the deceased approached the Supreme Court alleging criminal negligence on the part of the doctors (and the hospital) who performed the operation, stating that they injured the pancreas, leading to the complication resulting in death. The charge was of negligent murder under section 304-A of the Indian Penal Code. The appellants contended that the doctors lacked the kind of skill required to undertake such a complicated operation. They said the "anterior approach" adopted to remove the left adrenal tumour was not the standard one and the "posterior approach" should have been adopted.

The respondents in their submission to the Court argued that the anterior approach was preferred over the posterior one in cases of suspected cancer. This submission was supported by an expert witness as well. The respondents argued that merely because a complication had ensued, it did not mean that the doctors or the hospital was guilty of negligence. The law of negligence has to be applied according to the facts of each case and not by any general rule for all occasions.

The Court in its judgment examined the law of negligence as applied to professionals, distinguished the nature of proof required for civil and criminal negligence and evolved certain tests to decide the liability or otherwise of doctors in an action for negligence.

Negligence: civil and criminal

Negligence is the breach of a general duty of care which one owes to another in one's interaction with others. In civilised societies, human conduct is regulated by ordinary prudence expected of reasonable human beings. The duty of care is that of reasonable men in society. Doing something or refraining from doing something is part of that duty of care which varies from situation to situation and from time to time. The standard of reasonableness depends on the facts and circumstances of each case. Hence the law is not codified and is left to be evolved by judicial interpretation and common practice.

Apart from negligence per se, negligence can manifest itself by way of active and passive negligence, concurrent and continuing negligence, civil and criminal negligence, etc. Gross negligence, which is rash, reckless and hazardous in nature, often invites criminal liability as there is an element of *mens rea* or wilfulness involved in such acts. Such grossly negligent conduct resulting in death is what is made punishable as negligent homicide under section 304-A of the Indian Penal Code. Even when reckless conduct resulting in death is made a criminal offence, the penal code has provided exceptions to liability whenever the act is not intended to cause death and is done with consent in good faith for the person's benefit. Similarly, an act done in good faith for the benefit of a person even without his or her consent is protected by the penal code (sections 88 and 92 IPC). Thus perceived, criminal negligence is supposed to apply in extreme cases of rash and reckless conduct which no person with reasonable prudence would have hazarded in the circumstances.

Another point of distinction between civil and criminal negligence is on the point of evidence, the burden of proof and the application of the benefit of doubt. In civil proceedings all that is required to prove negligence is a preponderance of probabilities without the defendant being necessarily entitled to the benefit of doubt whereas, in criminal proceedings for negligence, the persuasion of guilt must be near conclusive beyond all reasonable doubt, the benefit of doubt being given to the accused.

Standard of proof in medical negligence

In the law on negligence, professionals are included in the category of persons professing some special knowledge and skills. A person who holds himself out as a medical practitioner and gives medical advice or treatment implicitly undertakes that he is possessed of the knowledge and skills necessary for the purpose. A breach of that duty of care in deciding what treatment to give and how, resulting in injury or harm, will entail an action for negligence. The standard of care expected of medical personnel is that prescribed by the profession or that accepted by a reasonable body of medical men skilled in that particular art. Of course, a physician does not assure the patient of full recovery in every case. A surgeon cannot and does not guarantee that the result of surgery will invariably be beneficial, much less to the extent of 100% for the person operated on. The only assurance which such a professional can give or can be understood to have given by implication is that he is possessed of the requisite skill in that branch of the profession which he is practising and while undertaking the task entrusted to him he would be exercising his skill with reasonable competence.

Applying the above test, a professional may be held liable for negligence on one of two findings: either he did not possess the requisite skill which he professed to have possessed, or he did not exercise, with reasonable competence in the given case, the skill which he did possess. The standard to be applied is that of an ordinary competent person exercising ordinary skill in that profession. It is not necessary for every professional to possess the highest level of expertise in that branch in which he practises. The competence of the defendant for fixing liability is to be judged by the lowest standard that would be regarded as acceptable by the profession. In the realm of diagnosis and treatment there is scope for genuine difference of opinion. So long as it can be found that the procedure which was in fact adopted was one which was acceptable to medical science as on that date, the medical practitioner cannot be held negligent merely because he chose to follow one procedure and not another and the result was a failure.

A case of occupational negligence is different from one of professional negligence. A simple lack of care or an error of judgment is not proof of negligence on the part of a medical professional. It is not possible for every professional to possess the highest level of expertise or skills in that branch which he practises. A highly skilled professional may be possessed of better qualities, but that cannot be made the basis or the yardstick for judging the performance of the professional proceeded against on indictment of negligence. The medical professional is often called upon to adopt a procedure which involves a higher element of risk, but which he honestly believes will provide greater chances of success for the patient than a procedure involving less risk but with higher chances of failure. Just because a professional looking to the gravity of illness has taken a higher element of risk to redeem the patient from his suffering but did not yield the desired result may not amount to negligence.

In short, to prosecute a medical professional for negligence under criminal law it must be shown that the accused did something, or failed to do something, which in the given facts and circumstances no medical professional in his ordinary senses and prudence would have done or failed to do. By such a categorical articulation of the law of criminal negligence, the Supreme Court has provided the desired protection to medical practitioners to practise their profession without fear of harassment or humiliation while ensuring the legitimate interests of patients. The Court added:

> ...it is the bounden duty of the civil society to ensure that the medical professionals are not unnecessarily harassed by complainants who use the criminal process as a tool for pressurizing the medical professionals and hospitals for extracting uncalled for compensation. It would not be conducive to the efficiency of the medical profession, if a doctor is to administer medicine with a halter around his neck.

This is a bold statement from the apex court which is bound to raise the comfort level of medical practitioners particularly against criminal prosecutions.

References

1. Supreme Court of India. Judgments, the judgment information system of India. Civil appeal no.1385 of 2001 Kusum Sharma & Ors v. Batra Hospital & Medical Research Centre & Ors. Supreme Court of India[Internet]. 2010 Feb 10 [cited 2010 Mar 15]. Available from: http://judis.nic.in/supremecourt/chejudis.asp
2. Supreme Court of India. Judgments, the judgment information system of India. Appeal (crl.) 144-145 of 2004 Jacob Mathew Vs. State of Punjab & Anr. Supreme Court of India[Internet]. 2005 Aug 5 [cited 2010 Mar 15]. Available from: http://judis.nic.in/supremecourt/chejudis.asp

Patent dispute: Delhi High Court gives a boost to access to affordable medicines

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Abstract

The Delhi High Court has rejected the petition filed by Bayer Corporation seeking to stop the Drugs Controller of India (DCGI) from registering a generic version of a patented cancer drug. The case was filed in 2008 by Bayer to try and introduce "patent linkage", which involves linking the registration (marketing approval) of drugs with their patent status. If Bayer's plea for "patent linkage" had been accepted by the court, it would have undermined public health safeguards contained in India's patent legislation. This comment discusses the Bayer case in the context of efforts by multinational pharmaceutical companies to introduce barriers to generic competition, the only proven means of reducing the prices of medicines to make them affordable to those in need. Bayer has filed an appeal in the Supreme Court, indicating that it does not intend to give up.

India is home to a large pharmaceutical generic industry that in addition to meeting domestic needs also supplies the developing world. However, its domestic production of essential medicines is constantly under threat – both from intellectual property norms adopted in trade agreements and from patent disputes that are being brought against the government of India by multinational pharmaceutical companies.

In a positive development, the Division Bench of the Delhi High Court stopped the German pharmaceutical company Bayer Corporation's latest attempt to introduce new "patent policing measures" to prevent generic competition in India. By ruling against Bayer on February 9, 2010, the Delhi High Court refused to undermine legal safeguards in India's patent law that help ensure access to more affordable essential medicines for patients in India and other developing countries. However, the battle is by no means over. Bayer has filed an appeal against the decision in the Supreme Court (1).

Background

Generic competition is the only proven means of reducing the prices of medicines to more affordable levels. AIDS and cancer treatment are an important illustration of the benefits of encouraging generic production. Currently the majority of people living with HIV on treatment in low- and middle-income countries use generic antiretroviral drugs manufactured mostly from India (2). It was only with the arrival of generic anti-retrovirals produced by Indian companies on the market in 2001 that prices started to reduce significantly – from $10,439 to $350 per patient per year for first-line AIDS treatment.

The first fixed dose combination of stavudine/ lamivudine/ nevirapine was developed by Cipla and went on to become instrumental in rolling out antiretroviral therapy in Africa, Latin America and Asia and other developing countries including India. Today, it is available for as little as US$80 per patient per year – 1/130th of the price demanded by multinational pharmaceutical companies in 2001. With continued generic production, the price of improved first-line AIDS treatment (the three-in-one fixed-dose combination of tenofovir/ lamivudine/ efavirenz) has also dropped considerably over the last two years (43% reduction) to US$ 243 per patient per year (3).

Similarly, the generic production, by Indian drug manufacturers, of imatinib, a crucial cancer drug essential in prolonging the life of patients suffering from chronic myeloid leukaemia (CML) played a crucial role in significantly increasing the access of cancer patients to this drug. The drug is considered to be the first line of treatment for CML, fights cancer cells without being toxic to healthy cells, and has to be taken lifelong. In addition, it is now being tested for treating other forms of cancer. The generic version of imatinib is priced at less than one tenth of the price of the originator at approximately Rs 8,000 per patient per month, compared to Novartis' price of approximately Rs 1,20,000 per patient per month.

That is because, until recently, India did not grant patents on medicines (4), which allowed Indian generic manufacturers to compete with multinational pharmaceutical companies and with each other to produce lower-priced generic versions of drugs patented in other countries. This sort of generic competition among multiple producers is what made the cost of AIDS medicines fall dramatically and helped facilitate the scale-up of antiretroviral therapy to millions living with HIV in the developing world.

Patents in India threaten a key source of affordable medicines

However, India is drying up as a source of affordable versions of newer and future medicines. This is due to amendments made to India's patent law in 2005 (5), when the country was required to begin reviewing pharmaceutical product patents according to its international obligations under the World Trade Organization (WTO) Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS).

Patenting of medicines in India could mean that Indian manufacturers will no longer be able to produce cheaper versions of newer medicines. Precisely such newer drugs are crucial, for example, for the treatment of HIV/AIDS, hepatitis C, cancer and other diseases.

Fortunately, when the Indian Parliament amended its patent law in 2005, an effort was made to find a balance between the intellectual property rights of pharmaceutical companies and the need to protect public health, ensure supply to national treatment programmes and make drugs as affordable as possible.

While section 3(d) of the amended Indian Patent Act, 2005, was inserted to safeguard against the granting of frivolous patents on trivial improvements of known molecules, there was also a great concern about those new drugs (new chemical entities) invented after 1995 that would be patented under Indian law. To this end, key safeguards in India's amended patent law such as the "early working exception" (section 107 A) and the provisions on compulsory licensing (sections 84, 92, 92A and 100) were also included in the law to ensure generic production in the event that patent holders failed to fulfill their duty to make patented medicines available and affordable to patients.

Now both the early working exception and compulsory licensing provisions that create mechanisms for generic competition are at considerable risk because of a pending court case filed by Bayer against the Union of India and the Drugs Controller General of India (DCGI).

The Bayer case against the Union of India

After the 2005 amendment of the Indian patent law, multinational pharmaceutical companies have been pushing India's drug regulator, the DCGI, to implement patent linkage in India.

Establishing a link between patent status on the one hand and the registration (also known as marketing approval) of a medicine on the other hand means that a national drug regulatory authority is required to withhold marketing approval to a generic version of a patented drug, regardless of whether the patent granted is valid or not.

A petition was filed by Bayer in 2008, seeking to stop the DCGI from granting marketing approval to a generic version of a patented cancer drug. The case was filed before the Delhi High Court on the grounds that the DCGI had entertained the application for granting marketing approval to a generic version of the anti-cancer drug sorafenib tosylate, for which Bayer has obtained a patent (IN215758) in India. (Sorafenib is a drug approved for the treatment of renal and liver cancer.)

By filing this case against the Indian government, Bayer seeks to ensure that Indian drug regulatory authorities do not register a cheaper generic version of a drug, if it is patented.

All medicines to be sold in the Indian market require prior marketing approval from the DCGI. If Bayer's demands in its case against the government of India are accepted, it will block the marketing approval of generic versions of patented medicines – even if the patent is wrongly granted or the approval is with the objective of applying for a compulsory license or entering the market once the patent has expired.

But a drug regulatory authority's role is to ensure that medicines marketed in a country are proved to be of quality, safe and effective: it delivers a necessary green light before a drug can be manufactured or marketed. Its role is not to deal with the patent status of the medicines, which is the role of a country's patent office.

Chronology of the Bayer case

The petition was first heard by a single judge bench of the Delhi High Court in 2009 and was dismissed as "vexatious and luxury litigation". Justice Ravindra Bhat rejected Bayer's petition seeking to prevent the DCGI from registering Cipla's version of sorafenib and made it clear that "Bayer's argument of inferring drug agencies' role in patent policing or enforcement is unacceptable."(6)

Bayer filed an appeal against the decision before the Division Bench of the Delhi High Court.

In a welcome move for access to medicines, this decision was upheld by the Division Bench in February 2010. In the words of the judges of the Division Bench,

> This Court concurs with the learned Single Judge that the scheme of both the Patents Act and the Drugs & Cosmetic Act are distinct and separate and that the attempt by the appellant Bayer to establish a linkage cannot be countenanced. If Bayer's argument were to be accepted, it would mean that instead of the validity of the patent being tested, if at all, either in revocation proceedings or by way of a counter-claim in infringement proceedings instituted by the patent holder, the DCGI will begin with the presumption that the patent granted in respect of the drug for which marketing approval is sought has been validly granted. (7)

But Bayer has now dragged the Indian drug regulator and the Indian government to the Supreme Court. It has filed a special leave petition against the decision of the Delhi High Court in the Supreme Court which was admitted for hearing on February 26, 2010.

Implications of the Delhi High Court decision

The Court's decision was very important because it stopped Bayer's attempt to introduce a new barrier to generic competition and ensured that different public health safeguards in India's patents law remain useable.

One safeguard in the patent law, known as the "Bolar" or "early working exception", allows a generic producer to manufacture a drug even when it is under patent and obtain marketing authorisation in advance, so that a generic can be put on the market as soon as the patent is invalidated or revoked, or expires. India's patent law allows manufacturers to do this without fear of facing an infringement suit.

A second safeguard is compulsory licensing. Compulsory licenses can be issued to generic producers if patented essential medicines are not available or affordable in India, or if other countries which lack production capacity order essential drugs

from India. But if Bayer had succeeded in introducing patent linkage in India, this could have blocked the marketing approval of generic medicines made under the terms of a compulsory license, thereby rendering the compulsory license useless.

These public health safeguards will become increasingly important as the effect of the newly introduced pharmaceutical product patent regime is felt in the country. The TRIPS Agreement made it mandatory for India to have a patent regime for medicines by 2005.

Five years after India revised its 1970 Patents Act, patent offices have granted product patents on several drugs, including medicines for HIV/AIDS, hepatitis C and cancer. The patented drugs are prohibitively expensive and in the absence of generic competitors will remain out of reach of patients.

On March 3, 2006, Roche proudly announced it was "becoming the first pharmaceutical company in India to receive a product patent under the new patent regime". The patent granted is on peginterferon alfa-2a, a new generation hepatitis C therapy. The cost of this therapy is prohibitively high – above Rs 12,000 for a single dose vial of 180 mg.

Patent linkage in other countries

Efforts to link registration (marketing approval) of drugs with their patent status are not new and have been pushed by the multinational pharmaceutical industry, its associations, and the United States. Several developing countries have been under pressure to introduce patent linkages. Chile, Morocco and Bahrain were made to accept TRIPS-plus provisions, including patent linkages, in the Free Trade Agreements that they signed with the US.

In 2006, Pfizer filed a case in the Philippines against the drug regulators (Bureau of Food and Drugs or BFAD) and a government-owned pharmaceutical company (PITC, Philippine International Trading Corporation) to prevent them from registering a generic version of a patented medicine. PITC had started the process of registering the generic version of amlodipine besylate with the BFAD by submitting samples imported from India so that it could obtain marketing approval (registration) and then promptly enter the market when Pfizer's Philippines patent on amlodipine besylate expired in June 2007. The drug is used to treat high blood pressure and is considerably cheaper (5 times) in India because of generic competition.

Subsequent to the above mentioned court case, the Philippines government eliminated patent linkage and intellectual property protection from the responsibilities of BFAD under a department of health administrative order, AO No 2005-0001. The order permits BFAD to consider and process applications for marketing approval of generic versions of medicines without the need to verify whether or not the pharmaceutical being submitted for registration is under patent (8).

The European Union does not implement patent linkage. The EU Directorate General for Competition has noted that "patent-linkage is considered unlawful under Regulation (EC) No 726/2004 and Directive (EC) No 2001/83" and has documented the widespread use of litigation (including that against drug regulators) in attempts to enforce patent linkages, much like Bayer's case in India (9). It is interesting that Bayer, a European company, is in court in India attempting to get rights that it does not even enjoy in Europe.

In the US, which has a patent linkage system, the use of the system by patent holders to delay generic entry has been recorded in detail by the US Federal Trade Commission (10). In addition, its Food and Drug Administration has officially stated that its resources would be better utilised in reviewing applications than in reviewing patent claims, in addition to the fact that it does not have the expertise to review patent information (11).

How companies use patent linkage to block generics: the case of fluconazole in Africa

Medecins Sans Frontieres (MSF) has documented a typical case of how patent linkage can affect access to medicines. An Indian generic manufacturer was refused marketing approval by the drug regulator in an African country for its generic version of fluconazole, a drug used to treat opportunistic infections associated with HIV. On investigation, MSF learnt that the grounds for this refusal was that the drug regulator had been informed by the originator pharmaceutical company that it had a patent on the drug in the country. The drug regulator had no legal obligation to refuse registration on such grounds, but it had been pressured to do so by the pharmaceutical company. Under further investigation, it was revealed that the originator pharmaceutical company's claim was false and that the patent had expired more than a year earlier. The drug regulator eventually retracted its decision, and allowed the registration of the Indian company's low-cost generic version of the drug (12).

World Health Organization's advice on the issue

In March 2006, the World Health Organization issued a briefing note on "access to medicines" in which it discussed the impact of TRIPS-plus provisions. This note states that patent linkages are problematic as drug regulators are likely not to possess the resources or manpower to check the patent status of medicines. Moreover they would lack the necessary expertise to assess whether a patent is valid or would be infringed and would thus be more likely to enforce all patents including invalid ones.

The Cancer Patients Aid Association intervenes to protect patients' interests

By filing this case against the Indian government, Bayer wants to set a legal precedent which will require the DCGI to block regulatory approval of affordable versions of patented medicines – even if the generic has been proved to be of quality, safe and effective. As discussed above, this will seriously undermine the use of provisions in Indian law that ensure that even patented medicines are available and affordable in India and other developing countries.

The Cancer Patients Aid Association had filed an intervention application in Bayer's case against the government of India in the Delhi High Court. It intends to continue defending patients' interests in the Supreme Court of India. At stake are patients' lives across the developing world.

References

1. Golikeri P. Supreme Court admits Bayer patent-linkage plea [Internet]. [place unknown]: DNA; 2010 Mar 2 [cited 2010 Mar 15]. Available from: http://www.dnaindia.com/money/report_supreme-court-admits-bayer-patent-linkage-plea_1354012
2. Medicins Sans Frontieres. Examples of the importance of India as the "Pharmacy of the Developing World",[Internet]. 2007 Jan. [cited 2010 Mar 15]. Available from: http://www.msfaccess.org/fileadmin/user_upload/medinnov_accesspatents/Overview%20Jan%202007%20FINAL.pdf
3. Campaign for Access to Essential Medicines. Untangling the web of antiretroviral price reductions: a pricing guide for the purchase of ARVs for developing countries [Internet]. Geneva: Medicins Sans Frontieres;2009 Jul [cited 2010 Mar 16]. Available from: http://www.msfaccess.org/fileadmin/user_upload/diseases/hiv-aids/09_28_UTWPricingGuide_IAS_LowRes_FINAL.pdf
4. WPO, World Intellectual Property Organisation [Internet]. Geneva: WPO. India Patents Act, 19/09/1970, No.39 ; 1970 Sep21[cited 2010 Mar 16]; 68p. Available from: http://www.wipo.int/clea/en/text_pdf.jsp?lang=EN&id=2393
5. Ministry of Law and Justice. Patents (Amendment) Act, 2005[Internet]. New Delhi: Government of India; 2005 Apr 5[cited 2010 Mar 16]. Available from: http://www.patentoffice.nic.in/ipr/patent/patent_2005.pdf
6. High Court of New Delhi. Bayer Corporation & Ors vs. Union of India & Ors. WP(C) No.7833/2008 [Internet]. New Delhi: High Court of New Delhi; 2009 Aug 18 [cited 2010 Mar 16]. Available from: http://lobis.nic.in/dhc/SRB/judgement/18-08-2009/SRB18082009MATC78332008.pdf
7. High Court of New Delhi. Bayer Corporation & Ors vs. Union of India & Ors. LPA 443/2009 [Internet]. New Delhi: High Court of New Delhi; 2010 Feb 9 [cited 2010 Mar 16]. Available from: http://www.lawyerscollective.org/sites/default/files/Bayer_v._Union_of_India_[Appeal]_0.pdf
8. Love J. PhRMA's aggressive Special 301 submission for the Philippines [Internet]. Washington: Knowledge Ecology International; 2009 Mar 12 [cited 2010 Mar 16]. Available from: http://keionline.org/blogs/2009/03/12/phrma-philippines-301
9. European Commission Competition Directorate General staff. Pharmaceutical Sector Inquiry - Preliminary Report [Internet]. Brussels: European Commission; 2008 Nov 28 [cited 2010 Mar 16]. Available from: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf
10. United States Federal Trade Commision. Generic drug entry prior to patent expiration: an FTC study [Internet]. Washington: Federal Trade Commission; 2002 Jul [cited 2010 Mar 16]. Available from: http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf
11. Waxman HA. Trade agreements and access to medicines under the Bush administration [Internet]. United States House of Representatives Committee on Government Reform - Minority Staff, Special Investigations Division. 2005 Jun [cited 2010 Mar 16]. Available from: http://www.twnside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/TradeAgreementsandAccesstoMedicationsUnderTheBushAdmini.pdf
12. Medicins Sans Frontieres. Access to medicines at risk across the globe: What to watch out for in free trade agreements with the United States [Internet]. Geneva: Medicins Sans Frontieres; 2004 May [cited 2010 Mar 16]. Available from: http://www.twnside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/AccessToMedicinesAtRiskAcrossTheGlobe-WhatToWatchOutForMSF.pdf

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Informed consent is a moral imperative

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Introduction

In their paper (1), Kotrashetti and colleagues present the results of a survey pertaining to the knowledge and practice of informed consent (IC) by dental practitioners in an Indian city. This is an important topic because although IC is considered to be an essential component of ethical healthcare delivery, medical as well as dental, very little information exists about its application in developing countries. Even less is known about this in the field of dentistry in the South Asian region. We lack systematic inquiry into existing IC practices among healthcare-related professionals to help us ascertain whether the process is being used to fulfil its primary objective to empower patients, or whether it is merely a mechanical exercise undertaken as part of hospital policy. Without this information it is not possible either to understand the nature and extent of the problem or to formulate the corrective steps that may be necessary.

The authors have attempted the first step to address this deficiency even though their study suffers from limitations some of which the authors acknowledge in their article. The small number of subjects (44 in all) limited to an urban locale, coupled with the wide range of experience of survey respondents from fresh dental graduates to seasoned practitioners with 29 years of practice, make it difficult to extrapolate existing IC practices within the wider Indian dental community from these results. Their data may also not be reflective of dental practices in rural areas and communities with lower literacy rates, and where the situation regarding IC may be even less satisfactory. Nevertheless, the survey does serve to provide indicators, if not a complete picture, of prevailing dental practices many of which echo the medical practices of physicians in this part of the world.

This study reveals a striking ignorance among the dental practitioners surveyed of the essential requirements of the informed consent process and the moral basis on which these rest. Although a large number of practitioners do report obtaining either verbal or written IC, a majority (68 - 77%) failed to explain or even mention the side effects and risks connected to diagnostic and therapeutic procedures. In addition, with only some 14% of dentists obtaining written consent in the local language (86% did so in English), and IC reportedly sometimes taken from relatives, patient comprehension of the proposed interventions, let alone meaningful participation in the decision making process, is highly unlikely. In the absence of the "informed" component of IC, the process seems to have been no more than an empty, mechanical exercise.

Our main contention with the authors, however, and on which we will focus in our commentary, is their almost exclusive focus on the IC document as a legal tool rather than informed consent as a moral process, and a view that the primary importance of this "document" is to safeguard dentists against litigation rather than a "process" that empowers and helps patients to make decisions. We will also comment briefly on India's Consumer Protection Act (1995) as extended to healthcare-related professionals, the prism through which the authors perceive the importance of the IC, but which in our opinion does not provide a safety net to the group of patients who need it the most in societies such as ours.

Informed consent a legal instrument, patients as "consumers"

Towards the beginning of their paper, Kotrashetti and colleagues state, correctly, that "Dentists' obligation to obtain the patient's consent to treatment is based on ethical principles, legal requirements and professional policies." In another section the authors also note that the "best arguments in favour of fully informed consent are moral rather than legal." But curiously, the authors' focus remains exclusively on legal rather than moral arguments in support of IC, and a view that the IC is a tool to avoid lawsuits registered against practitioners under the Indian Consumer Protection Act. Accordingly their advice to dentists is to "improve their knowledge regarding legal jurisprudence and legal medicine to avoid any litigation." In their emphasis on the legal, to the exclusion of the moral, they transform IC from a "patient centred" process as it is within ethical as well as legal contexts, to a "physician/dentist centred" tool which it ought not to be.

We agree with the authors that properly documented informed consent is now a universally accepted legal requirement in healthcare delivery and failure to comply, particularly in the case of major medical/dental interventions, can open the door to litigation. However, we differ with their belief that the IC document can provide a foolproof safeguard against civil suits. In reality, practitioners can be and are cited for negligence even in the presence of a signed informed consent form and thorough documentation in medical charts. One has merely to consider the prevailing situation in the US where despite the most stringent IC and documentation practices, healthcare practitioners continue to face litigation compelling them to hold expensive lawsuit insurance policies. An unfortunate fallout of this has been an erosion of mutual trust, increasingly adversarial healthcare professional-patient relationships, and defensive medical and dental practices which reflect back as higher costs to patients through exorbitant health insurance payments.

Regarding the Consumer Protection Act (CPA) of India,

now extended to cover interactions between patients and healthcare providers through a ruling of the Supreme Court, it can certainly be beneficial for patients through its check on healthcare providers. By providing "teeth" to force professionals to respect the rights of patients we see it as a support (not an alternative) to professional ethics. But it seems to us that, as currently framed, the CPA comes with an unfortunate lacuna. Structured within the paradigm of rights of "consumers" its applicability is limited to "paying" patients and practitioners involved in private practice. It would seem to us that it is the "non-paying" patients who form the majority of those seeking healthcare in the public sectors in our part of the world, the poor and the disadvantaged, who most need the protection of the law. In contrast to the CPA, bioethics teaches that properly obtained IC is a moral obligation on the part of all healthcare professionals towards all patients irrespective of the latter's paying capabilities.

The notion of consumer protection laws is market driven. Its primary objective is to make consumers aware of their legal rights as equal partners within a consumer-service provider contract, and to provide legal recourse to consumers if they perceive violation of their rights. On the other hand, the ethics of healthcare rests on the internal morality of professionals and their duties in a fiduciary, rather than legal, relationship based on trust. The authors themselves note that the doctor-patient relationship in India is "predominantly governed by trust". It would seem to us that within the culture and socioeconomic realities of our countries, it is important to strengthen rather than attenuate this relationship in which the IC process, one based on respect for the dignity and the right of self determination by patients, serves as the pillar (2, 3).

In reality, by its very nature it is difficult to define the physician-patient relationship as a partnership between "equals". The interactions involve one party (the patient) suffering from an illness the cure for which lies in the hands of the other (the healthcare professional) who possesses the requisite knowledge and skill. Even in an individualistic, litigious society such as the US, the particular nature of such relationships was underlined in a California Supreme Court ruling, Cobbs v. Grant. Alluding to the concept of IC, the justices ruled that "patients are dependent upon their physicians for truthful information and must trust them (making the doctor-patient relationship a 'fiduciary' or trust relationship rather than an arms-length business relationship)." (4)

IC a moral imperative, professionals as "ethical agents"

In societies characterised by rampant poverty, low literacy rates, a general lack of awareness of rights, ineffective and often corrupt legal systems, we believe that it is even more important to emphasise the moral rather than the legal dimensions of informed consent. This rests on the ethical notion of respect for the patient which, as the authors note, is reflected in the Hippocratic Oath formulated centuries ago. In the case of IC in modern times this translates into a moral, not legal, foundation and this has been endorsed by a wide range of professional organisations (3, 5-7).

In our opinion, the authors' focus on the legal contract between the dentist as service provider and the patient as consumer also drives their suggestions that addressing deficiencies in the process of IC within the field of dentistry should come through legal education. They recommend a greater emphasis on "undergraduate and postgraduate training on legal jurisprudence and legal medicine" with the objective of "[protecting dentists] from civil litigation". Based on our own understanding of the raison d'etre of informed consent in healthcare delivery systems we differ with both the recommendation and the stated objective. Instead, we would suggest the introduction of bioethics education for dental students and practitioners with the objective of providing society with ethical professionals who understand their duty to respect patients and to assist them in the decision making process.

In their article the authors mention that the Dental Council of India passed a notification that 30 hours in the forensic odontology curriculum should be dedicated to education in both jurisprudence and ethics. We believe that this provides an excellent opportunity to focus on not just jurisprudence issues but also the ethical components of IC that speak to professional obligations and duties. In Pakistan, too, the Pakistan Medical and Dental Council provides substantial time in the medical curriculum to forensic medicine and toxicology and we have encouraged graduates from our postgraduate diploma programme in biomedical ethics (PGD) to utilise this time to teach bioethics (8). One of our PGD alumni, a forensic medicine physician, has successfully incorporated bioethics topics for medical students along with legal aspects of medicine in the time allocated to forensic medicine. Another graduate, an orthodontist, has teamed up with a colleague in behavioural sciences to introduce bioethics to dental students and reinforces classroom education with practical sessions in his clinics during direct patient encounters. He is the first in Pakistan to bring bioethics to dental students and we hope that this will serve as the catalyst for others to begin doing so too (9).

We do not wish to discount the protective role of laws, when they are applicable and accessible to all citizens, as external checks. However, we continue to believe that the best protection for patients remains ethical healthcare professionals through an internal professional morality. We have arrived at this conclusion following our own years of experience as practising physicians in a country with cultural norms, legal systems, and socioeconomic realities that are not too dissimilar to those in India.

References

1. Kotrashetti VS, Kale AD, Mamata H, Hallikeremath SR. Informed consent: a survey of general dental practitioners in Belgaum City. *Indian J Med Ethics*. 2010 Apr-Jun;7(2):90-4.
2. Annas GJ. Informed consent, cancer, and truth in prognosis. *N Engl J Med*. 1994 Jan 20;330(3):223-5.
3. General Medical Council. Seeking patients' consent: the ethical

considerations [Internet]. London: General Medical Council;1998 Nov [cited 2010 Mar 15]. Available from: http://www.gmc-uk.org/Seeking_patients_consent_The_ethical_considerations.pdf_25417085.pdf
4. Cobbs v. Grant, 8 Cal.3d 229, 104 Cal. Rptr. 505, 502 P.2d 1 (1972) [cited 2010 Mar 15]. Available from: http://www.ache.org/pubs/hap_companion/Wing/ch.%208-10/cobbsgrant.pdf
5. British Medical Association. *Report of the consent working party: incorporating consent tool kit*. London: BMA, 2001.
6. Department of Health. Reference guide to consent for examination or treatment [Internet]. London: Department of Health Crown copyright 2010; 2001Apr 6 [updated 2009, cited 2010 Mar15]. Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006757
7. Royal College of Surgeons. *The surgeons' duty of care*. London: RCSENG - Professional Standards and Regulation;1997.
8. Pakistan Medical and Dental Council. Regulations for the Degree of Bachelor of Medicine and Bachelor of Surgery (MBBS)[Internet]. Islamabad: Pakistan Medical and Dental Council; c2006 [cited 2010 Mar 11]. Available from: http://www.pmdc.org.pk/Regulation/RegulationsForMBBS/tabid/114/Default.aspx
9. Jafarey A. CBEC graduates: success stories. *Bioethics Links*. 2008 Jun;4(1):6-7.

Issues related to non-heart-beating organ donation

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Abstract

Since the enactment of the Transplantation of Human Organs Act, 1994, the brain dead person remains the primary source of organs legally obtained for transplantation purposes in India. With the increasing demand of organs for transplantation purposes, non-heart-beating donors can help meet this need. However, the process of retrieving organs in non-heart-beating donors is more complex and raises ethical and legal as well as medical issues. This essay discusses some of these concerns.

Since the enactment of the Transplantation of Human Organs Act, 1994, the brain dead person remains the primary source of organs legally obtained for transplantation purposes in India. However, the demand for organs always been high and continues to grow, and potential donors are few, so the supply of organs remains limited. Therefore, alternative sources have been sought, including the retrieval of organs from individuals declared dead according to cardiopulmonary criteria, that is when cardiac function ceases. Such individuals are known as non-heart-beating donors (NHBD) (1).

The NHBD is defined as one who sustains cardio-respiratory arrest and whose organs are retrieved after irreversible cessation of cardiac and respiratory function (2). In contrast, a conventional heart-beating donor is one who sustains irreversible brain insult and whose death is based on neurological criteria. The concept of NHBD is not new. When organ transplant programmes first started, all organs were retrieved from patients immediately after cardiorespiratory arrest (3). However, with the recognition of brain death, the use of NHBD has decreased considerably.

The modified Maastricht classification of NHBD identified five categories of potential donors. A more practical classification may be "uncontrolled" or "controlled" NHBD depending on whether cardiopulmonary function ceases spontaneously or after medical therapy is withdrawn. Donors from categories 1, 2 and 5 have been classified as uncontrolled donors whereas those in categories 3 and 4 are described as controlled donors (3).

The modified Maastricht classification of non-heart beating donors	
Category	**Type of potential donors**
I	Dead on arrival
II	Unsuccessful resuscitation
III	Awaiting cardiac arrest
IV	Cardiac arrest in a brainstem dead donor
V	Unexpected cardiac arrest in a critically ill patient

It is proposed that NHBD could contribute to an increase in the number of solid organ and tissue donation for transplantation purposes. The solid organs that are suitable for transplantation purposes include the kidneys, liver, lungs and pancreas, and tissues such as corneas, bone marrow and pancreatic islet cells (1, 3-6). The results of transplantation of kidneys are encouraging (7, 8) and the recipients of NHBD kidneys have a five-year survival that is the same as those who received a conventional heart-beating donor kidney (2). It is estimated that the introduction of an NHBD programme would have the greatest impact on the cadaveric organ pool compared to cadaveric donations (9). However, the retrieval of organs for transplantation is more complex in NHBD due to time constraints, medical concerns about organ damage owing to "warm ischaemia" and the ethical and legal issues involved therein.

Ethical issues

The procedure of retrieval organs in NHBD raises ethical concerns and these issues deserve attention. In these donors, to minimise the organ damage due to warm ischaemia, some centres use postmortem *in situ* preservation. There are data showing that *in situ* preservation can lengthen the permissible period between the determination of death and organ retrieval from one hour up to six hours (1). Similarly postmortem interventions such as putting the dead on ventilation and cardiopulmonary bypass are done in an attempt to preserve the organs. At times, these procedures are done without the knowledge and consent of family members. The intention of these procedures is to prevent warm ischaemia and organ damage but they raise ethical concerns. Conducting an invasive procedure without the consent of the patient or relatives or, alternatively, failing to act in the patient's best interest, amounts to assault. It might be argued that it is unclear whether interference with a corpse without legitimate authority would be considered a crime, there being no property in a body. However, the act can be construed as indignity if done with intention (section 297 of the Indian Penal Code, IPC). Similarly the deceased's relative may file a claim for mental trauma, particularly if the interference has been witnessed (10).

The use of controlled donors allows organ retrieval to be planned, warm ischaemic time to be minimised and the usage of organs for transplant optimised (3). But ascertaining death is important. Questions are often raised regarding the certification of death. The NHBD protocol rests upon the "dead-donor rule": patients must be dead – according to a specified definition – before organ retrieval, and death must be neither caused nor hastened by retrieval (11). To

declare a person dead by cardiopulmonary criteria, it must be established that circulation and respiration have ceased and their function will not resume. However, these functions may reverse spontaneously (auto resuscitation) if they were due to a disturbance of the cardiac rhythm, or they may be reversed by interventional resuscitation (10). Menikoff (12) has criticised the definition of death in NHBD programmes, noting that the cessation of cardiopulmonary activity is not irreversibly lost as long as there is a possibility of its being restored by resuscitation. Supporters of NHBD argue that if a specified duration of absent cardiac activity is not associated with spontaneous "auto resuscitation", then the absence of activity can be considered irreversible (1). The Maastricht workshop considered that 10 minutes without perfusion of the brain was necessary before any intervention geared towards organ retrieval. The Institute of Medicine recommends a five-minute observation period. The Pittsburgh protocol sanctions surgical retrieval of organs at two minutes after asystole (10). Despite the premise of certainty in determining irreversible death, it is worrisome that centres cannot agree to adopt a common standard (1).

Second, concerns are raised about the methods used to decrease warm ischaemic time. NHBD protocols commonly use heparin to prevent intravascular clotting and pentolamine to maintain vascular perfusion. These agents are given when the patients are alive. Neither of these medications can be considered for use for the benefit of the patient. As such, would their use not seem to violate the ethical responsibility to the still alive patient?

The practice of cannulation of the patient, prior to withdrawal of care, for the purpose of preservative perfusion is also not acceptable. It could be argued that interventions of this nature would require an escalation of analgesic and sedative or anaesthetic agents with the potential for destabilisation of the cardiovascular system, thereby precipitating, or priming for, a more rapid death. The process too could not be contained within the principles of "double-effect". That principle holds that an action that produces a good effect and a bad effect might be permissible if the good effect is intended and the bad effect is merely foreseen but unintended. Cannulation might have been permissible for giving medicines; here it is done to preserve the organs by injecting a preservative perfusion. It does not benefit the patient, so any foreseen and harmful effect not ethically permissible.

Another question is related to the withdrawal of active treatment. In the United Kingdom, the decision to withdraw treatment is made in accordance with the guidelines of the Intensive Care Society, the British Medical Association and the General Medical Council. In the Indian context, explicit withdrawal of active treatment is a relatively new phenomenon. No national guidelines are available and there is a lack of education in bioethics and a paucity of case law in India (13) on this subject. While applying these programmes in India, uniform national guidelines are needed. Moreover, it is important that withdrawal of active treatment should be according to a protocol and should not differ when organ donation is being considered. While taking such decisions, the benefit of the patient should be paramount. There must be an absolute prohibition on active euthanasia. Similarly, if the withdrawal of active treatment is being considered for harvesting organs, it should be mandatory that the transplant team is not involved in any decision to withdraw treatment. This ensures that the interest of the dying patient remains paramount. The decision to withdraw treatment should be communicated to the family by the clinician and should be documented in the clinical notes.

Medicolegal issues

In India, the Transplantation of Human Organs Act, 1994, provides for the regulation removal, storage and transplantation of human organs for therapeutic purposes, and for the prevention of commercial dealings in human organs. It gives legal sanction to cadaveric organ donation. According to this Act, a deceased person means a person in whom permanent disappearance of all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense, at any time after live birth has taken place (14). According to section 3(3) of the Act, in the absence of a living will, the person in lawful possession of the body may make the decision to donate the organs. The medical team should use only those organs for which consent has been given, and the remaining tissues and organs should be treated with respect (15).

Medicolegal cases are a valuable source for organ retrieval for transplantation purposes. However, section 4(1) of the Act restricts the retrieval of organs. According to this section,

> ...removal of organs [is] not to be authorized, if the person required to grant such facilities, or empowered to give such authority, has reason to believe that an inquest may be required to be held in relation to such body in pursuance of the provisions of any law for the time being in force.

Therefore, without proper authority, the removal of organs before or at autopsy may attract action amounting to causing indignity to a human corpse under section 297 of the IPC against the doctors involved in the organ retrieval, or the autopsy surgeon. After the death of a person, in medicolegal cases, the body is handed over to the police for further formalities and investigation. The police take possession of the dead body. When a body is in police custody, no intervention of any kind can be done on the dead body without obtaining proper written consent, permission, or a no objection certificate from the police. Any intervention without permission may amount to destruction of evidence or "disappearance of evidence" as mentioned under sections 201 and 202 of the IPC.

It is also stated in section 6 of the Act that in cases where the body has to be sent for medico-legal autopsy, a person deemed competent under this Act may authorise the removal of certain organs from the body if he or she has reason to believe that such organs would not be required for the purpose for which the autopsy was being conducted, provided that he is satisfied that the deceased person has not expressed an objection to

any of his organs being used for therapeutic purposes after death. The competent authority under this Act is not clearly defined. The authority seems to have been vested in the autopsy surgeon who is in lawful possession of the dead body for postmortem examination (16).

The All India Institute of Medical Sciences, New Delhi, has framed guidelines to carry out the retrieval of organs in medicolegal cases without violating any of the procedures prescribed under the law. The advantage of these guidelines is that the procedure does not hamper the functioning of the investigating officer, the autopsy surgeon or the courts of law (16). However, these guidelines are formed for organ retrieval in brain-stem death cases. Similar, uniform guidelines are needed for an NHBD programme. The presence of such guidelines will help retrieve organs from medicolegal cases after observing legal procedures and without violating existing laws.

Conclusion

In conclusion, it can be stated that non-heart-beating donors can to some extent help meet the increasing demand for organs for transplantation purposes. In order to implement such a programme in India, a comprehensive discussion should be had to address the ethical, medical and legal issues involved therein and arrive at a clear policy. An NHBD programme should be implemented on a need basis and not on a demand and supply basis; in the medical field, especially when organs are being retrieved, the programme should be implemented for the benefit of the patient according to need and priority.

References

1. Doig CJ, Rocker G. Retrieving organs from non-heart-beating organ donors: a review of medical and ethical issues. *Can J Anesth*. 2003 Dec;50:1069-76.
2. Lacroix JD, Mahoney JE, Knoll GA. Renal transplantation using non-heart-beating donors: a potential solution to the organ donor shortage in Canada. *Can J Surg*. 2004 Feb;47(1):10-4.
3. Ridley S, Bonner S, Bray K, Falvey S, Mackay J, Manara A. Intensive Care Society's Working Group on Organ and Tissue Donation. UK guidance for non-heart-beating donation. *Br J Anaesth*. 2005 Nov; 95(5):592-5.
4. Steen S, Sjoberg T, Pierre L, Liao Q, Eriksson L, Algotsson L. Transplantation of lungs from a non-heart-beating donor. *Lancet*. 2001 Mar 17; 357(9259): 825-9.
5. Weber M, Dindo D, Demartines N, Ambuhl PM, Clavien PA. Kidney transplantation from donors without a heart-beat. *N Engl J Med*. 2002 Jul 25;347(4):248-55.
6. Clayton HA, Swift SM, Turner JM, James RF, Bell PR. Non-heart-beating organ donors. A potential source of islets for transplantation? *Transplantation*. 2000 May 27; 69(10):2094-8.
7. Goel MC. Outcome of transplantation of non-heart-beating donor kidneys. *Indian J Urol*. 1996;12:92.
8. Mani M K. Development of cadaver renal transplantation in India. *Nephrology*. 2002;7(4):177-82.
9. Taylor PE, Field PA, Kneteman NM. Non-heart-beating donors: one answer to the organ shortage. *Transplant Proc.* 1996 Feb;28(1): 201.
10. Bell MD. Non-heart beating organ donation: old procurement strategy _ new ethical problems. *J Med Ethics.* 2003 Jun;29(3):176-81.
11. Zamperetti N, Bellomo R, Ronco C. Defining death in non-heart beating organ donors. *J Med Ethics*. 2003 Jun 29(3):182-5.
12. Menikoff J. Doubts about death: the silence of the Institute of Medicine. *J Law Med Ethics*. 1998 Summer;26(2):157-65.
13. Puri VK. End-of-life issues for a modern India - lessons learnt in the West. *Indian J Crit Care Med*. 2005 Apr-Jun;9(2):81-5.
14. Ministry of Law, Justice and Company Affairs, Government of India. The Transplantation of Human Organs Act 1994 No.42 of 1994) [Internet]. New Delhi: Government of India; 1994 [cited 2010 Mar 15]. Available from: http://india.gov.in/allimpfrms/allacts/2606.pdf
15. Indian Council of Medical Research. *Ethical guidelines for biomedical research on human participants*. New Delhi:ICMR;2006.
16. Dogra TD, Lalwani S, Vij A, Vyas M, Venugopal P. Organ retrieval in medicolegal cases. *J Acad Hosp Admin*[Internet]. 2004[cited 2010 Mar 11];16(2):7-12. Available from: http://www.indmedica.com/journals.php?journalid=6&issueid=30&articleid=350&action=article

Are we ready for non-heart-beating organ donation in India?

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With the success of organ transplantation as an effective modality of treating end stage disease of various organs, increasing numbers of organ transplants are being performed all over the world. However, this procedure requires a "donor" pool of either "living" or "cadaveric" donors. Since this pool is limited, the gap between "demand" and supply is widening. In the context of organ donation "cadaveric" donation has largely meant "brain dead" or "heart beating" donors. In the last four decades, the concept of "brain death" – a state in which the brain is irreversibly damaged but the heart is beating – has been legalised and accepted in many countries of the world. However, in spite of the legal sanction as well as sustained campaigning, the number of such donors is limited.

In an effort to increase the donor pool, other strategies are now being implemented. The first area involved improving the consent rate for brain dead donors. This includes "donor cards" which citizens sign and keep during their lifetimes; "required request" where it is mandatory for a doctor to ask the relatives of a brain dead patient about organ donation, and, in some countries, "presumed consent" which grants authority to doctors to remove organs from brain dead individuals whenever usable organs are available, in the absence of objection from the deceased in his or her lifetime, or the family members. The ethical and social dimensions of presumed consent have recently been discussed in the pages of this journal (1, 2).

In this issue Bardale (3) discusses the relevance of a different type of cadaveric donor, the "non heart beating donor" (NHBD), otherwise called "donation after cardiac death" (DCD). As opposed to the brain dead donor, whose brain is irreversibly damaged but whose heart is beating and hence circulation is intact, these are donors whose heart has ceased to beat and hence circulation has ceased. It is obvious therefore that in this group of donors the organs need to be removed instantly for the organs to be viable for the purpose of transplantation.

It is interesting to note that historically some of the earliest attempts at solid organ transplantation were made from such donors. The first human kidney, liver and heart transplants, in 1958, 1963 and 1967, respectively, were performed using organs from non heart beating donors as at that time the declaration of death required heartbeat cessation. However, since techniques to keep the organs viable were not developed at that time, the results of these early transplants were poor, largely due to ischaemic damage to the organs. With legislation recognising brain death being adopted in many countries, the focus then shifted to using organs from brain dead or heart beating cadavers wherein the procedure to remove organs became a controlled one with much higher rates of success.

In the mid 1990s there was a resurgence of interest in using organs from NHBDs. Institutions in the US reported the use of these donors for kidney and liver transplants with good results (4). Soon this form of organ procurement gained increasing acceptance and in 1995 the Maastricht classification of NHBDs was put forward (5).

Over the last decade this form of organ donation has slowly gained wider acceptance. However, with its wider application, it has brought up a large number of complex ethical dilemmas. Bardale covers the various ethical and legal issues thrown up in this field. Although many of them are briefly mentioned, it would be obvious to the reader that these are sensitive and complicated areas dealing essentially with the end of life. Therefore the implementation of such programmes in a scenario such as India's will need on one hand social and cultural acceptance and on the other substantive regulatory mechanisms. Also it needs the presence of trained medical teams who can conduct almost instantaneous removal of organs in a planned manner.

When the Human Organs Transplant Act was passed by the Indian Parliament in 1994, it had a dual purpose. Besides banning the trade in organs, it legalised brain death, making the removal of organs from brain dead cadavers permissible after consent from the family. The last 15 years after the passage of the law have seen some sporadic activity in cadaveric donation. What has been heartening, however, is the response of potential donor families. In the hospital in Mumbai where I work, the consent rate is around 40 to 50%. This is on par with developed countries. The recent experiences of armed forces medical institutions and institutions in Chennai are similar. It seems that if an institution makes an effort to promote organ donation, and if ICU personnel make an effort to identify brain dead donors, the consent rate amongst the Indian population is good.

There is no reason to believe that families who consent to organ donation after brain death will not do so after cardiac arrest. In fact it is easier to understand and accept the concept of cardiac death. As a surgeon involved in cadaveric organ donation and liver transplantation, and hence regularly seeing patients dying on the waiting list, it is indeed tempting to consider starting an NHBD programme. The scientific and legal base for it has been prepared in the rest of the world.

However, as Bardale points out, this field is a quagmire of complex moral, social, ethical and legal issues. The critical question therefore is: are we ready for it in India?

Two issues flagged in the discussion on presumed consent bear repetition; do we have the ability to monitor the implementation of such a system in a completely unregulated market of healthcare? And, whilst trying to achieve an increase in organ availability, are we also looking at making transplantation more accessible and equitable?

References

1. Kaushik J. Organ transplant and presumed consent: towards an "opting out" system. *Indian J Med Ethics*. 2009 Jul-Sep;6(3):149-52.
2. Nagral S. Will presumed consent make transplantation accessible, ethical and affordable in India?. *Indian J Med Ethics*. 2009 Jul-Sep;6(3):155-6.
3. Bardale R. Issues related with non-heart-beating organ donation. *Indian J Med Ethics*. 2010 Apr-Jun;7(2):104-6.
4. Casavilla A, Ramirez C, Shapiro R, Nghiem D, Miracle K, Fung JJ, Starzl TE. Experience with liver and kidney allografts from non-heart-beating donors. *Transplant Proc.* 1995;27:2898.
5. Kootstra G, Daemen JH, Oomen AP. Categories of non-heart-beating donors. *Transplant Proc.*1995;27:2893-4.

LAW AND ETHICS

Legal changes towards justice for sexual assault victims

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Abstract

The crime of rape is a major problem in India, evident from the reports in the press as well as official statistics. The accused has often gone free, because the victim did not file a complaint, or because of poor evidence gathering and well as lacunae in the law. This paper presents an overview of the laws applicable to sexual assault cases and amendments in these laws, specifically in terms of the roles and responsibilities of healthcare providers to bridge the gap in providing medical evidence to the courts.

Introduction

The crime of rape is a major problem in India. More than 20,000 rapes were reported in 2008, and it is estimated that only one in 69 cases even gets reported (1). However, the concerted efforts of the courts, the legislature, the Law Commission of India, non-governmental organisations and women's activists have led to important steps forward in the delivery of justice to victims of rape. Amendments in the law have been made in both factual and procedural details. Further, changes have been made regarding the legal obligations of medical personnel and other healthcare providers in response to a case of sexual assault. The milestones discussed in this paper are those achieved by amendments in criminal law: the Criminal Procedure Code (CrPC), the Indian Penal Code (IPC), and the Indian Evidence Act (IEA), in 1983, 2003, 2005, and 2008, along with the judgments of the Supreme Court in 2000 and the Delhi High Court in 2009.

The Criminal Law (Amendment) Act of 1983

The infamous Mathura case (2) called for significant amendments in the Criminal Procedure Code in 1983, particularly regarding what constituted custodial rape, provision for enhanced punishments for offences under section 376(2) IPC and presumption of the absence of consent in cases booked under section 376(2) IPC. This was done by bringing in an amendment in the Indian Evidence Act, section 114(A) IEA. Thus, in cases of custodial rape, rape of a pregnant woman, and gang rape, if it is proved that the accused had sexual intercourse with the woman who is alleged to have been raped, and the question is whether it was without the consent of the woman, and she states before the court that she did not consent, the court shall presume that she did not consent. This amendment tries to overcome the gender inequities which can exist at workplaces, police stations, jails and other such situations, in which the victim is overpowered and a forceful sexual act committed. In such situations it is extremely difficult to prove that it was a nonconsensual act through the testimonies of other witnesses. By presuming the absence of consent (section 114(A) IEA) and awarding enhanced punishments in custodial rape cases (section 376(2) IPC), the legislature is trying to plug these loopholes. One more dimension to the issue of custodial rape situations is that the examining doctor should also understand that the victim's ability to put up resistance against the accuser's advances is largely dependent on gender-based power relations. There could be situations where a woman is overpowered and subject to sexual intercourse without her consent, but is left with no injuries, or few injuries, that might be seen as evidence of resistance (3).

The Supreme Court judgment in 2000

Prior to this landmark judgment in the year 2000 delivered by the Supreme Court in State of Karnataka V Manjanna (4), doctors would examine victims of rape only after they received a request from the police. For this to happen, the victim had to muster the courage to register a complaint against the accused in a police station of the correct jurisdiction. There could be inordinate delays in this, considering the social obstacles that women face in coming out in the open against the accused. Further, a woman is often ostracised just for being the victim of rape. Yet, society often blames the victim for delays in complaining about the offence, giving less importance to the heinous act of the accused and the mental and physical trauma that the woman has to overcome before registering a complaint. Only after this delayed registering of a complaint against the accused would the police investigation be initiated and a requisition forwarded to a doctor at the government hospital asking for medical examination of the victim of rape. On many occasions if the victim reported directly to the hospital, she would be denied this crucial medicolegal examination and collection of medical evidence because the police had not issued a requisition for it, addressed to the doctor. By the time the police requisition could be arranged there was substantial delay and much of the medical evidence was lost or could not be collected. This would result in acquittal of the accused in many cases, due to the lack of evidence to implicate the accused or link him to the offence. The benefit of doubt was awarded to the accused, denying justice to the already traumatised victim.

In its 2000 judgment, the Supreme Court recognised that the

rape victim's need for a medical examination constituted a "medicolegal emergency". Second, it was also the right of the victim of rape to approach medical services first before legally registering a complaint in a police station. The hospital was obliged to examine her right away; they could always subsequently initiate a police complaint on the request of the victim. As a result of this landmark judgment, the doctor or hospital is now required to examine a victim of rape if she reports to the hospital directly, and voluntarily, without a police requisition. The judgment recognises the three ways by which a hospital may receive a victim of rape: voluntary reporting by the victim; reporting on requisition by the police, and reporting on requisition by the Court. Unfortunately this information has not been disseminated to all doctors, and the majority of them still insist on a police requisition before examining a rape victim.

The Indian Evidence (Amendment) Act of 2002

Section 155(4) IEA earlier allowed the defence lawyer to discredit the victim's testimony by arguing that she was of "immoral character". This attack on her in the name of a legally allowed cross examination, questioning her past sexual acts, her personal life and other private matters, deterred many victims of rape from registering complaints. The Indian Evidence (Amendment) Act of 2002, (5) which came into force on January 1, 2003, deleted section 155(4) IEA and added a provision, section 146 IEA. According to the new provision, it is not be permissible to put questions in cross examination of the prosecutrix about her general moral character. This paved the way for an end to unwarranted attacks on the past sexual acts of the victim of rape.

However, a medical practitioner conducting an examination of a victim of rape often requires information about her past sexual acts, intercourse and sexual practices. This is to correctly interpret the physical and genital findings on the victim: the findings (injuries sustained) of a forceful sexual act in a virgin person (who has not experienced sexual intercourse) differ from those on a person who has experienced sexual intercourse in the past. Before this information is collected, the doctor must properly explain to the victim the purpose of collecting this information and how it would help her in her case to obtain justice by properly interpreting the physical and genital findings (the injuries sustained). She must also be explained the amendments of section 155(4) IEA. Otherwise the victim of rape may be hesitant to part with this crucial information, as she will believe that this information, once given in the medical records, may be used against her by the defence lawyer.

The Code of Criminal Procedure (Amendment) Act of 2005

Due to the liberal interpretation of section 53(2) CrPC by some high courts (Punjab & Haryana, Andhra Pradesh), it became a mandatory practice for a rape victim to be examined by a woman doctor only (wherever woman doctors were available). This was meant to make the victim more comfortable in the hands of a woman doctor. But the small number of woman doctors (especially in rural hospitals), and their workload with maternity services, often resulted in delays in the medical examination of a victim of rape. Even when a doctor eventually became available, his/her busy schedule often meant that only a cursory examination was performed and the collection of evidence was inadequate or improper. As there was no explicit law dealing with these issues, there was much confusion regarding who (male or female doctor) should examine victims of rape and the extent of such examinations (documentation of injuries and evidence / collection of evidence).

The Criminal Procedure Code (Amendment) Act of 2005 (6) introduced specific sections for medical examination of victims of rape (section 164(A) CrPC), medical examination of those accused of rape (section 53 (A) CrPC) and investigation by judicial magistrates of custodial rape and deaths (section 176(1A)(a)(b)CrPC).

Section 164(A) CrPC explains the legal requirements for medical examination of a victim of rape. One of the main elements of this is that the consent of the victim is mandatory and should be part of the report. Only with the consent of the victim (and in the case of a minor by the parent or guardian) may the examination be conducted by any registered medical practitioner (only allopathic doctors registered under the Medical Council of India (MCI)) employed in a hospital run by the government or a local authority, and, in the absence of such a practitioner, by any other registered medical practitioner. Thus this explicit provision mandates that any registered medical practitioner with the consent of the victim may do the examination, solving the difficulties caused by the requirement that only government doctors should do this examination. It also provides that when no woman doctor is available, there is no bar against a male doctor carrying out the examination, if the victim consents. Though getting the examination done by a woman doctor is ideal, the law does not mandate it, keeping in mind that a medical examination should not be postponed because of an extreme situation such as the want of a lady doctor. The same section mandates that a medical examination must be carried out within 24 hours of the police receiving information, thus recognising this as a medicolegal emergency and putting a timeframe for the investigating officer. The medical examination should be carried out without any delay and a "reasoned" report be prepared, recording the consent of the victim, her name and address, the person by whom she was brought, her age, a description of the materials collected from the victim for DNA profiling, marks of injury if any, her general mental condition other material particulars in reasonable detail, and the exact time of commencement and completion of the examination. The law mandates that the report should state precisely the reasons for each conclusion made. Also, it should be forwarded without delay to the investigating officer who, in turn, shall forward it to the magistrate concerned.

Section 164A (7) CrPC explicitly states that nothing in this section shall be construed as rendering lawful any examination without the consent of the woman or any person competent to give such consent on her behalf. This makes it clear that

consent is essential and nobody can force a victim to undergo a medical examination without her consent, not even the Court. If we read the same section closely, we find that it also recognises her right to consent for partial examination. That means she may also decide on whether she wants to undergo a physical examination and / or genital examination and allow the collection of bodily evidence. She may also separately decide on whether to file a police complaint and initiate criminal proceedings against the accused. So in those cases in which a victim of rape voluntarily reports to the hospital, she has a final say in whether she wants the hospital to initiate a police complaint by recording her case as a medicolegal case and sending an intimation of this fact to the police. However, many hospitals argue that they are dutybound to notify the police of all medicolegal cases, even though there is no legal provision explicitly stating which cases must be recorded as medicolegal cases. Even section 39 CrPC (allowing the public to give information in certain offences) does not enumerate section 375 IPC or 376 IPC. Doctors and hospitals argue that they prefer to inform the police right away as they do not want to get into legal problems later on for treating these cases without informing the police. These doctors argue that the victim of rape is always free to explain to the police that she does not want to initiate criminal proceedings. Though this may look like a solution that meets both the hospital's duty and the victim's rights, in reality the police have often booked cases and started a criminal investigation on the hospital's medicolegal case intimation alone. In such cases, the victim of rape has had to undergo an unnecessary ordeal for which she has not consented at all, for an act initiated by the hospital, apparently in its own defence. The law must be clear on this issue, because there is confusion in those cases where the victim consents to have medical evidence collected from her body but does not want to initiate criminal proceedings for the time being, as she requires time to make up her mind on this. In such cases the period for which hospitals must safeguard the collected evidence must be made clear, and we must also confirm that our hospitals are equipped for such work.

Section 53(A) CrPC sets down the requirements of medical examination of a person accused of rape. Prior to this amendment there was no explicit law defining the details of medical examination. There were no guidelines on whether age estimation had to be done, whether a potency examination was sufficient, whether evidence of injuries, stains, trace evidence or DNA evidence was required to be collected, etc. So there was confusion on whether to take samples of blood, hair, stains, nail clippings, etc. The explanation to this section now clearly states what must be included in this medical examination. A detailed medical examination is to be carried out by a registered medical practitioner (only allopathic doctors registered under the MCI) employed in a hospital run by government or local authority – and in the absence of such a practitioner within the radius of 16 km from the place where the offence has been committed, by any registered medical practitioner acting on the request of a police officer not below the rank of a sub inspector. By this it is clear that the law recognises the need for an immediate medical examination of the person accused of rape. The medical examination should be carried out without any delay and a "reasoned" report be prepared recording the name and address of the accused, the person by whom he was brought, the age of the accused, marks of injury if any, a description of materials collected from the accused for DNA profiling, other material particulars in reasonable detail, and the exact time of commencement and completion of examination. The law mandates that the report should state the reasons for each conclusion arrived and this report should be forwarded without any delay to the investigating officer who in turn shall forward it to the magistrate concerned.

Amendments are also made to section 176 CrPC regarding an inquiry by a magistrate into the cause of death, by adding section (1A) by which if "(a) any person dies or disappears, or (b) rape is alleged to have been committed on any woman, while such person or woman is in the custody of police or in any other custody authorized by the Magistrate or the Court under this Code, in addition to the inquiry or investigation held by the police, an inquiry shall be held by the Judicial Magistrate or the Metropolitan Magistrate, as the case may be, within whose local jurisdiction the offence has been committed." This amendment now mandates that a judicial magistrate must investigate all cases of custodial rape and deaths in custody.

The Code of Criminal Procedure (Amendment) Act of 2008

Many victims of rape do not want to register a police complaint due to the cumbersome procedures that it involves, and the unsupportive atmosphere at police stations. Further, they must narrate their ordeal to male police officers. Even if a woman musters up the courage to initiate criminal proceedings, there are inordinate delays in the trial of the case, with needless adjournments. She is always psychologically harassed in open courts, undergoes long trials and is forced to repeatedly describe her traumatic experiences in front of people who view her testimony with suspicion. It has also been found that in most cases the accused gets acquitted for lack of evidence. The courts have also failed to provide immediate and long term relief to the victim, let alone punishment to the accused. All these issues were looked at when the CrPC was amended in 2008 (7). These amendments came into effect in 2009.

A provision has been added to section 157 CrPC dealing with the procedure of investigation in relation to the offence of rape. The recording of the statement of the victim shall be conducted at the residence of the victim or in the place of her choice and, as far as practicable, by a woman police officer in the presence of her parents or guardians or near relatives or social worker of the locality.

The amendment to section 173 CrPC (7) now mandates that investigation in relation to rape of a child must be completed within three months of the date on which the information was recorded by the officer in charge of the police station. Also, when the report is forwarded to a magistrate it should contain the report of the medical examination of the woman where an

investigation relates to an offence under sections 376, 376A, 376B, 376C, and 376D IPC.

The amendment to section 309 CrPC has the additional proviso that when the inquiry or trial relates to an offence under sections 376 to 376D IPC, the inquiry or trial shall, as far as possible, be completed within a period of two months (7) from the date of commencement of the examination of witnesses.

Though the CrPC amendment of 1983 to section 327CrPC itself mandated *in camera* inquiry and trial for rape of an offence under section 376, 376A, 376B, 376C or 376D IPC, victims of rape were still not comfortable in court proceedings. The 2008 amendment to section 327CrPC allows an *in camera* trial be conducted, as far as is practicable, by a woman judge or magistrate. It also partially lifts the ban on printing or publishing trial proceedings in relation to an offence of rape, subject to maintaining confidentiality of the names and addresses of the parties.

The amendment of the CrPC in 2008 has brought in progressive legislation by inserting a new section 357(A) CrPC, the victim compensation scheme. All state governments in consultation with the central government are to prepare a scheme for victim compensation. On recommendation by the court for compensation, the district legal service authority or state legal service authority must decide on the quantum of compensation. There is also a provision for relief after inquiry by the state or district legal service authority in those cases where no trial takes place because the offender cannot be traced or identified.

Though the procedural formalities (quantum and disbursal procedure of compensation) have yet to be worked out, this is indeed a progressive development. It has identified the need for monetary support towards the immediate and long term rehabilitation of the already shattered victim of rape.

The Delhi High court judgment in 2009

A landmark judgment by the Delhi High Court in Delhi Commission for Women v. Delhi Police (8) mandated certain changes in the police system, health services, child welfare committees, legal services and support services in order to give justice to victims of rape. These changes were to be completed within a time frame.

Looking at the dismal conviction rates in sexual offences, complaints about the insensitive police (investigative) system and an insensitive society, the fact that medical opinions often lack in clarity and completion, and much medical evidence is not collected at all, the Delhi High Court pronounced its judgment specifically mandating that a SAFE Kit (Sexual Assault Forensic Evidence collection kit) be used by all medical personnel for gathering and preserving physical evidence following sexual assault. It explicitly mentions the contents of the kit: detailed instructions for the examiner, forms for documentation, a tube for the blood sample, a urine sample container, paper bags for clothing collection, a large sheet of paper for the patient to undress over, cotton swabs for biological evidence collection, sterile water, glass slides, unwaxed dental floss, a wooden stick for fingernail scrapings, envelopes or boxes for individual evidence samples, and labels. The following items could also be part of the kit – a Woods lamp, Toluidine blue dye, a drying rack for wet swabs and/or clothing, a patient gown, a cover sheet, a blanket, a pillow, needles and syringes for blood drawing, speculums, "post-it" notes used to collect trace evidence, a camera (35mm, digital, or polaroid), batteries, a medscope and/or colposcope, a microscope, surgilube, acetic acid diluted spray, medications, clean clothing and shower/hygiene items for the victim's use after the examination. This is the first time that the court has mandated the requisite infrastructure for a proper examination and also the extent of examination, insisting on detailed documentation of history and findings. Special rooms are to be set up for rape victims to be examined in privacy at every hospital where such cases are received. All hospitals are required to cooperate with the police and preserve the samples (that are otherwise likely to putrefy) in refrigerators or cold chambers till such time that the police are able to complete their paperwork for dispatch to a forensic laboratory for tests, including DNA. This is to ensure proper and safe storage of evidence.

This judgment also mandates that all police stations have a woman police official round the clock to comfort the victim and her family while registering a complaint. There should be adequate privacy for recording the statement of the victim. All complaints of rape are referred immediately to rape crisis cells and child welfare committees, depending on the need. Dedicated helplines, speedy investigation, immediate medical examination, and training modules for all police staff are also mandated. Help from psychologists, psychiatrists and sign language experts should be sought depending on the need. The judgment also asks for payment of compensation to victims of rape as per the Supreme Court order in the Delhi Domestic Working Women's Forum v Union of India (9). At present, this judgment is applicable to the State of Delhi. Such progressive judgments and laws are required at the national level to streamline the process of getting justice for all victims of rape.

Expectations

When a sexual assault victim or an accused is brought to a doctor or hospital, only evidence is collected. It is not realised by the majority of doctors and hospitals (unless there are obvious and large visible injuries) that the treatment of hidden (not obviously visible) injuries, prophylaxis for and treatment of sexually transmitted diseases, advice on pregnancy and contraception, and psychological assessment and counselling are part of their medical role apart from evidence collection. Perhaps we require an explicit law in this regard.

Even though the 172nd report of the Law Commission (10) in 2000 has recommended widening the scope of section 375 IPC by including anal sex, oral sex and digital sexual assault (fingering) as offences, the insertion of a new section 376(E) IPC

on unlawful sexual contact and even the deletion of 377 IPC; nothing has been done by the legislature in the last decade. The Delhi High Court's observation decriminalising male homosexuality created a stormy debate, only to end with the Supreme Court referring the case back to the legislature to make the necessary amendments. Many of the accused in sexual assault cases do not get convicted as anal sex, oral sex and digital sexual assault do not figure in section 375 IPC. The argument that these cases can still be booked under section 377 IPC or section 354 IPC has no meaning. When it is difficult to prove the offence of section 375 IPC in the courts (given constraints such as the lack of evidence) it is obviously more difficult to prove the offences of section 377 IPC or section 354 IPC.

The recent amendments in the CrPC to help speed up trials in sexual assault cases may not have an impact due to the existing backlog of cases in our courts. Though the union law minister has issued a public statement about the government's commitment to establish separate courts to examine sexual assault/harassment cases (11), the time has come to ask when such separate courts will actually start functioning.

A PIL filed in the Nagpur bench of the Bombay High Court (12) has succeeded in obtaining directions (similar to those given in the Delhi High Court judgment) mandating the central and state governments to form committees to look into the formation of uniform guidelines to examine victims of sexual assault. The final judgment is awaited. Such progressive moves will gain momentum in mandating every state to accept positive changes towards providing justice to victims of sexual assault.

Conclusion

Though much needs to be done to provide justice to all victims of sexual assault, various changes, spread across three decades, have brought some hope for justice. Due to active legislative and judicial actions, major changes have been made in the approach to be taken by investigative officers and healthcare providers, and in the process of trial or rehabilitation, in a case of sexual assault.

References

1. Nayar M. India: The rape kingdom [Internet].[place unknown]: Meri news, power to people; 2009 Aug 28 [cited 2010 Mar 15]. Available from: thttp://www.merinews.com/article/india-the-rape-kingdom/15782707.shtml)
2. Supreme Court of India. Judgments, the judgment information system of India. Tukaram and Another v/s State of Maharashtra Cr L J 1864 of 1978.
3. Commonwealth legal information institute, free access to commonwealth and common law [Internet]. [place unknown]: Common LII. Criminal Law (Amendment) Act, 1983 (43 of 1983); 1983 Dec 26 [cited 2010 Mar 15]; [about 3 screens]. Available from: http://www.498a.org/contents/amendments/Act%2046%20of%201983.pdf
4. Supreme Court of India. Judgments, the judgment information system of India. State of Karnataka v. Manjanna (2000 SC (Crl)1031)/CriLJ 3471/2000(6) SCC 188.
5. Indian Evidence (Amendment) Act, 2002 (4 of 2003) [Internet]. 2002 Dec 31[cited 2010 Mar 15]. Available from: http://www.commonlii.org/in/legis/num_act/iea2002205/
6. Commonwealth legal information institute, free access to commonwealth and common law [Internet]. [place unknown]: Common LII. Code of Criminal Procedure (Amendment) Act, 2005; 2005 Jun 23[cited 2010 Mar 15];[about 5 screens]. Available from: http://www.commonlii.org/in/legis/num_act/cocpa2005310/
7. Commonwealth legal information institute, free access to commonwealth and common law [Internet]. [place unknown]: Common LII. Code of Criminal Procedure (Amendment) Act, 2008 (5 of 2009); 2009 Jan 7 [cited 2010 Mar 15]; [about 5 screens]. Available from: http://www.commonlii.org/in/legis/num_act/cocpa2008310/
8. High Court of Delhi. Delhi Commission for Women v. Delhi Police, W.P(CRL)696/2008 [Internet]. 2009 Apr 23 [cited 2010 Mar 15]. Available from: http://www.ncw.nic.in/PDFFILES/Delhi_High_Court_judgement_on_guidelines_for_dealing_rape_cases_by_various_authorities.pdf
9. Supreme Court of India. Judgments, the judgment information system of India. Delhi Domestic Working Women's Forum V Union of India (1995)1 SCC 14.
10. Law Commission of India. 172nd report on review of rape laws. 2000 Mar 25. [cited 2010 Mar 14]. Available from: http://www.lawcommissionofindia.nic.in/rapelaws.htm
11. Banerjee C. Gun minus the fire: the law on rape is still an impotent being. OutlookIndia. 2010 Feb 15[cited 2010 Mar 14]. Available from: http://www.outlookindia.com/printarticle.aspx?264115
12. High Court of Judicature at Bombay [Internet]. Dr Ranjana Pardhi and Another v/s Union of India in WPST/46/2010 (Nagpur bench). [cited 2010 Mar 15]. Available from: http://bombayhighcourt.nic.in/casequery_action.php?auth=bV9oYz0wMyZtX3NyPVMmb

MEETING REPORT

Ethical review, remit and responsibility in biomedical research in South Asia

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In recent decades, research in the biomedical sciences has been increasingly located in settings outside of the global north (1). Much of this research arises out of transnational collaborations made up of sponsors in richer countries (pharmaceutical industries, aid agencies, charitable trusts) and researchers and research subjects in poorer ones. A recent workshop on the ethics of international collaboration, held in Sri Lanka,* confirmed that in addition to the usual concerns about the protection of human subjects in biomedical research, these engagements raise a host of new ones.

Research may well be carried out in populations rendered vulnerable because of their low levels of education and literacy, poverty and limited access to health care. The protections that medical and research ethics offer in these contexts tend to be modelled on a western tradition in which individual, informed consent is paramount and, furthermore, is couched in legal and technical requirements. When science travels, so does its ethics. Yet, when cast against a wider backdrop of global health, economic inequalities and cultural diversity, such models often prove limited in effect and inadequate in their scope (2, 3). Attempts to address both of these concerns have generated a wide range of "capacity-building" initiatives in bioethics in developing and transitional countries. Organisations such as the Global Forum for Bioethics in Research, the Forum for Ethical Review Committees in the Asia Pacific Region and the World Health Organization have sought to improve oversight of research projects, refine regulation and guidance, address cultural variation, educate the public about research and strengthen ethical review committee structures according to internationally acknowledged "benchmarks" (4, 5). They are also an essential prerequisite when it comes to attracting and hosting future collaborations, whether these are commercially sponsored, humanitarian or complex hybrids of the two.

Bioethical capacity building

As part of a larger study of the ethics of international collaborations in biomedical research, the work of BS, RDJ and SS has focused on the ways in which a heightened preoccupation with the ethics of research is playing out in contemporary Sri Lanka. The aim is to map and to understand both the spread of international collaborative research as well as the intellectual, bureaucratic and political activity that is stimulated in the name of bioethics capacity building. However, in studying collaboration, we ourselves are also drawn into collaborations of various kinds. In this article we report on an event which was held to facilitate dialogue between ourselves and other regional stakeholders **. The event focused on the ethics of international collaboration and provided an important context for reflection on the current state of play and an opportunity to air some of the issues that are faced when it comes to national and regional engagement with global science and experimentation.

At one level, the workshop provided an opportunity for participants to show the considerable progress made in responding to the ethical challenges posed by the growing traffic in international collaboration and particularly where these concern the outsourcing of phase II and III clinical trials. Significantly, many of the discussions gravitated towards ethical review committees: their constitution, operation, remit and effectiveness. In conformity with the Declaration of Helsinki, such advisory groups are seen as crucial when it comes to anticipating the costs and benefits to those who are to be enrolled into biomedical research projects. Here, continuities with ethical review as a global bureaucratic form were clearly in evidence: reference to international protocols, membership of trans-national fora and operation within standard guidelines. However, what became apparent in discussions throughout the day was the difficulty that participants had in stabilising this form in practice. The field of international biomedical research is changing extremely quickly, as are the mechanisms that are put in place to regulate and ensure protection of subjects. The effect of this would seem to leave the work of ethical review in a state of perpetual insufficiency: an ever-widening remit, not enough committees, not enough scrutiny, not enough trained people and not enough public participation. Anxieties were expressed that shortcomings in ethical review could bring charges of being "unethical" due to "incompetence". Such anxieties are greatly exacerbated when operating in settings where inequalities of risk are high, for example, because of poor education and literacy on the part of subjects and where negligence, corruption and exploitation are made possible by paternalistic and poorly regulated medical systems.

Where external audiences are concerned, there is anxiety that such charges might be indexed to estimations of national development and scientific credibility. Apart from feeding unwelcome national stereotypes, appearing inadequate when it comes to the conduct of ethical review could have real consequences when it comes to the ability to attract

research to the region, be this researcher-led research (funded by universities, charities, non-governmental organisations or governments) or sponsor-led research (funded by pharmaceutical companies). Where internal audiences are looking on, a different set of anxieties present themselves. Discussion of contentious cases suggested that the committees find themselves walking a fine line. On the one hand, they may be perceived as too restrictive, that is, unreasonably protective of human subjects and their interests and therefore impeding scientific and economic development. On the other hand, the expectation that ethics committees will operate as a kind of bulwark against moral and scientific imperialism might bring charges of excessive permissiveness, that is, they are not nearly protective enough of subjects and therefore are complicit in abuse, injustice or exploitation in research. Members can easily find themselves vilified from all sides. In this regard, an important question that emerged from the discussions is what happens when things go wrong following positive approval by an ethics committee and how to manage the professional and, possibly, legal ruptures that this brings.

Ethical vanishing points?

The way to prevent "unethical" process and outcome in the ethical review of research that was proffered by many of the participants was further resort to "capacity building". Yet, it was hard to see that this strategy would not result in a remorseless game of catch-up into which all are drawn in the quest for some kind of ethical vanishing point. Indeed, as the discussions progressed, the load that ethical review was taking on seemed to get heavier and heavier, and, as a consequence, focus fell more on operating procedures and the way that these might be tightened up to ensure effective regulation of research. The momentum appeared to be moving firmly in the direction of greater procedural elaboration, more formulaic approaches to evaluation and a consequent consolidation of power in the process of ethical review, as national ethics cultures expand to fill the ambiguous moral spaces that international research increasingly opens up.

On the evidence of the collaborative workshop, the list of competences and responsibilities that ethics committees active in the field of international collaboration might be expected to have is a long one. They must cover relevance of the trial design, its scientific validity, the balance of risks and benefits, the suitability of investigators and the appropriateness of informed consent procedures. Furthermore, the list is expanding as ethics committees strive to discharge their duties responsibly and embrace new dimensions of what it is to be "ethical". Here committees must, perforce, move into complex cultural territories for which there is little in the way of guidance. Examples alluded to included information sheets, the technicalities of translating informed consent documentation, insurance and compensation arrangements and the complex entanglement of voluntarism and commerce that runs through questions of payment to research participants. The waters were further muddied as participants grappled with "social benefit" or assessing the extent that certain kinds of research might result in "ethnic disharmony". There was little evidence that the participants were in anyway shying away from the challenges that engaging with this agenda carries despite the considerable investment needed in terms of knowledge, time and resources. However, it was clear from the discussions on this particular occasion that those who are most centrally involved in conducting ethical review see themselves as carrying enormous and, on occasion, impossible responsibilities and expectations. The task of making appear stable and authoritative that which is constantly evolving is a significant one. For these reasons, the emergence and consolidation of ethical review in developing world contexts is an increasingly important site in which to study the transactions in knowledge, resources and finance that currently constitute international collaboration in biomedical research.

This comment is reprinted from* IIAS Newsletter*, 52 (Winter 2009): 27. ISSN 0929-8738 with permission from the editor.

Notes

* The International Science and Bioethics Collaboration is funded by the UK's Economic and Social Research Council [RES 062 23 0215] and is a collaboration between the Universities of Durham, Cambridge and Sussex.

* The workshop took place in March 2009 in Colombo and was co-organised by three researchers from Durham University along with staff of the Faculty of Medicine of the University of Colombo (specifically the Human Genetics Unit and the faculty's ethics review committee). The theme for the day was the ethics of international collaboration. Case studies of international collaboration were presented by Harun Ar-Rashid (director, Bangladesh Medical Research Council), Vasantha Muthuswamy (former deputy director general, Indian Council for Medical Research), Shri Krishna Giri (secretary, Nepal Health Research Council), Hemantha Senanayake (chairperson of the ethics review committee, Faculty of Medicine, University of Colombo, Sri Lanka). Cristina Torres (co-ordinator, Forum for Ethical Review Committees in the Asia Pacific Region) gave an overview of the challenges faced in developing ethical review capacity in the region. The audience consisted mostly of local academics, doctors and clinical researchers.

References

1. Petryna A. *When experiments travel: clinical trials and the global search for human subjects.* New Jersey: Princeton University Press; 2009.
2. Benatar S. Reflections and recommendations on research ethics in developing countries. *Soc Sci Med*. 2002;54(7):1131-41.
3. Bhutta Z A. Ethics in international health research: a perspective from the developing world. *Bull World Health Organ*. 2002;80(2):114-20.
4. Emmanuel EJ, Wendler D, Killen J, Grady C. What makes clinical research in developing countries ethical? The benchmarks of ethical research. *J Infect Dis*. 2004; 189:930-37.
5. Lavery J V, Grady C, Wahl E R, Emanuel E J. *Ethical issues in international biomedical research: a casebook*. Oxford: Oxford University Press; 2007.

SELECTED SUMMARY

How does a nation decide what healthcare to pay for?

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Susan Gilbert. The nesting-egg problem: why comparative effectiveness research is trickier than it looks. *Hastings Center Report*, 2009 Nov-Dec; 39(6): 11-4.

The US healthcare debate is an old one and has long defied easy solutions. But it continues to entertain, and to stimulate. President Obama's ongoing attempts to persuade the nation to give up a degree of perceived freedom of choice in healthcare, so that basic healthcare could become available to all, has injected more energy and at least a temporary sense of urgency into the debate. A series of essays in the November-December 2009 issue of the *Hastings Center Report* highlights some of the current struggles of that society to provide itself an acceptable system of determining who has access to what kind of healthcare. It is easy to dismiss some of these struggles as self-imposed, but they are instructive for the rest of the world, particularly for more chaotic democracies such as ours, and especially in the context of rapidly increasing options in diagnostic and therapeutic technologies.

The current US government has begun to move towards containing healthcare costs and thus spreading access more evenly. One of the several initiatives in this direction has been to fund comparative effectiveness research (CER). CER, in simple terms, is research directed at comparing newer technologies to known ones for relative effectiveness. The premise for funding this is straightforward: in the US president's words, "There is going to be some disagreement, but if there's broad agreement that in this situation, the blue pill works better than the red pill, and it turns out the blue pills are half as expensive as the red pills, then we want to make sure that doctors and patients have that information available to them." However, notice that this statement is carefully calibrated: he does not say, "... then we want to make sure we have a policy for doctors to use the blue pills instead of the red." As Susan Gilbert points out, there are very good reasons why he cannot say this, and why CER alone may not allow him to say it.

For one, CER has certain inherent limitations. Gilbert calls one of them the nesting-egg problem, where the research opens up more questions than it answered. She quotes two recent studies that compared vertebroplasty, an expensive form of treating osteoporotic fractures of the spine in the elderly, involving the use of injections of acrylic cement into the damaged bone, to a placebo injection. Both studies found that both treatments provided a certain degree of pain relief but were no different one from the other. While one concluded that vertebroplasty could not be recommended, the other called for more studies, considering the possibility that the anaesthetic used in both injections might have had something to do with the extended pain relief. Presumably, such conclusions indefinitely prolong the wait for definitive answers.

The other inherent limitation is that most CER studies are unlikely to provide more than a relative idea of effectiveness in populations of patients on the assumption of randomisation. The research usually ends up concluding, say, that treatment A is 10% more likely than treatment B to provide relief or produce a cure. The study is usually not designed to say which subgroup constitutes the 10% who benefited, or whether at all such a subgroup exists. This evidence alone is therefore not sufficient to dictate what a physician should do in an individual case, and there is justified concern that such research should not lead to "cookbook" practice, where the physician is forced to abandon the more commonsensical approach of tailoring treatments to the contexts of individual patients. Apparently, last year's economic stimulus bill, of which the CER funding was a part, specifically prohibits the use of reports or recommendations of such research "as mandates or clinical guidelines for payment, coverage, or treatment". Sensible, but then, how does the government justify why it funded the research in the first place, if there is no way to ensure its use? Apparently, the federal structure allows individual states to then determine how to use the findings of these studies. For some years, now, a couple of states have apparently been using evidence from such studies to decide what treatments to offer under state-funded insurance schemes to good effect, achieving modest cost savings and the maintenance of quality, such as by choosing less harmful treatments – also based on comparative studies. For instance, when studies found Merck's Vioxx (rofecoxib, an anti-inflammatory medicine commonly used for arthritis) to be linked to heart disease, Washington state immediately took it off the Medicaid list, well before it was taken off the shelves in the market.

True to form, the centre of the healthcare debate in the US often rests on whether at all the government should involve itself in this matter. The state needs to fund such research, presumably because it needs to direct policy based on evidence, which is often not available, since the free market of privately-funded research has no incentives for generating sufficient evidence. Also, the case for state-funded research

gains impetus each time there is suspicion of bias in industry-funded drug trials, a phenomenon that is increasingly evident. Gilbert quotes Marcia Angell, a former editor-in-chief of the *New England Journal of Medicine*, to make the point that industry-sponsored trials "consistently favor sponsors' drugs – largely because negative results are not published, positive results are repeatedly published in slightly different forms, and a positive spin is put on negative results." The opposition to independent, government-sponsored, assessment of technologies has come, not surprisingly, from two groups – professional physicians' associations and the health industry – which unfortunately can no longer be assumed to represent mutually different interests today. Previous attempts by the federal government and the Congress to generate independent evidence have been scuttled because such groups became incensed at "governmental intrusion". The example provided, relating to one such federally-appointed agency being virtually disbanded because it dared to issue a guideline that stated, on the basis of solid evidence, that much of the spinal surgery being performed in the country was unnecessary, is sobering. The body was renamed, and now merely provides advice (on a website) that is binding to no one, not even government-funded health insurance.

Nevertheless, following the new funding for CER from the stimulus bill, a fresh start has been made. A committee of experts constituted by the Institute of Medicine leads the effort to determine how best to use the funds. A shortlist of 100 priority topics for research has been drawn up from a larger list that was canvassed from all interest groups, based on a range of concerns: conditions whose treatment is costly and varies widely across the country, conditions that are common but whose current treatments lack evidence of effectiveness, conditions that affect vulnerable groups such as the elderly and African Americans, and health problems of specific groups such as women and people with disabilities. Some of the top priorities include low back pain, attention deficit hyperactivity disorder, dental cavities and emotional disorders – illustrative of the nature of the prioritisation, and a refreshing departure from the esoteric choice of research topics when business is as usual. With assured funding for at least two years*, and a large and capable base of researchers, evidence should soon start becoming available. Considering the burnt fingers of yore, how this evidence will be used is something no one yet wants to bet on, and it will be interesting to see how the society adapts to new realities.

The US context is one of a democratic society where a lot of medical care is provided by private, for-profit providers, paid for by a mix of private and state-funded insurance and regulated by a "free" market in which the health industry wields enormous influence. It is a society that instinctively abhors regulation by the government, and loves to litigate. Other prosperous democracies, such as in western Europe, have evolved significantly different models of healthcare, apparently because there is greater acceptance of the role of government in regulating and providing for healthcare. While we in India can compare the relative merits and learn lessons from these and from other models in socialist states, it is particularly instructive to note the methods adopted to steer what are ultimately moral, ethical and political decisions.

One of the most important reasons to engage in CER is to understand healthcare costs and keep them manageable, even while improving effectiveness of healthcare. The current initiative for CER in the US began with a candid assessment of the fact that healthcare costs were irrational, in the sense that differences in healthcare costs across regions and countries did not co-vary with health outcomes, and that these high costs were a challenge for both, the government and the private sector (1). The initiative then survived a major change in the federal government, procured a funding of $1.1 billion from the current dispensation, and has made a solid start in identifying priorities for research. From the perspective of India, where policy making is led by hazy evidence at best, this willingness of a government to seriously engage in generating and examining evidence about the effectiveness and real costs of healthcare should be seen as remarkable. The jury is still out on whether this initiative will lead to more accessible healthcare for all, much less improve health, but the US is at least taking a rational approach to determine how to move forward. The approach is probably more relevant for us in India than the specific results of research. Such an approach, which looks closely at our own situation to find a package of services that will be beneficial to most and at a cost that we can afford, may not solve all the problems of healthcare access, but is surely a necessary step in that direction. Engaging the public in examining such evidence, owning it, and determining for itself what is desirable, may actually make the task easier.

** The Institute of Medicine has made a strong case for making this an ongoing funding priority of the government.*

Reference

1. Congressional Budget Office. Research on comparative effectiveness of medical treatments: issues and options for an expanded federal role. Washington, DC: Congress of the United States. Congressional Budget Paper; 2007 Dec.

BOOK REVIEWS

Morality is natural – but difficult

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Gurcharan Das. *The difficulty of being good: on the subtle art of dharma*. New Delhi: Allen Lane; 2009. 434 pp. ISBN 9780670083497

In 2002, Mr Das "decided to take an academic holiday". His purpose was not to visit destinations frequented by tourists, howsoever enlightened they may be. Instead he travelled to the University of Chicago, where he and his wife spent the next two years. He delved into the rich collection of books and other texts on the Mahabharata in the Regenstein Library and interacted with scholars such as Sheldon Pollack, Wendy Doniger, Steve Collins, Mathew Kapstein and Dan Arnold. Eventually he was to spend six years continuously with the epic before crystallising his thoughts and concept into this book. His comparison of the Mahabharata to the great western epics such as the Odyssey and the Iliad is especially welcome as it emphasises the many strengths of the former.

As far as possible he studied the almost 100,000 couplets of the Mahabharata in Sanskrit – hard labour but "good for the soul". Over time he made more than nodding acquaintance with scores of works on the epic. One of the strengths of his book is the privilege he grants his readers of seeing these master works through his eyes whilst providing opportunities for consulting them through his list of references.

He summarises the epic at the start of the book and then proceeds through its crucial episodes, providing illustrative anecdotes and drawing lessons from the thoughts and actions of the various protagonists.

He derives the first part of the title of his book from the fact that the epic is about our incomplete lives, about good people acting badly and about how difficult it is to be good in this world.

"All very well," you might say, "but how does this concern readers of a journal on medical ethics?"

In the prelude Mr Das tells us of his increasing disquiet at the "moral failure that pervades our public life and hangs over it like Delhi's smog". Envy, self-importance, anxiety on one's own status and the desire for revenge are some of the ugly sides of human vanity encountered in the epic and dissected by Mr Das for our benefit. Let me just quote Mr Das on one of these: "Envy is thus a leveler and it levels downwards. Instead of motivating one to better performance... envy prefers to see the other person fall. The envious person is willing to see both sides lose..."

In undertaking his study he sought ideas that would give meaning to life under these circumstances.

At the heart of the epic he encountered the changing concepts of *dharma* – moral and cosmic balance. He devotes chapter 10 to this subject and not surprisingly quotes at the start from Mahabharata XVIII.113.8: "One should never do to another what one regards as injurious to oneself. This, in brief, is the law of dharma." Elsewhere in the chapter we learn that when Yaksha asks Yudhishthira, "What is the highest dharma in the world?" Yudhishthira replies simply, "Compassion is the highest dharma." The quotation from the Mahabharata sums up this concept in the final chapter: "Who has in his heart always the well-being of others and is wholly given, in acts, thoughts and in speech to the good of others, he alone knows what dharma is." Mr Das reminds us that the basic principle of *dharma* is the realisation of the dignity of the human spirit. Vivekananda's "dharma of humanity" forms an ethical code applicable to the whole of mankind.

Throughout the book we encounter references to *satya*, *ahimsa* (not harming others) and *maitri* (benevolence) as the components of compassion. We are also introduced to the term *anrishamsya* – embodying compassion, altruism and paying heed to the needs and interests of others. The 18th century philosopher Francis Hutcheson's phrase "calm universal benevolence" strikes a chord, as does Auguste Comte's "religion of humanity".

If "moral rules are the minimum demands of behaviour that a civilised society expects from its members," our society in general and in our profession appears to give these rules short shrift. In the final chapter Mr Das tells us about how we are false to others, how we oppress fellow beings, how deeply unjust we are in our day-to-day lives and the lessons to be learnt from the Mahabharata on the means for overcoming these failings. In his concluding chapter he points out that morality is natural to the way human beings have evolved.

There is much else that is of great interest in this book. Take the concept of heroes. "A society without saints and heroes would be impoverished." "Heroes (are) of many kinds: heroes of sacrifice, heroes of self-control,...heroes of truth,...heroes of giving, ...heroes of intellect, ...heroes of patience,...heroes of honesty,...heroes of tranquility".

He discusses more than once the questions: "Why do bad things happen to good people?", "Why be good?", "Is it right to

abandon the individual to save the family?", "Can *dharma* be taught?" and other similar issues.

Lest you think that this book is an epitome of sobriety, let me allay your anxiety by pointing to just one example of hilarity – Mr Das' account of the frustration experienced by Mr Arun Shourie when, as minister of administrative reforms, he tried to answer a query on whether government officers could use inks other than blue and black. He also uses several contemporary examples of unethical acts such as the misdeeds of the Ambanis and Mrs Pratibha Patil.

After reading this book for the first time (as I shall surely return to it), I am also inspired to revisit the epic itself. I shall now do so with fresh insights provided by Mr Das and the host of philosophers to whom he refers throughout his book. I strongly commend this book.

Matters of life and death

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Nancy S Jecker, Albert R Jonsen, Robert A Pearlman, editors. *Bioethics: an introduction to the history, methods and practice*. Second edition. New Delhi: Jones and Bartlett India Private Ltd; 2010. Student edition. 545 pp ISBN 978-93-80108-09-4

This is a textbook on bioethics with contributions from major writers in the field. The editors are professors at the University of Washington and have carried out pioneering research in ethics. Part 1 of the book takes the reader through the history of bioethics, explaining its emergence as a discipline. Part II examines the methods of ethical reasoning and developing justification of moral beliefs. Part III covers ethical concerns related to reproductive decisions such as abortion, prenatal genetic testing and assisted reproductive technologies.

Albert Jonsen sets the tone by providing information on developments in medical ethics. Daniel Callahan comments on the use of technical jargon in the discussion of ethics. He points out that the discipline of bioethics should be so designed as to help physicians and biologists make practical decisions.

The essay by Leon Kass is an attempt to provoke discussion on the meaning of concepts such as "betterment of mankind", a "good man", a "good life", a "good community" and the values that should guide society. According to Kass, all decisions to develop or use biomedical technologies inevitably contain judgments of value. He argues that the very definitions of benefit or risk to individuals or society are based upon value judgments, not simply technical ones

James Childress takes on the question of "who can live when not all can live", giving examples of moral questions specifically related to scarce life-saving medical resources such as haemodialysis and kidney and heart transplants.

Hans Jonas's contribution is a philosophical reflection on experimenting with human subjects. This essay, considered a seminal exposition on the ethics of medical research, exhorts us to remember that while slower progress in the conquest of disease will not threaten society, the erosion of moral values most definitely will. This erosion will render the most dazzling research achievements worthless.

The article by Nancy Jecker examines the central methods of ethical reasoning used to support ethical judgments in particular cases. She comments that none of these methods offers ways of dealing with human rights questions such as health inequities between rich and poor nations, a statement that also has serious implications for medical practice in India.

The challenge of caring for patients in multicultural settings and the related philosophical problems of ethical relativism are brought out by Ruth Benedict and James Rachels. They state that different societies have different moral codes which determine what is right in that society. Further, there is no universal truth in ethics and there are no moral truths that hold for all people at all times. Thus, the moral code of any society at any given time has no special status; it is one among many. They conclude that we cannot sit in judgment on the conduct of other people and we should adopt an attitude of tolerance towards the practices of other cultures.

Arguing that women's moral experience has been discounted in the construction of ethical theories and principles, Virginia Held concludes that the practice of mothering has important perspectives to contribute to ethics. Susan Shermin adds that the critical question of the structure of medical practice and its role in a patriarchal society is largely ignored and is not considered a part of the standard curriculum in textbooks of medical ethics.

Writing on the ethics of reproductive technologies, John Robertson states that theological, social, psychological, economic and feminist perspectives would emphasise different aspects of these technologies. Susan Shermin, discussing the context of the alarming increase in the range of reproductive technologies, argues that in vitro fertilisation should be

understood against the backdrop of the social and political structures that have maintained power relationships to the disadvantage of women and people of lower socioeconomic status.

This book is a "must read" for professionals in the human care sector. The writers and editors are senior bioethicists, eminently qualified to discuss these issues. However, it could have benefited from a few additions. An introduction explaining the three-part framework could have been provided by the editors. Although this is a large volume comprising 545 pages, the original articles of certain authors could have been included in place of abridged versions, as these are seminal articles on medical ethics. Though this is the Indian edition of the book, readers who wish to explore specific aspects of Indian ethics or biomedical ethics in India will be disappointed. Finally, the format employed throughout the book could have been made more accessible by the inclusion of introductions and summaries capturing key elements.

Despite these limitations, this textbook is well suited to advanced graduate and undergraduate students who plan to pursue careers in healthcare ethics as well as in the medical and social work professions.

FILM REVIEW

Warding off the evil eye

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***Matti o manush* (The soil and the people). Bengali with English subtitles. Rimjhim Gupta and Sabyasachi Chakraborty. Directed by Sisir Sahana, cinematography by Asim Bose, music by Nachiketa.**

Sisir Sahana is a "stormist" from the metaphor of the storm that he uses in his second feature film venture, *Matti o manush*, with its anguished portrayal of ritualism that is mindlessly practised even in the new century. Sahana holds a mirror to our middle-class hypocrisy that reduces the sacred pursuit of the truth to the mechanical following of insipid rituals and superstitions.

The film's story revolves around a teacher of scientific temperament who gives in to his mother's wish, in a moment of emotion, and agrees to leave no stone unturned in driving the so-called "evil" out of his mute daughter's life. He joins the band of village sanyasis who insist that he join them in rituals like dancing around the village in the hot sun, and hanging upside down from a banyan tree - all to ward off the evil eye.

The teacher's daughter, Jhonu, is a happy-go-lucky, uncomplaining adolescent, a keen observer of nature and a connoisseur of line, light, and artistic depiction. Jhonu's portrayal is reminiscent of the woman in Picasso's famed Guernica, her extended hand holding the lamp of light and hope. Jhonu is engrossed in the delight of life and draws stunning pictures, some of these on the walls of the room in her mud house. Her mother is a genuinely fond parent, indulgent but protective. The girl's happiness is put at risk when her father begins to participate in the rituals.

Then, when a baby falls and dies in what is a rare mishap in a Santhal tribal fair, the mute girl who happens to be present (and attending the fair like any other "normal" person) is called a fiend and hounded. The anguished child recalls how, over the years, everybody around her has developed a hatred towards her, unreasonably singling her out as the cause of the village's calamities. The youngster's spirit rapidly ebbs.

People's irrational faith in amulets and unscrupulous soothsayers is presented as thoughtless, everyday compulsion. What will our society come to if educated people do not rise as one against blind beliefs? How can we allow meaningless, unreasonable and unscientific ideas to kill the very spirit that keeps each of us alive, playing our individual roles in the cosmic dance drama of life?

The film offers several moments of visual candy: the teacher leading sanyasis in paying obeisance to the lifegiving water of the river, the girl's thrill at the blowing gale, the saffron-clad sanyasis walking across the river complemented by the serene blue waters in the foreground, and the girl in a blue sari, dancing carefree along with the santhals on the silver sands. The artful creation of storms, the fish-eye-lens close-ups of the enraged girl, the baby falling to its death, and the earthen colours of rural Bengal make for some scintillating cinematography by Asim Bose.

Music by Nachiketa adds much to the film's production values, especially lifting high the memorable opening sequence of the sanyasis crossing the river. "*Bam bam bole*," too, is a definitely hum-along tune.

The film was shot in Bankura, in West Bengal state, during April 2009. The lead is convincingly played by Rimjhim Gupta with Sabyasachi Chakraborty in the role of her teacher-father. Maati o manush was screened at the International Film Festival of Kolkata in November 2009. It is scheduled for screening during the New Hope Film Festival, a forum for art films in the United States, in June 2010. The film's director, Sisir Sahana, is a reputed sculptor and painter based in Hyderabad and now, with his second film, has begun to earn a reputation for his powerful visualisation. The film's music and cinematography have come together well and have added considerably high production values - something which perhaps he could not have succeeded in showing through any other art medium.

As with his earlier film, Prithvi, Sahana's artistic oeuvre and angst serve to provoke the viewer. Those who profess to be near God have totally missed the learning point of life when they beat the life spirit out of a voiceless girl. When divinity is personified in this world as elemental silence, why then can we not be accepting of this mute witness to life? Why are we inimical toward one who is also a part of the whole of life? Who are we to play with so sacred an entity as another's life-soul? These and other questions come across loud and clear in the film. Are we, as thinking persons, willing to listen, to traverse the path of truth and do so against societal pressures? Each one of us must ask ourselves these questions with which Sahana seeks to prod us out of our complacency.

FROM OTHER JOURNALS

Cancer treatment: is it about survival alone?

The authors of this essay discuss an ethical framework for comparative effectiveness research in the management of cancer.

Over the past decade, oncology has undergone revolutionary changes with the advent of new drugs and techniques to combat cancer, and many types of cancer are now considered chronic diseases. However, the chronic disease exemplar, which emphasises the management of the disease by the patient with support from the clinician, fails in the case of cancer, where treatments may change as the disease progresses.

Comparative effectiveness research is sought after by oncologists for the management of chronic cancer. Clinical trials in this field have compared the effectiveness of new drugs against old drugs and of combination regimens versus single drugs in sequence. A review of data from clinical trials suggests that the decision on the treatment regimen should be based on a consideration for the patient's quality of life and the therapeutic index (the ratio of the quantity required to produce the desired effect to the quantity that will produce dangerous side effects). The authors cite a number of studies to argue that effectiveness cannot be defined solely on the basis of progression-free survival. Factors such as overall survival, toxicity of the new regimen, costs and other burdens are also significant while judging the effectiveness of a regimen. Effective treatment should also encompass palliative care for relieving toxicity associated with the treatment regimen.

Further, with the availability of data online, patients and their relatives are also equipped with more knowledge and will have their own assessments of a regimen's effectiveness and the options. Comparative effectiveness research can actually improve the patient-provider interaction and facilitate an informed decision making process for patients while choosing a treatment. The authors bring to close the essay with this noteworthy conclusion: "The story of living with a chronic disease is the patient's own story. The disease's natural history and how it responds to interventions is part of this story. By defining 'effectiveness' with reference to life as it is lived, oncologists support the practice of informed decision-making and honor the story in progress."

Berlinger N, Flamm AL. Define "effective": the curious case of chronic cancer. *Hastings Center Report*. 2009 Nov-Dec;39(6):17-20.

Genetic information: balancing civil rights and the public good

On August 30, 2009, the University of Akron in the USA approved an addition to the employee background review policy. It asked for blanket criminal background checks, including DNA sampling, for all prospective employees excluding student employees. This new rule led to widespread protests and was eventually amended, shifting the role of pre-employment DNA screening to law enforcement authorities.

The first federal law against genetic discrimination, the Genetic Information Nondiscrimination Act (GINA), came into effect in November 2009. GINA prohibits employers from seeking DNA material from employees even for criminal background checks. It also precludes any discrimination based on genetic information. The US Equal Employment Opportunity Commission also prevents the collection of, and discrimination based on, genetic information. The only law enforcement exception that GINA has pertains to forensic laboratories and to those seeking identification of human remains, and to detect sample contamination. But there is still lack of clarity as to how GINA will apply to law enforcement agencies acting on behalf of employers.

There is also the dimension of screening potential employees to identify risks to the security of other employees and students. But many consider that such a blanket check would be discriminatory against certain socioeconomic and ethnic groups. Compulsory DNA sampling would produce sensitive information about the health status of employees and their family members. There are logistical issues pertaining to the presence of trained personnel, properly equipped, monitored and secure laboratory facilities, and appropriate policies for managing the samples. If linked to a law enforcement agency, the employee DNA database gets linked to criminal databases, exposing more people to the risk of false positive matches and also to constant surveillance. The authors opine that simply avoiding the practice of DNA identification will not be a solution to the larger issue at stake. There should be a balance between the privacy concerns of the employee, the security interests of the employer and law enforcement.

Callier SL, Huss J, Juengst ET. GINA and preemployment criminal background checks. *Hastings Center Report*. 2010 Jan-Feb;40(1):15-9.

The equity efficiency trade-off

The argument about tradeoffs between equity and efficiency while scaling up programmes is an age-old one. One of the key issues in scaling up is whether to maximise coverage across the whole population (which may result in greater use by those with more access, who are frequently the wealthier as well) or to target resources to reach poor and vulnerable groups. The first approach would result in a widening of the existing inequalities between the different socioeconomic groups.

The author argues that the cost effectiveness of a chosen treatment strategy influences the cost and constraints associated with scaling up and thereby the costs of broader coverage. The point is illustrated with examples from the

efforts to scale up HIV treatment in South Africa. The financial as well as logistical feasibility of scaling up programmes should be an important consideration for health policy makers. In the case of cost constraints, a more cost effective programme might improve potential coverage among those in need of the services. However, the ethical dilemma in such an approach is that very often the more cost effective treatment (producing the greatest impact for the amount of money spent) might not be the most effective one (having the greatest impact regardless of the cost) and vice versa. The author argues that in a resource strapped setting, if equitable access to effective forms of treatment is unavailable, then a more cost-effective form of care with higher access to those who are in greater need of services should be sought.

Cleary SM. Trade-offs in scaling up HIV treatment in South Africa. *Health Policy and Planning*. 2010 Jan;25:99-101.

Palliative care awareness in urban and rural areas

Palliative care which began in the hospice movement got established as a hospital-based programme in the 1980s in the United States. It is still a relatively new concept in Indian society. A study was undertaken in rural and urban areas of a district in Kerala to assess the knowledge and attitude of the public towards palliative care. Only 20.5% urban and 5.4% rural participants had heard about palliative care, with the major source of information being newspapers. The study also found that all the rural and more than 90% of the urban population felt that the treating physician should honestly inform the patient about his/her illness. But while urban participants believed that the patient should be the first recipient of the bad news, rural participants were in favour of informing the family first. The authors opine that this could be due to the greater value attributed to the family in rural areas. There was a great keenness expressed by study participants, both rural and urban, to know more about palliative care. Awareness measures through the mass media about palliative care should be scaled up and the services should be made more easily available to those in need. The authors argue that the concept of palliative care should be customised to meet the specific needs of the Indian community and more healthcare providers, including grassroots level health workers, should be given training to meet the increasing needs of palliative care.

Joseph N, Jayarama S, Kotian S. A comparative study to assess the awareness of palliative care between urban and rural areas of Ernakulam district, Kerala, India. *Indian Journal of Palliative Care*. 2009 Jul-Dec;15(2): 122-6.

UN resolution against medical torture

There have been many reports, from all over the world, of the involvement of doctors in torture and the inhumane treatment of refugees and prisoners. Because of strong political and social pressure, or in the course of fulfilling their professional obligations during their tenure in the military or police of a state agency, doctors are often forced to overlook their ethical obligations and be part of torture indirectly, by tampering with medical reports, more directly by medicating prisoners to keep them alert during torture, and so on.

In March 2009, the United Nations Human Rights Council passed a resolution to curb medical torture. The resolution calls on states to initiate steps to prevent the involvement of doctors in torture and to protect those doctors who take an open stand against torture. The resolution, which also addresses the healthcare professional and the UN special rapporteur, giving him more authority on medical torture-related issues, has adapted ideas from the ethical principles of the World Medical Association, the Hippocratic Oath and the Declaration of Tokyo. This resolution wields more power and can be enforced in a court of law. It is also an expression of a non binding commitment to take action against medical torture. Medical associations worldwide will find it easier to implement and adhere to the principles of the new resolution as the states are also involved in the process.

Polatin PB, Modvig J, Rytter T. Helping to stop doctors becoming complicit in torture. *BMJ*. 2010;340:c973

Financial incentives to the research team

There are many factors influencing the conduct of biomedical research. Financial remuneration is one incentive for the researcher to participate in research. This factor gains much significance with the growth of industry-sponsored clinical trials. The authors of this paper explored the question of whether financial remuneration influences the research team in recruiting patients for a particular study and also what the factors are behind the decision of patients to participate in a study. They investigated the recruitment and informed consent rates for two clinical trials with identical inclusion criteria in a neonatal ICU setting in a hospital in Canada. Study 1 was a multi-centred, funded study involving an 18-month-follow up and providing financial remuneration to respiratory therapists who were to enrol participants in the study. Study 2 was a single-centre, non-funded study which offered no remuneration to the research team.

The authors found that the rate at which parents were approached was higher for the first study but the consent rates by parents were significantly higher for the second study. Participation rates were similar in both studies. None of the researchers reported financial incentive as a motivation for higher approach rates but they mentioned that they were more motivated to ensure success of the bigger multicentre trial. Institutional ethics committees now oppose remuneration to the research team to enrol eligible participants and many IECs have made it mandatory that the financial ties of the researcher be clearly stated in the informed consent form. Clinical research should be encouraged but remunerations to researchers should not undermine the ethical conduct of research.

Unger S, Wylie L, Fallah S, Heinrich L, O'Brien K. Motivated by money? The impact of financial incentive for the research team on study recruitment. The *Hastings Center Report IRB: Ethics and Human Research*. 2010;32(1):16-9.

Exhibition of plastinated corpses

This editorial comments on the controversy surrounding a unique exhibition in Birmingham, UK. Bodies Revealed, an exhibition of plastinated corpses, was banned in Venezuela and the subject of a lawsuit in the USA. The lawsuit forced the exhibitors in the US to display a disclaimer saying that the bodies on display were those of Chinese residents or citizens received by the Chinese bureau of police. However, they did not mention that the bodies might be those of Chinese prisoners.

At the Birmingham exhibition the exhibitors did not display any information about the origin of the bodies. According to the website of the exhibitors, the bodies were of people who died of natural causes and they were donated with their relatives' consent for educational purposes. However, the exhibitors failed to independently verify the origins of the bodies. The writers of this editorial point out that informed consent is not required in the case of imported tissues as per the 2004 Human Tissue Act which is the legal framework for the storage and use of human bodies, tissues and organs in the UK. The editorial calls for action so that proof that human tissue was obtained with informed consent is made mandatory for public display of human remains irrespective of whether they are of UK or foreign origin.

Editors. Bodies revealed, but whose? *Lancet*. 2010 Feb 20;375:612.

Research data sharing

Sharing of health data has immense benefits in the field of public health research. But there are significant technical, ethical and professional obstacles that must be overcome to make data sharing a standard practice. The major ethical impediment in data sharing is regarding the maintenance of confidentiality of participants. The pressure on researchers to publish also prevents them from sharing their data. There is also a need to improve data management standards in developing countries.

International funding agencies and journals are trying to make the process of data sharing routine in research. Disclosure of data sharing plans is part of many grant requisition forms of funding agencies, and journals are asking for a replication data set with articles. But it is equally important that secondary users and funding agencies work at building capacities among primary researchers from developing countries, and in developing and expanding data management and archiving standards in the primary research settings. The authors emphasise that "fair trade and not free trade" should be the driving force behind international data sharing initiatives.

Pisani E, Whitworth J, Zaba B, Abou- Zahr C. Time for fair trade in research data. *Lancet*. 2010 Feb 27; 375:703-5.

Compiled by Divya Bhagianadh
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Healthcare rationing conference, Rotterdam, The Netherlands, December 9-10, 2010

The Erasmus Observatory on Health Law has organised an international conference on healthcare rationing. Participants will discuss questions arising from the Dutch government's experiments with "regulated competition" in social health insurance. Some of these questions are: Who is responsible for rationing? How does it function? What are relevant and acceptable selection criteria? To what extent is current rationing just? What can be done to make it more just? How will healthcare rationing affect equal access to healthcare? What is the relationship between healthcare rationing and differences in health status?

Each conference day will open and close with plenary sessions with keynote presentations and debate. During each day, the conference will host parallel sessions addressing certain defined questions. The conference language is English.

A special poster session for young researchers is planned for Friday, December 10.

For more information, write to: info@erasmusobservatoryonhealthlaw.nl

LETTERS

Globalising the rot within?

Dr Pandya in his hard-hitting commentary, "Medical Council of India: the rot within" (1), characterises the problems plaguing the council. The Medical Council of India (MCI) is entrusted with supervising the quality of medical education in the country and promoting medical ethics; but such has been the disrepute of the MCI, due to allegations of favouritism and corruption, that the central government has now finalised a draft bill to replace the MCI and other councils (such as the Dental Council of India, the Indian Nursing Council and the Pharmacy Council) with a National Council for Human Resource in Health (2). The draft bill is available on the Ministry of Health and Family Welfare website (3). The current system of working through the various councils which have been characterised as "dens of corruption" (4) definitely needs an overhaul. It still remains to be seen if the establishment of the national council, an autonomous body, will bring in much needed reform in the regulation of professional health education in the country.

Dr Pandya has listed in detail allegations of impropriety against the various officials associated with the MCI. Dr Ketan Desai, the current president of the MCI, has had several concerns raised about his conduct and the receipt of large amounts of funds in the past. In its recent general assembly, held at New Delhi from October 14 to 17, 2009, the World Medical Association elected Dr Ketan Desai, unopposed, as president of the WMA for the term 2010-11 (5). The WMA on its website states: "As an organization promoting the highest possible standards of medical ethics, the WMA provides ethical guidance to physicians through its Declarations, Resolutions and Statements." (6) It is surprising that in spite of the past questionable history of Dr Desai, the WMA, as the torch-bearer of ethical conduct by physicians, still chose to elect him. This makes one wonder if we are now globalising the rot within.

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References

1. Pandya SK. Medical Council of India: the rot within. *Indian J Med Ethics*. 2009 Jul-Sep;6(3):125-31.
2. Sinha K. Goodbye MCI? Bill on health edu watchdog ready. *The Times of India* [Internet]. 2009 Nov 16[cited 2010 Mar 15].[about 3 screens] Available from: http://timesofindia.indiatimes.com/india/Goodbye-MCI-Bill-on-health-edu-watchdog-ready/articleshow/5237014.cms
3. The Ministry of Health and Family Welfare. The National Council for Human Resources in Health Draft Bill, 2009 [cited 2010 Mar 15]. Available from: http://www.mohfw.nic.in/nchrc-health.htm
4. Sharma G. Benign or malignant. *The Week* [Internet]. 2009 [cited 2009 Nov 18]. Available from: http://week.manoramaonline.com/cgi-bin/MMOnline.dll/portal/ep/theWeekContent.do?sectionName=Current+Events&contentId=6093468&programId=1073754900&pageTypeId=1073754893&contentType=EDITORIAL
5. The World Medical Association [Internet]. World Medical Association General Assembly. [updated 2009 Oct 20; cited 2010 Mar 15]. Available from:http://www.wma.net/en/40news/20archives/2009/2009_15/index.html
6. The World Medical Association [Internet]. What does the WMA do? [cited 2010 Mar 15]. Available from: http://www.wma.net/en/60about/20whatwedo/index.html

Safety and ethical issues of bare hand cadaver dissection by medical students

Dissection is not only a skill, but also an art that is identified as the signature of a surgeon. Besides the surgeon, all medical practitioners exhibit their proficiency, or the lack of it, while performing procedures such as the draining of an abscess, removal of a cyst, venesection, and so on. The initial learning seat for this marvellous art is the anatomy dissecting room.

Beginning from the basics of sanitation like simple hand washing, we follow strict aseptic precautions while performing surgery or invasive procedures in patients. This also applies to cadavers, which may harbour a multitude of organisms like Mycobacterium tuberculosis, prions causing Creutzfeldt Jacob disease and Gertsmann Straussler Scheinker syndrome, even after embalming (1). There is no definitive evidence to show that HIV is inactivated after embalming (2,3). Moreover, there is no system in practice to check the presence of these infections, either before or after the cadavers are embalmed. Against such a scenario, it is imperative that all persons handling cadavers follow universal precautions. However, in reality most students and teachers of anatomy in medical schools in India do not take even simple precautions, like wearing gloves while dissecting cadavers. Students who want to wear gloves are sometimes prevented from doing so by senior faculty members who believe that students will be able to appreciate the feel of the various tissues and organs better with bare hands. There is no rationale to their point of view because, as surgeons, these students will feel the same structures in live individuals in the operating theatre, only with gloved hands. So they're actually supposed to know how structures feel to gloved hands, not to bare hands.

The principles of universal precautions will be hammered into young brains only if they are made to follow them in every invasive endeavour. Not only do gloves help in warding off infections, they also protect the skin from the irritant effects of formalin used to preserve cadavers.

It's even more disheartening to know that the instruments used by these students are never sterilised. They are simply washed with water at the end of each session. As students are handling sharp instruments for the first time, they are more prone to cuts and bruises. There is also a high probability of these medical students being infected by highly pathogenic organisms. Adding to the problem, there is not even a steam steriliser or an autoclave in most of the departments of anatomy in medical colleges in India, to sterilise the instruments used during dissection. Even the regulatory body which approves the establishment of medical colleges in India does not make it mandatory to have these simple instruments in departments of anatomy (4).

In western countries, these precautionary measures are mandatory for everyone performing a cadaver dissection. So a

basic tenet of ethics, justice, is violated by us. Moreover, as bare hand dissection of cadavers is hazardous, the second basic principle of ethics, beneficence and non maleficence, is clearly violated. Even if some students bring their own pair of gloves, preventing them from wearing them violates the third basic principle, autonomy. So it is very unsafe and unethical to allow – and sometimes force – students to dissect cadavers with bare hands. It is time that we realise this and start practising universal precautions during cadaver dissection. The regulatory bodies should also modify their regulations to include sterilisation equipment as a basic necessity in the departments of anatomy of medical colleges in India.

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References

1. Demiryürek D, Bayramo_lu A, Ustaçelebi S. Infective agents in fixed human cadavers: a brief review and suggested guidelines. *Anat Rec*. 2002 Aug 15;269:194-7.
2. De Craemer D. Postmortem viability of human immunodeficiency virus - implications for the teaching of anatomy. *N Engl J Med*. 1994 Nov; 331:1315.
3. Healing TD, Hoffman PN, Young SE. *Commun Dis Rep CDR Rev*. 1995 Apr 28;5:R61-8.
4. Medical Council of India. Essential requirement for college/course: Minimum requirements for 150 admissions [Internet]. New Delhi: [updated 2009 Dec 3; cited 2009 Dec 5]. Available from: http://mciindia.org/helpdesk/how_to_start/STANDARD%20FOR%20150.pdf.

Quacks in anorectal practice in India

Most human beings will do almost anything to prolong their lives or relieve themselves from the suffering of a disease. Others will do anything to exploit these desires by selling what they claim to be magical remedies even for incurable diseases. "Quack" is one of the several names used for those who pretend to practise medicine but without training, qualification and registration from the appropriate council or authority (1). Although some may be harmless, many are very dangerous.

Quacks in surgery are mainly in the treatment of anal canal diseases where they are often more popular than trained and registered practitioners. One can find their advertisements in every city and town.

Anorectal diseases are considered a divine curse and a matter of shame, so victims of fake doctors suffer without complaining. Patients from all walks of life and sections of society seek treatment from these charlatans. Educated and affluent people visit them clandestinely, either because mainstream treatment has failed to give relief or a cure, or because they are too shy to discuss the ailment with their family physician.

Patients also visit unqualified practitioners because of their publicity gimmicks claiming a faster, cheaper and sure cure (2). In contrast, general or family practitioners are less enthusiastic in treating these ailments. A misconception also prevails that surgery for anal ailments is followed by severe pain, incontinence, bleeding and so on, and that treatment by these people is just a "treatment" involving no surgical intervention. What's more, unqualified practitioners charge much less than real doctors do.

Some patients are happy, when their ailments get cured. But many must repent the visit for life.

Many of these "specialists" claim to provide instant relief from piles using corrosive injections that cause severe inflammation and pain. They say they practise traditional herbal medicinal therapy but use toxic chemicals and then try to correct the resultant infection with antibiotics and analgesics used in veterinary practice. The reuse of needles without sterilisation also puts patients at risk of blood borne infections.

Injection sclerotherapy is generally considered to be safe. However, it needs knowledge of anatomy of the region and the skill to inject the medication in the correct dose, depth and direction. Misapplication results in complications including severe pain, injection site haemorrhage and ulceration. Phenol injections given without aseptic precautions and in the wrong dose can have severe consequences. The injection of corrosives can cause complications like necrotising fasciitis, septicaemia and renal failure.

"Ksharasutra" is an established and proven ayurvedic therapy provided that the treating doctor is well versed with the anatomy and basics of anal fistula pathology. Wrongly done, it can cause severe pain, infection, pelvic cellulitis with progression to shock and death.

According to a study, there are around 1.5 million unqualified and unregistered practitioners in India, i.e. more than the number of qualified doctors (3). Patients who suffer the complications of their treatment are shy to come forward consult the appropriate experts (4). Medical associations and law enforcing agencies are supposed to deal with these charlatans (5). But apathy on the part of enforcement agencies has allowed these fraudsters to thrive.

To distinguish themselves from quacks, doctors should display their certificates in their clinics, abiding by the new code of ethics of the Medical Council of India. The public must be educated about the dangers of being treated by unqualified practitioners. Awareness must be created about anal canal diseases and their scientific treatment.

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References

1. Hammerschmidt DE. The quack doctor. *J Lab Clin Med*. 2005 Dec;146(6):352-3.
2. Pray WS. Ethical, scientific, and educational concerns with unproven medications. *Am J Pharm Educ*. 2006 Dec 15;70(6):141.
3. Ramesh G. Quackery_a feedback discussion. *J Indian Med Assoc*. 2007 Nov; 105(11):656.
4. Kulkarni ND. Price of visiting a quack_case reports. *Indian J Med Sci.* 2000 Jul; 54(7):290-2.
5. Verma S. Proposal to ban quackery. *J Indian Med Assoc.* 1987 Feb; 85(2):60-1.

Surgical training in India – a long and winding road

Recent advances in the field of medicine in general and surgical specialties in particular have been mindboggling. These have greatly improved the care of patients. Problems which were initially incurable are beginning to be solved. Keyhole surgery has revolutionised both the care and the cure of patients requiring surgical treatment. Advances have taken place in such fields, all over the world. On the downside, the career of a surgical trainee is becoming increasingly difficult.

Every surgical trainee, whether in a government-run or a private institution, enters the training programme after a great deal of effort. In a government institution, he or she enters after at least a full year of "preparation" for an entrance exam. In a private institution, a lot of money has to be spent by parents, running into many lakhs of rupees, sometimes even crores. Either way, it is a lot of hard work - whether for the trainee or his parents.

No standard goals are set in any surgical programme in this country as to what the trainee is expected to know within a certain timeframe. This is in relation to skills as well as theoretical and clinical knowledge. Institutions which have attempted to set some goals have not been able to follow them through, for one reason or the other.

Teachers of surgical specialties do not take it upon themselves to "make" surgeons of the trainees who pass through their departments. Many trainees pass out of their programmes without any knowledge of basic techniques essential for them. No institution has made it compulsory that trainees should have completed doing or assisting with a set of procedures within a certain timeframe. This leads to the production of half-baked surgeons. Many times, trainees have to spend more years in other institutions trying to acquire these skills. This results in prolonging an already long training period in a surgeon's career.

Although the development of sub-specialties does have its own advantages, it takes even longer for trainees to acquire such extra skills that are available only at select centres. Entry into these centres, either as trainees or as staff, is extremely difficult at the best of times. In most cases, especially in private hospitals which advertise training posts in surgery or Diplomate of the National Board, the ulterior motive is to get cheap labour out of people who enrol for the training programme. To get a trainee to do any job is an "advantage" because he or she will do it without question, for fear of the repercussions of refusing. The amount of money paid to them is substantially less than the prescribed pay for a non-trainee recruited for the same job. The trainee is most likely to complete the stipulated period of time (usually three years), making it unnecessary to search for a regular, qualified employee. Fellowship programmes, which are floated by many so-called "institutes of excellence", also offer jobs to fellows in order to obtain cheap labour.

Medical students aspiring to become surgeons go through a lot of hardship right from the time of qualifying for the training programme to the time that they complete their training. If the above mentioned flaws are corrected, it will make surgical training more meaningful and fruitful. After all the system needs to give its young professionals a fair deal.

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CLINICAL TRIALS WATCH

Clinical Trials Registry - India (www.ctri.in)

Total number of trials registered

N = 689

Number of Trials	Year missing 4	2006 & prior 54	2007 100	2008 211	2009 320
Recruitment status					
Active, not recruiting		16	17	29	19
Completed	1	25	17	16	8
Enrolling by invitation					
Not yet recruiting	1		2	21	72
Recruiting	1	12	62	142	219
Suspended					
Temporarily not available					
Terminated	1	1	2	3	
Withdrawn					
Temporarily halted/suspended					1
Recruitment status not known					1
Type of study					
Behavioural		5		2	6
Device		2	4	8	8
Dietary supplement			2	4	4
Drug	3	30	80	155	233
Procedure		3	4	16	9
Radiation		2			2
Biological	1	9	7	16	45
Gene transfer					
Other		3	3	10	13
Disease conditions					
Bacterial infections, intestinal infections, STDs	1	4	10	17	37
Neoplasms		10	28	34	38
Endocrine, nutritional & metabolic		4	5	30	38
Mental & behavioural diseases		3	1	4	18
Dis. of the nervous system		3	6	16	18
Dis. of the circulatory system		2	9	27	35
Dis. of the respiratory system	2	2	3	12	18
Dis. of the digestive system		4	11	10	14
Dis. of the musculoskeletal system & connective tissue		3	4	7	22
Diseases of the eye & adnexa		3	2	6	11
Diseases of the genitor-urinary system		2	4	5	16
Pregnancy, Childbirth & the puerperium		4	5	7	3
Double disease condition	1	6	4	12	11
Other		3	5	22	37
Disease conditions not known		1	3	2	4
Sponsor Profile					
Institution/Agency		26	32	57	41
Pharma	4	27	57	140	270
Both					
Sponsor profile not known		1	11	14	9

Clinical Trials Registry - India (www.ctri.in)

Total number of trials registered

N = 689

Number of Trials	Year missing 4	2006 & prior 54	2007 100	2008 211	2009 320
Sponsor ownership					
Non-profit		2	6	16	8
Public, private		2		2	10
Non-profit, public				1	
Non-profit, private			3	1	2
Individual investigator		3	4	9	6
Individual investigator, public		1	2		1
Individual investigator, non-profit		1	1	1	
Sponsor ownership not known		1	10	14	9
Phases					
0					
I		1		7	33
II	2	6	22	45	53
III	2	22	39	90	139
IV		7	8	27	43
I/II		4	1	5	10
II/III		4	13	12	13
III/IV		2	6	2	6
Not applicable		8	11	23	23
Sampling					
Cross sectional					
Non-randomised		2	4	5	5
Prospective					
Randomised	4	43	81	152	237
Cluster				3	1
Other		6	10	29	29
Sampling not known		3	5	22	48
Assignment					
Crossover		2	2	5	19
Factorial			2		2
Parallel	3	43	77	146	212
Single group		3	4	22	48
Other	1	6	14	37	34
Assignment not known			1	1	5
Control					
Active		19	25	63	115
Placebo	3	19	43	71	83
Uncontrolled		3	4	22	48
Multi-arm		5	13	17	19
Crossover		2	2	5	19
Other	1	6	12	29	34
Control not known			1	4	2

Clinical Trials Registry - India (www.ctri.in)

Total number of drug trial settings

N=3138

	Year missing	2006 & prior	2007	2008	2009
Number of drug trial settings	13	119	452	917	1637
Drug trial settings by states (in alph. order)					
Andhra Pradesh	1	16	55	105	167
Delhi	1	20	51	68	94
Gujarat		8	19	52	171
Haryana		2	3	6	14
Karnataka	3	14	72	141	249
Kerala	1	2	21	51	52
Madhya Pradesh		3	6	19	55
Maharashtra	4	26	97	228	458
Punjab	1	3	15	25	27
Rajasthan	1	3	15	40	74
Tamil Nadu	1	14	55	95	148
Uttar Pradesh		2	10	30	49
West Bengal		3	20	29	36
Others		3	13	28	43
Drug trial settings by cities/towns (in alph. order)					
Ahmedabad		7	14	38	111
Aurangabad				5	31
Bangalore	3	5	40	100	172
Chandigarh		1	6	9	12
Chennai		6	21	47	77
Cochin	1		8	23	18
Coimbatore	1	3	6	18	29
Hyderabad	1	14	49	83	133
Indore		3	2	13	38
Jaipur	1	3	11	36	70
Kolkata		3	19	28	35
Lucknow		1	8	13	25
Ludhiyana	1	2	7	17	20
Madurai		2	4	11	19
Mangalore		3	10	11	44
Mumbai	1	15	53	97	145
Mysore		3	2	14	14
Nagpur			3	23	56
Nashik				9	47
New Delhi	1	21	52	76	102
Patna		1	1	7	12
Pune	3	11	39	84	163
Trivandrum		2	12	17	28
Vadodara		1	3	9	22
Vellore		2	25	15	16
Vishakapattinam		2	3	9	11
Others	0	8	54	105	187

This is the second fact-sheet of Clinical Trials Watch. CTW, which was first published in the October-December 2009 issue of *IJME*, aims to employ the Clinical Trials Registry-India (CTR-I) for regular monitoring of clinical research activity in India.

The fact-sheet initially presented information from two registries, the Indian Council of Medical Research's Clinical Trials Registry-India (CTR-I), www.ctri.in , and the US National Institutes of Health's registry, www.clinicaltrials.gov .

On July 1, 2009, the Drugs Controller General of India (DCGI) made registration of all drug trials being conducted in India mandatory. As a result, there was a twofold increase in the number of trials registered on www.ctri.in between June 2009 and December 2009. Thus, this database is now more representative of the clinical research scenario in India. For this reason, from this point on, we will be presenting data only from CTR-I. The data presented in this fact-sheet are updated up to December 31, 2009. All the registered trials on www.ctri.in were revisited and information was revised to ensure that changes made in the record of each trial in the registry were incorporated in the database.

Methods

The Indian registry yielded 689 registered trials on December 31, 2009. Trial information pertaining to each registered clinical trial was manually exported into an Excel spreadsheet via the copy-paste mechanism of Microsoft Office. The fields of information exported included CTR-I ID, brief study title, study status, trial location, ethics committee details, sponsor, disease condition, trial start date, DCGI approval and study type. This Excel spreadsheet was then exported to SPSS for analysis.

Definitions

***Year*:** CTR-I provides a record of the last date on which the study was verified, the date on which the study was updated and the date of first enrolment for each trial. The date of first enrolment was coded as the "year" for each trial.

Study type: The trials listed in the CTR-I were classified according to the different types of studies as "drug", "behavioural", "device", "procedure", "radiation", and "other" after careful reading of the study title. These codes were in line with the classification for different types of trial intervention listed on Clinicaltrials.gov.

***Disease condition*:** The disease conditions were coded according to the 10th revision of the World Health Organization (WHO) International Classification of Diseases (ICD 10). There were 18 categories including diseases of the nervous system, circulatory system and digestive system. An additional category for "double disease conditions" was created to include combinations of the disease conditions involved in the trial. After running the frequencies for all disease conditions, only the prominent ones were chosen for representation, while the less significant categories were truncated and labeled as a separate category referred to as "other."

***Sponsors*:** Sponsors were categorised as: Indian and non-Indian; private, public and non-profit; and, lastly, institution/agency and pharmaceutical company.

Trials starting before 2006 were combined with trials starting in 2006 in CTR-I All the data pertaining to phase, disease condition, sponsor, study type, recruitment status, and location (by cities and states) have been analysed by "year".

***Drug trial setting*:** This refers to the institution where the trial site was located. The city/town in which this institution is located was coded. Similarly, the state in which this institution is located was coded. Each "drug trial setting" represents a single trial site. Thus, each trial can have multiple "drug trial settings". Likewise, the same city may be listed more than once for the same trial, depending on the number of institutions from that city participating in that trial. This variable was coded only for those trials categorised as "drug trials" in study type.

In this factsheet, the data on drug trial settings has been reported in more detail. All cities/towns reporting more than 20 trials, over the entire period, have been listed separately. Likewise, all states reporting a significant number of trials have been listed. The remaining have been clubbed into a category called "others".

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CSER thanks Prof Roger Jeffery, Department of Sociology, University of Edinburgh, UK, for making available financial support for the project.

HELP offers a grant to 100 doctors for a free website

Millions of Indian patients go online looking for medical information. Unfortunately, most of what they find comes from sites like mayoclinic.com . We need Indian doctors like you to establish your own web presence so that information about Indian healthcare services is easy to find. Even though you may understand the importance of having your own website, setting one up is expensive, and web designers do not have the technical expertise to publish medical websites . With the help of our unique offer, we hope to correct these problems. Plus91, a healthcare technology company, normally charges Rs 4,995 for a professional website. HELP will offer this website free for 100 doctors.

We hope these grants will help you to showcase your talent and help you develop your practise ethically. This will also help patients, who will become aware of the medical facilities available in India. The transparency which the web imposes will help to improve the doctor-patient relationship by allowing much more open communication between doctor and patient and cutting out the middleman. Interacting with patients online will help doctors become more patient-centric and empathetic.

Information Therapy – the right information at the right time for the right person – can be powerful medicine. Ideally, every doctor and clinic should have an online patient education resource centre where people can find information on their health problem. We hope this initiative will create a positive virtuous cycle.

Please email me at malpani@vsnl.com and explain why you feel you should be awarded this free website. Include your resume, what your present online activities are, details of your publications, and how you expect to grow your website. I will shortlist 100 doctors and Plus91 will get in touch with them so they can publish their website. Doctors who are specialists and have an academic interest will be given first preference.

Plus91 will provide all the technological support needed including registering the unique personalised domain name that you choose (or example, if you are a paediatrician, this could be www.mumbaipediatrician.in or www.childdoc.in); hosting your website; and uploading the initial content, so your website is live in two days.

You can check out what your website will look like by going to www.websitefordoctors.in

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INDIAN JOURNAL OF MEDICAL ETHICS

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national bioethics conference

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NATIONAL BIOETHICS CONFERENCE - 3

Theme : Governance of healthcare – ethics, equity and justice

Dates: November 17, 18, 19 and 20, 2010

Venue: All India Institute of Medical Sciences, New Delhi

In recent decades, the Indian health sector has seen revolutionary changes. With globalisation, world class technologies, super-speciality institutions and big corporate and private sector hospitals have emerged in India. It has also paved the way for international collaborations in the field of research, service delivery and health education. However, healthcare still remains beyond the reach of the poor and needy in the country. Moreover, the healthcare system is far from achieving the goals of equity and justice. The absence of ethics and poor governance contribute significantly to these problems. In this context, the *Indian Journal of Medical Ethics* aims to bring together diverse perspectives on governance in healthcare, towards building an equitable and just health system to achieve a productive dialogue between practitioners, administrators, policy-makers and activists by organising the Third National Bioethics Conference.

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Dr Samiran Nundy , Head, Department of Surgical Gastroenterology, Sir Gangaram Hospital, Delhi

Call for abstracts and proposals for workshops

The scientific committee of the Third National Bioethics Conference seeks abstracts of papers, and proposals for holding workshops, on topics relevant to bioethics. These must be in line with the conference theme: "Governance of healthcare – ethics, equity and justice."

Abstract and proposal deadline: June 18, 2010

Some of the issues which will be discussed in the conference:

* Universal healthcare
* Indian systems of medicine
* Medical education
* Regulation of healthcare
* Accreditation of health institutions
* Clinical research
* Community participation
* Medical tourism
* Ethics committees
* Public private partnerships
* Stem cell research
* Organ transplantation
* Healthcare reforms
* Publication ethics
* Medical technologies (ART, imaging technologies, etc)

To register for the conference and submit abstracts, please visit http://nbc3.ijme.in

National Secretariat, NBC-3, *Indian Journal of Medical Ethics* National Bioethics Conference, Centre for Studies in Ethics and Rights 501, Dalkhania House, B Wing, Behind State Bank of India, Nehru Road, Vakola Pipe Line, Santacruz (East), Mumbai 400 055 INDIA e-mail: nbcdelhi@gmail.com

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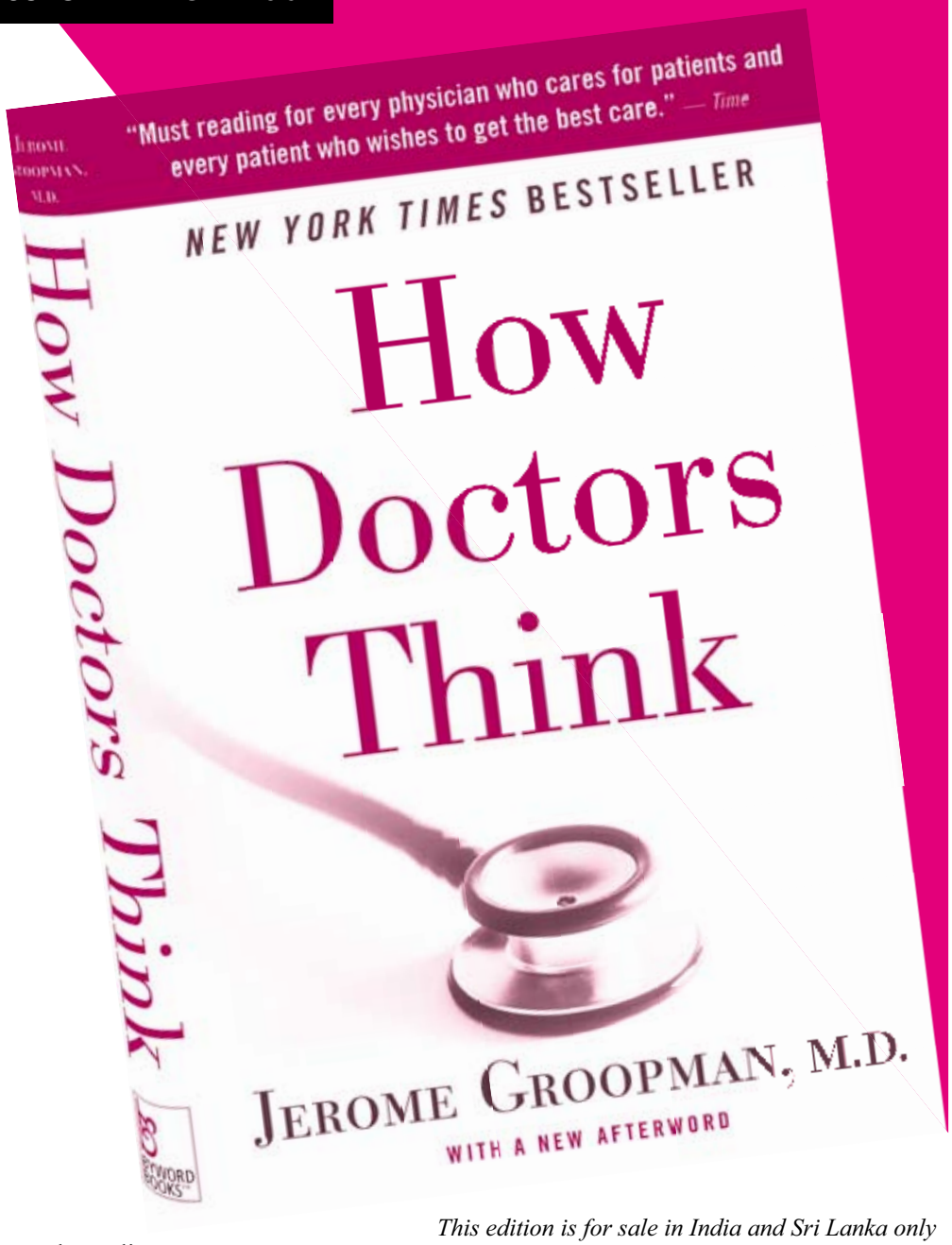

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INDIAN JOURNAL OF MEDICAL ETHICS
VOL VII NO 2 APRIL-JUNE 2010
(incorporating Issues in Medical Ethics, cumulative Vol XVIII No 2)

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Ethics and the law

Writers in this issue of the journal have a lot to say about the role that the law and regulatory bodies can and do play in supporting ethics at various levels. An editorial speculates on whether the Medical Council of India's ban on doctors receiving gifts from the drug industry has any meaning given the poor credibility of this institution. Another editorial asks whether the MCI's rural doctors scheme will result in more equitable access to healthcare. A senior jurist comments on the recent Supreme Court judgment on criminal medical negligence and its implications for medical practice. An activist comments on the legal battle launched by Bayer to block generic drug production, and the implications for people's right to affordable medicines. An article discusses laws relevant to decisions on patenting of human genetic material.

A survey of boundary violations in the doctor-patient relationship found enough evidence that sexual and nonsexual boundary violations occur in India, and this is a matter that needs urgent attention. Professional bodies need to implement existing guidelines on this subject.

With this issue we start a regular column, Ethics and the Law. In the first column, a forensic doctor presents an overview of laws applicable to sexual assault cases and amendments in these laws as they relate to the responsibilities of healthcare providers. We welcome submissions to this column.

But the law is not enough, as the writers commenting on a survey of informed consent point out. Obtaining informed consent for treatment is not about getting a patient to sign a form that protects the doctor from liability; consent is not a legal requirement but an ethical imperative. They write: "We do not wish to discount the protective role of laws, when they are applicable and accessible to all citizens, as external checks. However, we continue to believe that the best protection for patients remains ethical healthcare professionals through an internal professional morality."

The *Indian Journal of Medical Ethics* (formerly *Issues in Medical Ethics*) is a platform for discussion on healthcare ethics, with special reference to the problems of developing countries such as India. It hopes to involve all cadres of, and beneficiaries from, this system, and strengthen the hands of those with ethical values and concern for the underprivileged.

The Journal is owned and published by the Forum for Medical Ethics Society, a not-for-profit, voluntary organisation. The FMES was born out of an effort by a group of concerned doctors to focus attention on the need for ethical norms and practices in health care.

Contributions to the journal, in the form of original papers, research findings, experiences in the field, case studies, debates, news and views on medical ethics, are welcome. All submissions must be in English and are subject to editorial review.

Contributors are requested to refer to the detailed guidelines for submission available on the journal website, www.ijme.in

Printed and published by Sanjay Nagral on behalf of the Forum for Medical Ethics Society
Printed at Vibha Offset, Royal Industrial Estate, Wadala, Mumbai 400 031
Published at FMES, 0-18, 'Bhavna', Veer Savarkar Marg
Prabhadevi, Mumbai 400 025 Editor: George Thomas